MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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P R O C E E D I N G S

[9:52 a.m.]

DR. CROSSON: Let me welcome our guests to our January meeting. For those of you who are not familiar with MedPAC, January is the time during which we discuss and vote on recommendations for payment updates. That process will begin this afternoon.

In addition, at this January meeting, however, we're going to take on a set of policy issues, and the first one we're going to talk about is in preparation for a discussion that we're going to have tomorrow on potential approaches to drug cost control. We're going to have a status update on the Part D Medicare prescription drug program. Rachel and Shinobu are here, and it looks like, Rachel, you're going to begin.

DR. SCHMIDT: Good morning. Shinobu and I are bringing you a status report on Part D, Medicare's outpatient drug benefit. Under Part D, private plans deliver drug benefits to enrollees, and in return Medicare pays plan sponsors monthly capitated amounts and other cost-based subsidies. This morning I'll give you some information about the program and tell you about some

recent program changes, and then Shinobu will lay out some trends we see and some concerns we have about the program's incentives for cost control.

In 2018, among nearly 60 million Medicare beneficiaries, 73 percent were enrolled in Part D plans; 2.5 percent got drug benefits through the retiree drug subsidy, in which employers provided primary drug benefits to their retirees in return for Medicare subsidies. The remaining 24 percent was divided fairly equally between beneficiaries who had other sources of drug coverage as generous as Part D and beneficiaries with no drug coverage or less generous coverage. That 24 percent has held stable in recent years.

Medicare program spending for Part D was nearly $80 billion in 2017, predominantly for payments to private plans, but with about $1 billion for the retiree drug subsidy. Part D makes up about 13 percent of total Medicare spending.

In addition, Part D enrollees directly paid $14 billion in premiums for basic benefits, as well as additional amounts for cost sharing and supplemental coverage. More than eight in ten enrollees say they are

satisfied with the program and with their plan.

Let me describe the plans that enrollees chose in 2018 and what's available for 2019.

In 2018, 58 percent of Part D enrollees were in stand-alone prescription drug plans and 42 percent of enrollees were in Medicare Advantage drug plans, compared with 70 percent in PDPs and 30 percent in MA-PDs during 2007.

In 2018, 28 percent of all enrollees received Part D's extra help with premiums and cost sharing called the low-income subsidy. This is compared with 39 percent in 2007. A growing share of LIS enrollees are in Medicare Advantage drug plans. In 2018, this share rose to 39 percent. That is much higher than at the start of Part D, but still most LIS enrollees are in fee-for-service Medicare and in stand-alone drug plans.

For 2019, there was a very healthy increase in the number of plans offered -- 21 percent more MA-PDs and 15 percent more PDPs -- so a very broad choice of plans. Most of the increase in PDPs was for plans that combine basic and supplemental benefits, and that is likely the effect of some recent regulatory changes. The number of

PDPs that qualify as premium-free to enrollees with the low-income subsidy remains stable in 2019. One region, Florida, has two qualifying PDPs, but the other regions have three to ten available.

Since the start of Part D, enrollment has grown at about 6 percent per year. Enrollment among beneficiaries who do not receive the low-income subsidy has grown faster than among those with LIS. Since 2010, a number of employers have moved their retirees out of the retiree drug subsidy program and into Part D plans that are set up just for them. And today about 16 percent of Part D enrollees are in employer group plans.

The average Part D premium has remained steady at around $30 to $32 per month between 2010 and 2018. However, that's the average, and there's a lot of variation among Part D plans and their premiums.

Over the same period that average enrollee premiums have been flat, there's been much faster growth in Medicare's cost-based reinsurance payments to plans. The Commission has been pointing this out for many years now and in 2016 made recommendations that were designed to address this issue by reducing Medicare's reinsurance and

simultaneously increasing capitated payments to plans. So far, though, the recommendations have not been implemented.

Part D uses a market-oriented approach in the sense that plan sponsors compete for enrollees through the benefits and services they offer and the attractiveness of their premiums. Part D plan sponsors manage pharmacy benefits using the same general approaches that PBMs use for commercial populations, such as: designing tiered formularies that use differential cost sharing and tools such as prior authorization to encourage the use of certain drugs over others; negotiating rebates with drug manufacturers in drug classes where there are competing therapies; and developing pharmacy networks.

There are restrictions Medicare places on these approaches that are tighter than what plans can do for their commercial populations. For example, Part D plans cannot exclude willing pharmacies from their networks. Nevertheless, these sorts of management approaches have been effective at encouraging Part D enrollees to use lower-cost drugs and generics.

However, we've got concerns that certain trends and changes in the program may be eroding some of Part D's

incentives for cost control. I've already described how a growing share of Medicare's payments to plans take the form of cost-based reinsurance. There are also phases of Part D's benefit in which plan sponsors don't have much financial responsibility for paying for covered benefits, yet plans collect rebates for that spending. The magnitude of rebates has been growing over time, and so this gives us concern about the underlying incentives behind which plans are selected for formularies.

Let me describe some recent changes to Part D that have taken place over the past year. Through regulatory actions, CMS has given plan sponsors new flexibilities with their formularies. Sponsors can now make certain changes to their formularies midyear if a generic comes out on the market and it's therapeutically equivalent to a covered brand-name drug. Sponsors can set prior authorization or step therapy criteria differently for the same drug depending on the indication for which the drug is being used. That strategy is hoped to give sponsors more bargaining leverage with manufacturers in certain drug classes. And Medicare Advantage drug plans may now use step therapy for provider-administered Part B

drugs. For example, in certain drug classes a plan sponsor could require an enrollee to try a covered Part D drug before the Part B drug, and the idea behind this is to spur more price competition among drug therapies that fall across medical benefits and pharmacy benefits.

There are also some changes to Part D that were enacted in law. Last year, the Balanced Budget Act called for closing the coverage gap for brand-name drugs one year earlier than scheduled. Remember, there has been a benefit phase that has higher cost sharing called the "coverage gap," which I'll show you in a minute. The change in law means enrollees pay consistent cost sharing for brand-name drugs instead of higher cost sharing in the coverage gap. The law made this change by increasing the discount that brand manufacturers must pay in the coverage gap from 50 percent to 70 percent, leaving plan sponsors with just 5 percent plan liability in that benefit phase.

I'll show you the change I just mentioned as we go over the structure of the defined standard benefit for 2019. This is what it looks like for a person who does not have the low-income subsidy.

On the left, starting from the bottom to the top,

you can see there's a $415 deductible, and then the enrollee pays 25 percent of covered benefits and the plan pays 75 percent until the enrollee reaches the initial coverage limit. After that, there's the coverage gap phase. And then if an enrollee has even higher drug spending and reaches the out-of-pocket threshold, he or she pays 5 percent, the plan pays 15 percent, and Medicare pays 80 percent through reinsurance. In practice, nearly all Part D plans use benefit designs that look different from this but that meet certain requirements around actuarial equivalence.

Now let's talk more about the coverage gap. The right-hand side graphs show you brands and biologics on the top and generic drugs at the bottom. So starting at the top this time, in 2019, an enrollee taking a brand-name drug will pay 25 percent cost sharing in the coverage gap, so he or she pays the same 25 percent from just after the deductible through the initial coverage phase, and then through the gap all the way to the out-of-pocket -- until you reach the out-of-pocket threshold.

In the coverage gap, brand manufacturers are paying a 70 percent discount, up from 50 percent in 2018.

And the plan pays just 5 percent in the gap. Also, remember that the manufacturer discount gets counted as if it were the enrollee's out-of-pocket spending. So with a higher manufacturer discount, enrollees move toward the out-of-pocket threshold more quickly than before. And Medicare covers 80 percent after that point.

On the bottom right, in 2019, if a beneficiary fills a generic prescription in the coverage gap, he or she pays 37 percent cost sharing and then the plan covers 63 percent. Cost sharing for generics will fall to 25 percent in 2020.

This table compares Part D spending at the first full year of the program, 2007, with 2016 and 2017.

The direct subsidy is the monthly capitated payment, adjusted for risk, that Medicare pays plans for each enrollee. Reinsurance is a cost-based payment because Medicare reimburses plans 80 percent of the actual prescription cost in the catastrophic phase of the benefit, and those two subsidies combined are designed to cover about 75 percent of the cost. The low-income subsidy is Medicare's payment to plans to cover the extra assistance that LIS enrollees receive for cost sharing and premiums.

You can see that total Medicare program spending for Part D was basically flat between 2016 and 2017. That seems like good news after big increases that we saw related to spending for hepatitis C drugs a few years earlier.

Nevertheless, we're not so sanguine about program spending because Medicare's payments for reinsurance continue to grow rapidly. In 2017, reinsurance grew to $37.4 billion, up from $35.5 billion in 2016. Over those same two years, the direct subsidy declined. Between 2007 and 2017, reinsurance grew by an annual average of nearly 17 percent, compared with a 2 percent decrease for the direct subsidy. Remember that Medicare's reinsurance is cost-based while the direct subsidy is risk-based, and it's risk-based payments that generally provide sponsors with stronger incentives to manage spending.

MS. SUZUKI: Increase in price is one of the main factors driving Medicare's reinsurance spending.

Overall prices, including generics, moderated, decreasing slightly in 2016 and increasing by 1.6 percent in 2017.

These are in contrast to the uptick we observed after the launch of the new hepatitis C treatment at the

end of 2014.

In 2017, prices of brand-name drugs continued to grow but not as fast as in previous years. However, it remained strong in some classes, such as insulin.

Notably, drugs in some specialty drug classes, such as anti-inflammatories for rheumatoid arthritis and therapies to treat multiple sclerosis, grew more slowly during 2017. But even in these classes, manufacturers' price increases over the previous decade had already increased the prices of those therapies to three or more times what they were in 2007.

Media and drug trend reports suggest that prices of brand-name drugs generally continued to grow at a modest rate for 2018, which may have been affected by the uncertainty around potential policy changes to address high drug prices. However, recent announcements by some manufacturers about increasing prices may indicate a return to the higher growth rates.

In 2016, 3.6 million or about 8 percent of Part D enrollees had spending high enough to reach the catastrophic phase of the benefit. Among the high-cost enrollees, the number of non-LIS enrollees have grown more

rapidly than LIS enrollees.

Part D's spending is increasingly driven by high-cost enrollees. A larger share of the spending is accounted for by those high-cost enrollees. That share has grown from 40 percent in 2010 to nearly 60 percent by 2016.

Rapid growth in the price of prescriptions filled by high-cost enrollees explains most of the growth in their spending. Between 2010 and 2016, average prices of drugs used by high-cost enrollees grew 10 percent annually compared with an annual decrease of 3 percent for other enrollees.

Patterns of drug spending differ between LIS and non-LIS enrollees with high costs, and that difference explains why we're seeing faster growth in the number of non-LIS enrollees who reach the catastrophic phase.

Overall, one in ten high-cost enrollees filled at least one prescription in which a single claim would have been sufficient to reach the catastrophic phase of the benefit. The use of such a prescription is significantly higher among non-LIS enrollees, with 18 percent having filled such a prescription compared with about 6 percent among LIS enrollees in 2016.

Between 2007 and 2016, average spending for high-cost non-LIS enrollees has grown faster, increasing by 190 percent compared with 100 percent for LIS enrollees. As a result, by 2016 high-cost non-LIS enrollees had spending that averaged about $30,000 per year compared with just under $21,000 for LIS enrollees.

The cost difference between high-cost enrollees with and without LIS are largely attributable to the drug classes used by these two groups. One study found that high-cost non-LIS enrollees were more likely to use drugs and biologics in classes dominated by high-priced specialty drugs, such as therapies to treat cancer, multiple sclerosis, and pulmonary hypertension. LIS enrollees, on the other hand, were more likely to use medications for diabetes, mental health, and pain -- classes which are mostly non-specialty drugs. Our own analysis of the 2016 data corroborates these patterns.

Going forward, the pharmaceutical pipeline will continue to shift its focus on biologics and specialty drugs that command high prices. Use of these new therapies will further increase the burden on Medicare's reinsurance.

Already, the effects of this shift towards

higher-cost products are affecting Part D spending. Specialty tier drugs, which, by definition, have high prices, accounted for less than 1 percent of all Part D claims in 2017, but 25 percent of all Part D spending, up from 6 percent in 2007.

Average cost of a single claim for drugs placed on a specialty tier grew 14 percent annually from about $1,100 in 2007 to nearly $4,500 by 2017.

The growth in prices of specialty tier drugs have led to a rapid increase in the use of drugs in which a single claim would be sufficient to reach the catastrophic phase. In 2010, just 33,000 beneficiaries filled such a claim. By 2016, that number rose more than tenfold to about 360,000.

Many changes are taking place in the environment that is going to affect the Part D program. Specialty drugs and biologics will continue to drive the growth in drug spending -- not just in Part D but for the entire U.S. health care system.

The market structure of plan sponsors has changed dramatically and continues to do so, with some sponsors merging with insurers, and thereby becoming more vertically

integrated.

To manage benefit costs, more insurers and PBMs are using high deductibles and/or percentage coinsurance for higher-priced drugs and biologics, resulting in sticker shock for patients at the pharmacy.

There are also changes that are specific to Part D, such as regulatory changes to allow Part D plans to use some of the tools they use to manage pharmacy benefits for their commercial populations.

Increase in manufacturers' coverage-gap discount that Rachel described reduces plans' insurance risk, raising concerns about financial incentives sponsors face.

Medicare's payments to plans are increasingly retrospective and based on cost, and many of the changes happening in the environment will likely contribute to this trend.

So there is an urgent need to better align plans' financial incentives with that of the beneficiaries and taxpayers while at the same time giving formulary tools to encourage benefits management.

In April, we plan to bring to you potential policy approaches to address two issues we highlighted

today. One relates to coverage gap discount, and the other relates to beneficiary's out-of-pocket costs for high-cost drugs.

And with that, we'd be happy to take any questions.

DR. CROSSON: Thank you, Rachel and Shinobu.

We'll take clarifying questions. I see Brian, Amy, Jon. Jonathan, did I see your hand? Brian, Amy, Jon, David, Pat, Warner.

DR. DeBUSK: First of all, thank you for a great chapter. In the reading materials, on pages 34 and 35, you start to talk about the growing divergence in point-of-sale prices and net prices. And in the text -- and I think it as sometime last year, we talked a little bit about the allocation of DIR and how it's disproportionately allocated, I think, to the plan and away from the reinsurance program. You mentioned that in this chapter when it said, "Medicare reinsurance payments that reduce plan liability for a benefit may create a situation in which there is a financial advantage to plan sponsors when they select high-cost, high-rebate drugs over lower-cost alternatives."

Could you refresh me on that just a little bit? I went back and looked at some of that material, but I noticed we seemed to stop short in the chapter of describing it again.

DR. SCHMIDT: I think there's two pieces to that. I mean, Bruce has raised in the past the general notion that the odd structure of Part D's benefit and the facts that plan sponsors don't have consistent financial liability for the benefit spending can create a situation where the rebates -- there may be an un-incentive in some cases to put high-rebate, high-cost drugs on the formulary relative to lower cost alternatives. That's a general thing.

But I think the DIR case -- I'll let you know who to speak to -- that's something a little bit different.

MS. SUZUKI: So the DIR, currently CMS uses gross spending, so the prices at the pharmacy, to figure out what share of Medicare keeps versus what share plans keep, and the share that plans keep for the most part are weighted heavily because they use gross spending below the catastrophic threshold. And that includes the coverage gap phase where plans have very little liability, particularly

for brand-name drugs.

So relative to the benefit cost, using the gross drug spending, weighs -- gives plans more, larger share of the DIR than had they used the actual benefit liability to calculate how much plans keep versus Medicare keeps.

DR. DeBUSK: So it's a two-tier mechanism is what you're saying, then, because there's sort of the overt incentive to have the high-price, high-rebate drug, but then when it's time allocate the DIR, there's a compounding of that effect because it gets disproportionately allocated.

[Staff nods head in the affirmative.]

DR. DeBUSK: Okay. Thank you.

DR. CROSSON: Amy.

MS. BRICKER: Great job on the chapter.

So a couple questions around price increases. You make a couple of different observations, and I just thought it would be helpful to maybe connect the dots for the room.

At one point, we talk about how overall spending has moderated, and then there are other places throughout the document that we talk about price; prices are actually

increasing at double-digit rates.

To what extent are we factoring in rebate? And so just to -- period. To what extent are we factoring in rebate when we talk about the overall cost implications to the program?

MS. SUZUKI: So the price index that we talk about -- and we mention that even the pharmacy prices have moderated in recent years -- that is a pharmacy price. So it doesn't include the post-sale rebates and discounts from manufacturers.

And we talk about how for some classes, such as insulin, that may not be the accurate picture; but for other classes like cancer therapies, there may not be as much rebate. And the price index that we show in the chapter or the mailing material may be more of an accurate prediction of how the prices have grown over time.

In terms of spending, we do use data that incorporates the retrospective rebates and discounts. So those growth rates do reflect the amount -- the rebates from manufacturers.

MS. BRICKER: So which number is that exactly, then, in the material you just presented that would be

reflected of rebate?

MS. SUZUKI: The spending.

DR. SCHMIDT: The $80 billion and spending for 2017, for example. That's inclusive.

MS. BRICKER: But it's flat from '16.

DR. SCHMIDT: Right. That's net of rebates.

MS. BRICKER: I think that's important. I think that's important because it's easy to look to one data point, like list price, and say in Part D, we have a problem. We could debate that, but overall spending, if I have it right, is flat, '16 to '17. Is that accurate?

DR. SCHMIDT: That's accurate.

MS. BRICKER: Thank you.

DR. CROSSON: David.

DR. GRABOWSKI: Thank you for this great work.

I wanted to come back to the first bullet you had on Slide 5: private plans compete for enrollees. I'm not disagreeing with that, but I want to reconcile that with an observation from the literature. There's a lot of academic work suggesting enrollees often end up in a plan, whether they choose it, that doesn't best meet their drug needs, and so there's a lot of suboptimal decision-making that's

out there. That's not something that's dealt with a lot in the chapter.

How much does that interact with some of the trends you presented in the material and in the chapter and the presentation today, and is that something we've thought about as a Commission?

MS. SUZUKI: So we have in the past looked at switching behavior by Medicare beneficiaries, particularly those without low-income subsidies. So they're voluntarily switching.

We found somewhere between 12 and 14 percent voluntarily switch from year to year during the annual enrollment period.

It's hard to say whether that's sufficient or not, but in the focus groups with beneficiaries, some of them have indicated that they do check Plan Finder annually to see whether their drugs are covered at more favorable rates with other plans. So it seems like they are looking to lower their out-of-pocket cost, not just the premiums.

We have found when people switch, they tend to minimize their total out-of-pocket cost in terms of cost sharing, despite maybe using even a little more drug than

in the previous year.

DR. GRABOWSKI: We did a chapter recently on post-acute care decision-making, and my sense is some of what we recommended there could filter over to here in terms of helping beneficiaries with choice here in this sector.

You raised the Plan Finder tool. I think that that tool is really poor. I'll say that. I don't think it provides a clear indication to enrollees about the lowest-cost plan necessarily, and so I've wondered if we've done any previously about that and whether we might think about sort of some revisions there and also building on some choice architecture here around thinking about placing beneficiaries into a default plan and making better use of some of the big behavioral economics literature.

DR. SCHMIDT: Last year, we were considering doing some work on Plan Finder, but there were some other organizations that are already taking that under and did some pretty thorough looks at it and had some suggestions for how to improve that. So we decided with our limited resources, you have to kind of pick and choose where to put your emphasis.

In the past, we have kind of looked at things like intelligent assignment ideas around the low-income subsidy population, but the Commission that was gathered at that time chose not to go ahead with those ideas. It was looking as though there was a tradeoff so that there was higher government spending associated with picking optimal plans, and there was some concern around selection, so are you going to perhaps get plans into a spiral by picking what's optimal for each enrollee based on their past drug use.

DR. CROSSON: Okay. I've got Pat -- Warner, did you have your hand up? -- Warner and then Dana.

MS. WANG: Thank you.

DR. CROSSON: Did I miss somebody? Oh, Jon. Sorry.

DR. CHRISTIANSON: Am I next?

DR. CROSSON: You're next. Sorry. I didn't see your hand go up.

DR. CHRISTIANSON: This is really quick.

DR. CROSSON: You're too close.

DR. CHRISTIANSON: Yeah.

This is really, really quick. So on the slide, I

didn't see this, and I didn't see it in the chapter. So maybe we don't have this number, but do we know what percentage of Medicare beneficiaries have no drug coverage?

DR. SCHMIDT: Not exactly. We know that it's about half of the 24 percent have coverage that's either less generous than the -- or no, and we think -- we're not sure exactly what that is.

DR. CHRISTIANSON: Yeah, I saw that, but we can't break that down and say 5 percent have no drug coverage at all.

DR. SCHMIDT: No, we can't.

And I think it used to be a question we could sort of get to on the Medicare Current Beneficiary Survey, but it's no longer there.

DR. CHRISTIANSON: It's odd because that seems like sort of a basic piece of information we'd like to know.

DR. CROSSON: Pat.

MS. WANG: Going back to Slide 10, 11-ish, were you -- and you've mentioned this before. Is the growth in spending for non-low-income beneficiaries going to the reinsurance later, and that they have surpassed the low-

income subsidy beneficiaries in terms of the high-drug expenditures?

I wondered whether you have more information about sort of the characteristics, I guess, of spending between the non-low-income and the LIS population.

In other words, you mentioned the difference in the drug utilization, but in terms of -- I don't know if this is the right word -- "preference," I guess, of the non-low income, is it a fewer number of people who have extraordinary drug cost as opposed to the LIS, which is maybe more people have similar drug expenditures?

The reason I ask is -- and maybe this is the implications for what are the policy questions to be answered as well as implications. As you know, I'm very interested in refining risk adjustment for the Part D premium that exists. I just was curious if you knew anything about that or whether that was a --

MS. SUZUKI: So we did look at non-LIS versus LIS among the high-cost beneficiaries, and you're probably talking about this piece. That, for example, cancer treatments accounted for a much higher share of non-LIS high-cost enrollee spending compared to LIS enrollees who

reach the catastrophic phase.

And we were also finding that among the low-income subsidy population, a lot of the spending weren't because individual prescriptions were extremely high cost. It was that they were using more medications, and some of them were in common classes like antihyperlipidemics.

And one that showed up in one of the lists that I looked at is Nexium. That sort of thing tends to add up to get a lot of those enrollees to the catastrophic phase.

MS. WANG: So is it kind of the right direction, then, to be saying that for the non-low income, the focus on the cost of the specialty drug is probably the thing to focus on, but for the low-income population, a generic substitution is a fruitful avenue?

MS. SUZUKI: And I think that was one of the recommendations we made.

MS. WANG: Yeah. Apparently different avenues. Okay.

DR. CROSSON: Warner.

MR. THOMAS: So in Slide 7, the construct here with the initial coverage and the out-of-pocket threshold, are those indexed, or do those numbers change over time?

DR. SCHMIDT: Yes, they do. They're indexed to the average per capita spend for Part D.

But there's been some difference in each of these different parameters and their treatment over time.

In 2010, the Affordable Care Act, one of the goals was to close the coverage gap.

MR. THOMAS: Right.

DR. SCHMIDT: And so they indexed the out-of-pocket threshold more slowly. So it actually will increase in 2020, as you heard about in the mailing materials, by over 20 percent because that was scheduled in the Affordable Care Act. That it would bounce back up to what it otherwise would have been.

MR. THOMAS: And on Slide 8, just looking, it looks like in the mailing materials that the premium increase in relatively nominal, yet the total cost of the program is escalating. So can you comment on your thoughts around that or the rationale behind that?

DR. SCHMIDT: Right. So let's be clear. In 2016 to 2017, it's been flat, but we have seen fairly rapid growth in spending before that, certainly.

The flatness of premiums, we think speaks to this

reinsurance increase I spoke about on this particular slide. That a lot of the cost growth has been in the catastrophic range of the benefit spending, where the Medicare program is picking up 80 percent of the costs in that benefic phase. So the portion of benefits that go into the premiums remained relatively flat.

MR. THOMAS: But if you look at this slide -- and I just want to make sure I understand this slide. So the Medicare program total, that's the total cost of Part D, kind of all in, or that's the government portion to be paid at the program?

DR. SCHMIDT: Those are essentially the government payments to the plans, and in addition, there's another $14 billion that the enrollees have been paying to plans for basic benefits. And there are other costs for cost sharing and for supplemental premiums.

MR. THOMAS: Okay.

So kind of looking at this, the makeup of this, is there transparency or clarity around the profit in the Part D programs or the Part D insurers, or is that kind of aggregated in all of their profits?

MS. SUZUKI: So we have looked at plan payment

data through 2015, and we found that the majority of the plan sponsors do make profit in the risk corridor and risk corridors of part of the cost-based portion of the payment, and there's a risk corridor around it. And plans are allowed to keep -- the risk-based portion. Sorry. The plans are allowed to keep, plus or minus, 5 percent of the profit or the loss. That's on them.

The next piece of it is 50-50 from 5 percent to 10 percent on both sides, that sort of thing.

And we found that plans on average were making profits above those that were included in their bids. A lot of the plans got to keep the extra 5 percent plus whatever else they got to keep in the second tier and third tier.

DR. SCHMIDT: There isn't as much visibility into it as you might want. The information that goes into bids, for the MA side of the house --

MR. THOMAS: Right.

DR. SCHMIDT: -- you can go back and look at historical data and see the profits in there to see what the profit rates have been.

On the drug side, it's less easy to do because

the data that are submitted in bids are not reconciled data.

MR. THOMAS: Okay. Thank you.

DR. DeBUSK: On that --

DR. CROSSON: On that point?

DR. DeBUSK: On Warner's specific questions because I think in the reading material, you alluded to this. Could you explain a little further? There seems to be a dominant strategy for how to proceed with a Part D bid, sort of a can't-miss strategy. And you sort of spoke to that, but could you sort of clarify it?

MS. SUZUKI: So related to Warner's question about why premiums have been flat is that plan sponsors on average have been underestimating the reinsurance portion of the benefit. What that does is -- because reinsurance is the cost base that's reconciled after the end of the benefit year, the part that's in the premium is the expected piece, expected amount of reinsurance.

At the end of the year, Medicare, on average, have been paying plans additional amounts for reinsurance. So whatever the extra payment that Medicare made to plans were not included in the premium the beneficiary paid.

DR. CROSSON: Okay. I have Dana and Marge and Jaewon.

Dana.

DR. SAFRAN: Thank you.

Can you go back to Slide 7? I'm just trying to make sure I understand. I have to say I find this topic confusing every time we talk about it. So I think this is my moment where I may be having a breakthrough in some of my understanding, but I just want to check a couple things.

So on the left side, I'm trying to make sure I understand the coverage gap and what happens in there, and one of the things that I think you're showing us here is that the coverage gap is not really entirely a gap for the beneficiary. In fact, they're paying 25 percent in their initial coverage, and they're still paying 25 percent in the coverage gap if they're using a brand and in fact, as of next year, even for a generic.

So is that right?

DR. SCHMIDT: You got it.

DR. SAFRAN: Am I reading this right?

DR. SCHMIDT: Yeah, right. But that's a new thing. It's been kind of phasing in that direction since

2010.

It used to be, before 2010, 100 percent on the bene cost sharing during the coverage gap phase. After 2010, there was immediately a 50 percent discount provided by brand-name manufacturers. That also counted towards the out-of-pocket threshold, but the bene was paying the other 50 percent. And over time, it's been phasing down, down, the cost sharing for the beneficiaries, and as of 2019, it's 25 percent on brands in the coverage gap.

DR. SAFRAN: Okay. Thank you.

And then the other thing I want to understand is beyond that. So above the out-of-pocket threshold, I'm assuming that when you refer to catastrophic levels, you're referring to that point.

And so later in the presentation, you made the point that it's about 8 percent of beneficiaries that reach that level, and this sort of shocked me that one in ten of those get there with one claim.

So I just wonder what can you tell us about those folks? What are those medicines, and is it actually just a one-time claim? Or is this a medicine that costs a boatload of money, and they're having to take it all the

time -- it's for cancer treatment; it's for chronic illness -- that specialty drug? Can you just tell us a little bit more about that?

MS. SUZUKI: So 1 in 10 beneficiaries have at least one claim for which, just that one claim would have gotten them to the catastrophic phase. That doesn't mean it was the only claim.

So a lot of the drugs that are used by non-LIS enrollees were cancer drugs, which had an annual spending of $30,000, leukemia drugs, Copaxone for multiple sclerosis, which was also in the $20,000 range for annual costs. So they tend to use a lot of those very expensive drugs.

To get to the threshold, you only need, you know, $7,000 or $8,000, and these are drugs that annual cost average is in the tens of thousands of dollars.

DR. CROSSON: Dana.

DR. SAFRAN: What I hear you saying is these are drugs that they are taking over the course of the year, not one time. So even though that one claim could have put them over that threshold, they're continuing to take a medicine that, over time, costs $20,000, $30,000 in the

year.

MS. SUZUKI: And that's shown by the average cost for non-LIS enrollees that's reached $30,000, on average.

DR. SAFRAN: Thank you.

DR. CROSSON: I mean, you could have some patients like hepatitis C where it's one time.

Okay, Marge.

MS. MARJORIE GINSBURG: In the report itself, talking about the low-income subsidy folks, there's a quote I pulled up that says "plan sponsors cannot encourage use of lower-cost in the same way as non-LIS." I'm curious as to why that was written. Obviously, some categories of LIS, a few, have no copayments, but most of them, they're small, do have copayments that differentiate between generic and brand name.

So I was just curious what the basis for this statement was.

DR. SCHMIDT: I think our point is that just the magnitude of the difference in the copays is fairly small and not necessarily large enough to make a change in behavior. You look at the cost-sharing applied to non-LIS, and the differentials that are quite substantially larger.

MS. MARJORIE GINSBURG: We know historically, then, that LIS participants, you know, it's like $8 versus $3, that that's not big enough to influence their choice, or are physicians not encouraging the lower cost? I mean, I guess I -- these are low-income folks --

DR. SCHMIDT: Right.

MS. MARJORIE GINSBURG: -- and even that $5 may be meaningful. And I just wanted to make sure there was some evidence behind this that said it's really hard to move them to lower cost.

DR. SCHMIDT: I think we're basing that on seeing it. Even though generic dispensing rates for low-income subsidies, overall, average -- they're lower than non-LIS, not substantially lower but a few percentage points lower -- but some LIS folks, particularly the ones who are reaching what we're calling the catastrophic phase, are using the Nexiums and things where there are generic options available, and they haven't quite switched.

DR. CROSSON: Okay. Jaewon.

DR. RYU: Yeah, I also had questions about Slide 10 and the high-cost enrollees and the impact of the LIS versus the non. I'm just trying to tease apart, I guess,

the impact of -- because a lot of different variables here. There's a volume dynamic, there's unit cost dynamic, there's a brand preference and maybe behavioral dynamic, which I think is kind of where Marge is going, depending on your copays, versus a disease prevalence and what happens to hit the LIS folks versus the non-LIS folks.

Do we know, or has there been studies around within a certain drug class or disease class, within that high-cost enrollee population, whether there's a difference in trend between the LIS population and the non-LIS population, in terms of, you know -- it would have to be a drug class, I guess, that would have alternatives. But is there a behavioral difference there, or do we just chalk it up to, you know, it's just because different disease states hit those two populations differently?

DR. SCHMIDT: I don't know that we've seen any studies that would get to that specifically. I guess -- I don't know, do you have a thought?

MS. SUZUKI: So I'm trying to figure out -- so what we looked at a couple of years back, in making the recommendation about generic, increasing generic drug use for LIS population, is that even for classes such as

antihyperlipidemics or antihypertensives, those most commonly used therapeutic categories, we found higher brand use among LIS population compared to the other people who did not reach the catastrophic phase of the benefit. And it may not be that they're not using the direct generic substitute. A lot of them do, are automatically substituted to generics.

I think what we're seeing between LIS and non-LIS population is that non-LIS beneficiaries may be more likely to ask for a therapeutic generic substitution compared to LIS beneficiaries. And I know some of the categories of low-income population pay $8, potentially, for a brand-name drug. Not all of them do. Some of them don't have any cost sharing. Some of them pay lower copay amounts. And so we thought that if the Secretary thought that some classes could use some therapeutic generic substitution, that's when these copay differences could really move LIS populations to use lower-cost generics. And we also recommended that in those class maybe Secretary could make the generics free to those beneficiaries.

DR. CROSSON: Okay. We're going to move on. Put the last side up, if you would. We're going to move on to

further comments. This is a status report, and I make two notes.

Number one, as you see on the slide we are planning, this spring, to take on two Part D issues, restructuring the coverage gap discount and reducing out-of-pocket costs for high-cost drugs. In addition, as I mentioned in the beginning, tomorrow morning we're going to have a broader discussion here at the Commission on a wider range of approaches to reducing the cost of prescription drugs, as a jumping-off point for future work in the next session or two.

Actually, Amy is going to start.

DR. BRICKER: Thanks. Thanks again for a chapter that I think has a lot of people leaning in to better understand and to really begin to grapple with what this Commission, and, more broadly, the industry needs to do to take on a very sensitive issue.

I made the point earlier around spend being flat, only to highlight that there are winners and losers in this program and in this sort of phenomenon. I think it does bear consideration that we have to think about the beneficiary at the point of sale. The structure, if Bruce

is the one that highlighted it, I agree. The structure is unique and it's hard to draw parallels because there isn't anything else like it in the commercial market.

I think the unfortunate scenarios are those that beneficiaries are faced at the counter not being able to afford, you know, deductibles, not being able to afford co-insurance, and again, because of the way this is structured, bear a lot of that burden.

And so absolutely in favor of taking a look at how we can ensure that beneficiaries are getting the value of rebates, and whether or not it's a wholesale application and rebate at point of sale, I'm not there yet. But for those specialty products that are high cost, having a cost cap for those beneficiaries and, in effect, using rebate dollars to hold down the out-of-pocket for beneficiaries I think is something to consider and one that we should further review.

There are many things that this program can still do within the traditional space, and you've highlighted many of them in your paper. You mentioned briefly any willing pharmacy. There have been a number of studies that demonstrate that any willing pharmacy actually raises

costs, not just improves access. So the extent that, again, looking at any willing pharmacy allowance, so long as certain access requirements were met, doing away with that.

There have been a number of conversations around DIR, whether or not DIR should be factored into the patient's out-of-pocket if it could be reasonably known, and there's another sort of round of this now with CMS putting out some additional observations on this point. So I think we should also address that in the work that we have in the future and our perspective.

I'm encouraged by B-versus-D management. I think this is the right direction. It came out very late last year so we're likely not going to see much of that in '19, and so we won't be able to see the impacts of that change likely until '21. So I think that is something that will play out over time.

And for manufacturers, I think that today, through B, have not feared exclusion, not feared having to be competitive. This now is a different dynamic and so I'm encouraged by that.

I think it should be noted, though, the

manufacturer requirement from 50 to 70 percent likely will have an unintended consequence, and while the political environment isn't comfortable for manufacturers and raising list prices have moderated to some degree, you would expect that this additional obligation on the part of the manufacturer will result in list price increases and, therefore, the commercial market will bear a lot of that -- because of this change will bear that impact.

Lastly, value-based programs. I encourage us to look at what has been done successfully in the commercial market, these high-cost drugs that you can set measurable and objective, you know, goalposts around what does success look like. And if the program is going to cover a drug, refunding of putting incentives in place that if the drug doesn't work, if the patient isn't compliant, if there is lack of outcome that the program would seek a refund for that drug. So there are many things to consider if that were to be allowed, but again, it's worth taking on.

And lastly, while pharmacy payment at the point of sale is real-time, meaning you know if a drug is covered, you know the co-insurance, you know if it's on formulary, the pharmacy, at the counter, knows this, we

still are lacking data to provide the pharmacist at the point of sale the most information about how to guide the patient. So if it's not the physician, the pharmacist, there has to be some investment in information-sharing so that we do seek the best outcomes for the beneficiaries.

There's so much work here to do. I am, though, I am encouraged by what feels like an opportunity for us to take advantage of some of the momentum in the market to begin to move the needle on this very issue.

So thanks.

DR. CROSSON: Thank you, Amy. I saw Brian.

DR. DeBUSK: Thank you again for a really great report.

In terms of topics for spring, and I saw that on the slide there, I would love to add us digging deeper into this whole idea around formulary construction, DIR allocation, and then this whole issue of bidding on the -- the way these bids are constructed.

The thing that fascinates me is since this program's inception, it doesn't look like it's ever reached its statutory 25.5 percent premium collection through beneficiaries. And I know actuaries are terrible at what

they do and do terrible jobs, but we're going on like -- Bruce -- we're going on to 11 years of missing the market. And I remember, when I read the 2016 report, I remember what really jumped off the page was that over half the plans were hitting their upper risk corridor, so they were giving money back. And I get that. I mean, I understand risk corridors are very important. But when over half the plans are hitting the risk corridor, it makes me think there's something systemic here. And, sure enough, on page 43 of the mailing materials, this year, again, more than half the plans returned that.

So I do hope this spring -- I want to understand more about the formularies, how the rebates are handled, how they're going to the plans, just sort of build that from the ground up, because it does feel like something's off when over 50 percent of the plans hit the upper corridor.

Thanks.

DR. SCHMIDT: Can I respond briefly, just to say we're happy to talk about some of this but also please look at our 2015 chapter from June. It goes into this in some detail.

DR. CROSSON: I'm seeing some quick, jumpy -- I think I saw Bruce first and then Paul and then Jaewon.

MR. PYENSON: It's hard to follow up on Brian, but this is actually perhaps a Round 1 item. I'm wondering if it would be possible to illustrate, with actual formularies, situations where higher-priced drugs are on the formulary and lower-priced equivalents are not. Shinobu, you had mentioned Nexium, which, of course, has, as an example, with a brand generic, but I think there are also examples with brands. So I think for sure the 2019 formularies are out, and I'm wondering if would be appropriate to give those as examples.

DR. SCHMIDT: I think the tricky thing is that we don't see rebates, so we're not going to know that side of things.

MR. PYENSON: Right, but you would have list price, and there are some differences that, you know, a 5 percent rebate or a 10 percent rebate is more than the list of the competitor product. So I think there might be some examples like that.

DR. CROSSON: On that?

DR. BRICKER: So you might want to look at --

there are a couple of manufacturers that just introduced alternate NDC, so Repatha did this. So you could look at where it's the same drug, they just introduced a lower NDC with presumably little to no rebate. So there are some examples, without knowing the rebate, just the behaviors of plans. That would then get to your question.

DR. CROSSON: Paul.

DR. PAUL GINSBURG: This was a terrific chapter and I agree on your singling out reinsurance and the way we handle coverage cap discounts is really important.

I was really struck by the differences in types of drugs used by the low-income people versus the other, and, you know, when you're working with prescription drug claims data you gain much more insight into what people's medical issues are, than when you're dealing with other types of data that we work with.

And just something that we should really always keep in mind when we're not seeing these differences is clearly when we're talking about hospital care and physician services, the fact that the differences are big. And I don't want to jump ahead to our next session but, you know, I'm really glad the way our HVIP handles the

difference between the low-income and higher-income beneficiaries.

DR. CROSSON: Thank you, Paul. Jaewon.

DR. RYU: Yeah. I was just going to add that the dynamic between the catastrophic and the capitated, and it may be just dusting off the prior recommendations or work from 2015. I think you alluded to that.

The other element, I just want to get back to the human behavior side and the price sensitivity around copays and cost shares. I think there's something there that would be good to get a little more fine-tuned around. Obviously I don't think we're trying to be prescriptive to the plans around how they structure those things but having a better understanding of the impact that that has on some of the decisions, where alternatives are possible. I mean, some of these you don't have alternatives and it's a unit cost issue. You know, that's a separate dynamic. But where there are alternatives it seems like, you know, what are the levers and how much can you shape human behavior.

DR. CROSSON: Okay. Dana.

DR. SAFRAN: I'm back on thinking about the coverage gaps issue and the point that reducing, over time,

the amount of cost-sharing for the enrollee like to have on the manufacturer pricing, which, you know, Amy brought up. And so that leads me to wonder, you know, are we, in the name of helping ease the out-of-pocket cost burden and thereby reducing cost-related non-adherence to necessary medicines, maybe creating a different kind of harm, which is raising costs across the board?

And so that just leads me to wonder whether there's a way that we could approach that analytically. Do we have data on cost-related non-adherence to prescriptions? It's something that years ago, before my time at Blue Cross, it was at the heart of what my research was about. I don't know that the Medicare beneficiary survey has that information, but if it did would there be a way to kind of do an analysis of the tradeoffs that we're making. While maybe we're reducing cost-related non-adherence, what are the other harms that we may be creating potentially by driving costs up across the board, or some of the other effects here. Just a thought.

DR. SCHMIDT: We can certainly brainstorm on it. The chapter includes a bunch of citations to previous literature that's kind of trying to measure adherence

between the LIS and non-LIS population because they have a difference in cost sharing. So there are some estimates for some particular classes.

DR. SAFRAN: And changes over time, not just --

DR. SCHMIDT: Less so.

DR. SAFRAN: Because it seems like that's what we'd need, like how much has reducing the out-of-pocket cost sharing, the coverage gap, helped improve cost-related non-adherence but at what expense? I think that is the question I'm asking.

DR. CROSSON: So, Dana, now that you understand the donut hole, as you look around in depth with your flashlight, you're going to find all kinds of things, I can guarantee it. Jon.

DR. CHRISTIANSON: On that same question, I guess, I was a little bit confused on the process of how this would work, Amy, so I probably didn't understand it. But it seems to imply that the drug manufacturers have some unexploited ability to raise prices that they would then take advantage of, which seems so unlike the perception of how drug manufacturers price their product. Can you say something more about that? It seems like if they could

have raised their price, they would have, irrespective of what happens to the rebates.

MS. BRICKER: They do.

DR. CHRISTIANSON: Okay. So I don't get why -- this seems like a similar argument we make around hospital pricing.

MS. BRICKER: No; they do raise their price, and it can -- and there's nothing that prevents it from, you know, being thousands of a percent. I mean, you see this across the spectrum. It's moderated in the last year just because of the political pressure, I think no other reason. And then we're starting to see it again, not to the same historical extent, but we're starting to see price increases again.

My point was just if you -- you can actually look at when there was an obligation for the manufacturer to contribute 50 percent discount, what happened to their prices at that point in time. I fear now with a 70 percent obligation we're just fueling this sort of indirect consequence of our action -- it's a direct consequence, actually.

DR. CHRISTIANSON: Yeah, so I don't understand

the argument here. I don't understand why they're not a profit-maximizing company and they've already set their price at approximately -- at the rate that they could get. But we could talk later about this.

MS. BRICKER: They raise them every year, again, for shareholder return, for a number of reasons, but they will raise their prices every year, unfettered.

DR. CROSSON: It also provides justification in the minds of some.

DR. PAUL GINSBURG: Actually, I think I heard from Amy something that you -- what would make sense to you, is that, you know, they're setting prices in different markets, and so in a sense, if they're constrained in one market, how the array of prices should look could be different.

DR. CROSSON: Warner.

MR. THOMAS: As we get to the recommendations, when we come back for the spring discussion, I guess one of the things I would ask the team to think about is, you know, in essentially the reinsurance area, which, you know, flips to 80 percent coverage from Medicare, should there be some additional rebate or discount provided by the

manufacturer to the extent that drugs get into the reinsurance pool, you know, so that there's kind of a -- that they're contributing to -- and, you know, maybe it takes some of the incentive away from, you know, getting into the reinsurance pool, but even if there is an incentive, once they get in there, they have to put some of those dollars back. Also, I just think that we need to make sure that the plan has incentive across all the pools, including the donut hole and in the reinsurance pool, to control costs. I mean, it seems like in the readings and in the article that was provided that was recently in the Wall Street Journal that there's just -- you know, maybe there's not as much incentive on the plan side once you get into the reinsurance area. And so I think, you know, some recommendations around how that could be modified and how the manufacturer could play in the reinsurance pool may provide more cost controls of this.

DR. CROSSON: Okay. Good discussion. Thank you very much. We'll look forward to hearing from you again tomorrow morning.

We'll move on now to the second presentation, final presentation for this morning's session.

[Pause.]

DR. CROSSON: Okay. We're going to proceed now with a discussion of an important public health issue, and that has to do with opioid use. And the question that was asked of the Commission was to undertake an analysis to see whether or not, in hospital settings at any rate, there were incentives for hospitals to use opioids as opposed to other methodologies to control pain. And Jennifer is going to present us with that analysis.

MS. PODULKA: Thank you, Jay. Today's presentation will be an update to the discussion we had in October.

So the SUPPORT for Patients and Communities Act calls on MedPAC to report to the Congress by March 15, 2019, on three items:

First, a description of how the Medicare program pays for pain management treatments (both opioid and non-opioid alternatives) in the inpatient and outpatient hospital settings;

Two, the identification of incentives and adverse incentives under the hospital inpatient and outpatient prospective payment systems for prescribing opioids and

non-opioid treatments, and recommendations as the Commission deems appropriate for addressing these;

And the third item is a description of how opioid use is tracked and monitored through Medicare claims data and other mechanisms and the identification of any areas in which further data and methods are needed for improving understanding of opioid use.

On the first item, Medicare uses bundled payments to pay for pain management drugs and services in both the inpatient and outpatient settings. They are applied somewhat differently in each. The inpatient prospective payment system, or IPPS, assigns stays to categories depending on patients' conditions and sets payment bundles that reflect the average costs of providing all goods and services, including any drugs, supplied during the stay. In contrast, the OPPS groups services into categories on the basis of clinical and cost similarity and sets payment bundles to cover the costs of providing the primary service plus goods and services that are integral to the primary service. Any additional goods and services are either paid separately or not paid by the OPPS.

You may remember that in prior reports and

presentations we've described situations where outpatient drugs are usually self-administered, separately payable, or paid on pass-through, but these rules don't apply to pain drugs in the outpatient hospital setting.

So the inpatient prospective payment system is fairly straightforward, but the outpatient payment system is not, so we'll dig into it.

Pain drugs in outpatient settings may be paid under Part B or Part D or not paid by Medicare at all.

First, when the drug is for pain, the next question to ask is: Is the drug directly related and integral to a procedure or treatment?

Drugs that are used for postsurgical pain management are, so these are paid under Part B as part of the OPPS bundled payment.

But pain drugs can be used in outpatient settings for other reasons. Rather than being directly related to a procedure or treatment, pain drugs can be the sole treatment -- for example, when a patient goes to the emergency department with migraine pain. In these cases, Part B doesn't pay for the drug, and the hospital usually charges the patient. If the beneficiary has a Part D drug

plan, the plan might pay for the drug if it is included in the plan's formulary and the hospital's pharmacy participates with the plan, but many don't.

And one last note before moving on. CMS' guidance about determining how drugs are paid for in the outpatient setting is directed to the MACs, or Medicare Administrative Contractors. This means that implementation of these rules is up to the discretion of the individual MACs, so there may be variation across geographic regions.

The mandate's second question directs us to identify the extent to which there are incentives and adverse incentives introduced by the hospital inpatient and outpatient prospective payment systems for prescribing opioids versus non-opioids. Our study focuses on evidence that these financial incentives could have an effect on hospitals' decisions about which drugs to include on their formularies and possibly promote for use by their physicians. But we recognize that actual prescribing happens on a case-by-case basis when a clinician or team selects the drugs to treat an individual patient, so in addition to any potential financial consideration, there are patient-specific and clinical factors that guide

prescribers' pain drug choices

In other words, the inpatient and outpatient prospective payment systems are designed to give hospitals a financial incentive to select the lowest-cost goods and services possible.

This incentive is balanced by Medicare's quality measurement and reporting programs along with providers' clinical expertise and professionalism.

Thus, these balanced incentives ideally result in high-quality outcomes for patients at the best prices for beneficiaries and other taxpayers.

To better understand the extent of any systematic financial incentives that would lead clinicians in hospital settings to prescribe opioids over non-opioid alternatives, we analyzed the differences in prices between opioid and non-opioid drugs commonly used in the inpatient and outpatient hospital settings.

To begin, we consulted with clinicians to determine which pain drugs to include in our study based on those that are commonly used in hospital settings, which means that this list does not include all pain drug options.

Also, this analysis has a key caveat: We do not know the actual prices that hospitals paid for these drugs as hospitals do not report their drug acquisition costs. And let me pause here to note just how little information that we and others have to go on. Hospitals don't report the prices paid for individual drugs or which drugs they pick for patients or anything about dosing, so we don't know the volume of pain drugs used in our study.

We considered as a substitute average sales prices, or ASP, which are a weighted average of manufacturers' sales prices for a drug for all purchasers net of price adjustments, but these are not available for many of the drugs in our study.

In lieu of either of these, we examined two publicly available list prices: wholesale acquisition cost, or WAC, and average wholesale price, or AWP. We found similar price patterns for these, so we present WAC alone for brevity.

We acknowledge that WAC represents an upper bound. Actual prices paid by hospitals are likely lower, as WAC is the manufacturer's list price and does not incorporate prompt-pay or other negotiated discounts.

But WAC is still useful as it provides the relative prices of opioids versus non-opioid drugs, which are informative for our study.

I'd also like to note that when clinicians prescribe pain drugs in the hospital setting, they have multiple options, including the drug's route of administration -- for example, oral or intravenous -- and the dosage form -- for example, tablet, capsule, and solution.

Prescribers can also opt to use multiple drugs in combinations -- that are sometimes called "cocktails" -- which give flexibility in the choice of drug agents to treat pain and related symptoms and can mitigate the drawbacks of individual drugs in the cocktail without unduly sacrificing drug efficacy. For example, a lower dose of an opioid can be used along with a non-opioid to reduce risk while still achieving sufficient analgesic effect. This flexibility is important in the hospital setting as opioids are more often indicated for acute, severe pain than many non-opioid alternatives. And while there are some recent studies that suggest similar analgesic effect of opioid and non-opioid drugs even for

some cases of moderate to severe pain, it is not clear that non-opioid alternatives can or should replace opioids for all cases of acute, severe pain.

Because of these options, our study's non-opioid drug category includes multiple groups, such as the more direct alternative of NSAIDs and other non-opioid pain relievers, as well as other drugs that can be used to partially or fully substitute for opioids when used in combination, such as general and local anesthetics, sedatives, and neurologic agents for nerve pain.

We found that the ranges of WAC list prices for opioids and their alternatives overlap. The available choices for opioids and non-opioids that are commonly used in hospital settings both include options that list at less than $1 per dose.

Specifically, for opioids there are ten commonly used options that list at less than $1 per dose. These represent 31 percent of the commonly used opioids where WAC is available in our study. The lowest list price is five cents per dose.

For NSAIDs and other non-opioid pain relievers, there are 27 commonly used options that list at less than

$1 per dose, representing 47 percent of options in this group. And the lowest list price is two cents per dose.

The commonly used drug groups of neurologic agents, sedatives, musculoskeletal therapy agents, ophthalmological agents, and local anesthetics all include an option that lists at less than $1 per dose.

We are not asserting that all of the drugs on this list are interchangeable. When prescribers pick which ones to use for individual patients, they should not always pick the two-cent choice. But there is no clear indication that Medicare's inpatient or outpatient prospective payment system provides systematic payment incentives that promote the use of opioid analgesics over non-opioid analgesics. Both opioids and non-opioids are available at a range of list prices, and there are options for either type of drug that list at less than $1 per dose.

You'll see that there are some non-opioid options that are much more expensive, but this is true for the opioid drugs as well.

Turning now to the third item from the mandate on monitoring, as we discussed in October, CMS tracks opioid use through data available in the Part D program. To

briefly review, CMS monitors opioid use in Part D in multiple ways. The three categories shown here might be the most relevant for Part A and B.

First, the Overutilization Monitoring System shares feedback securely with Part D plan sponsors and ensures that they implement opioid overutilization policies effectively.

Second, CMS uses quality measures to track trends in opioid overuse across the Medicare Part D program and drive performance improvement among plan sponsors. These include publicly available display measures and confidential patient safety reports that are sent to plan sponsors.

And, third, CMS makes data on clinicians' opioid prescribing patterns publicly available on the website through the Medicare Part D opioid prescribing mapping tool that shows comparisons at various geographic levels.

All three efforts rely on prescription drug event, or PDE, data. These data are summary records that prescription drug plan sponsors must submit every time an enrollee fills a prescription under Medicare Part D. The PDE data are not the same as individual drug claims, but

are summary extracts using CMS-defined standard fields. The distinction is important, and I'll come back to it in a bit. And the agency does not operate opioid tracking programs in either Part A or Part B.

In our last discussion, the sense of the Commission was that there are compelling patient safety and public health reasons for Medicare to track the use of pain drugs in hospital settings.

Reasons for undertaking a tracking program include the severity of the opioid epidemic, the gap in knowledge about the degree to which Medicare beneficiaries are exposed to opioids while in the hospital, and the opportunity for program oversight of hospitals' use of opioids versus non-opioids.

Last time we discussed some existing programs that might serve as alternative oversight programs in lieu of Medicare taking on this role. Other federal agencies besides CMS have jurisdiction over some aspects of opioid use, such as FDA, CDC, and SAMHSA, but none has programs that track opioid overutilization in the hospital setting.

States have also taken on a role through the use of prescription drug monitoring programs, or PDMPs, which

are electronic databases that track a state's controlled substance prescriptions. Along with some other features that affect the utility of the state PDMPs, hospital inpatient pharmacies are not required to report to them.

So that brings us to options for implementing a Medicare tracking program.

First, we could require hospitals to report PDE-type data. If Medicare were required to undertake an opioid monitoring program in hospitals, structural differences would require CMS to adapt its current program under Part D, which relies on plan sponsors to report the PDE data. CMS also relies on the plan sponsors to use analytic results to implement drug management programs and clinical contact with prescribers. While there are no drug plan sponsors in Parts A and B, prescribing clinicians or hospitals could be required to report summary information (similar to the PDE) about pain management drugs.

Second, we could require hospitals to report prescribed drugs on Part A and Part B claims, which currently do not include information on the pain management drugs included in bundled payments. CMS could take steps to incorporate these data into the claims and then require

hospitals to include it. This would require decisions about how best to proceed and would likely require a multi-year effort to implement.

And, third, CMS could incorporate opioid use disorder, or OUD, in its Hospital-Acquired Condition Reduction Program or any replacement program.

Last time we discussed that the existing program could provide a platform for tracking the effects of opioid use that originated in hospital settings. The program sends confidential hospital-specific reports and reduces payments to poor-performing hospitals. It includes six hospital-acquired condition quality measures such as rates of C. difficile infection.

Incorporating OUD and other opioid-related adverse events into the program would require the development and adoption of a measure, a source of documentation for use with the measure, (such as the PDE-type or claims options we just discussed), a longitudinal tracking effort to identify eventual OUD and other opioid-related adverse events, and, finally, a mechanism to link the outcome to the responsible hospital. Tracking of OUD and related diagnoses could defer identification and

feedback and also underestimate the effects of opioid use in hospital settings, as clinicians could delay or avoid diagnosing OUD because of its associated stigma and patients could similarly avoid receiving health care services and diagnoses.

I also want to note that I mentioned any replacement program here, if the Commission has discussed concerns with the design of the current hospital-acquired condition reduction program, and later today you will vote on eliminating the program and implementing aspects of it in an improved hospital value incentive program.

So I'll conclude here. Please let me know if you have any questions on the presentation or material in the paper. The paper will become the final mandated report and included as a chapter in our upcoming March report.

DR. CHRISTIANSON: Thank you, Jennifer.

Are there any questions of clarification? Brian, Marge, and Amy.

DR. DeBUSK: First of all, thank you for a great report and for choking through that. I'll ask you a really long-answer question.

On Chart 12, the center bullet here, you talked

about requiring hospitals to report prescribed drugs on Part A and Part B claims. Do we have a feel for what the administrative burden of that would look like? Is that flipping a switch on an EMR? Or is that an overhaul of how coding and claims are handled?

MS. PODULKA: We did specifically talk to CMS about what this would entail. They wanted to convey that it's not instantaneous. There would need to be some modifications. They stand ready, if asked by the Congress, to modify. As usual, CMS responds to congressional requests and action. So we do mention that it would require some effort. It couldn't happen right away. It may be months before it could be implemented. I don't have a specific time frame for you, though.

DR. DeBUSK: Will we get a chance to talk to some hospitals and get some feedback on just how big of an administrative hurdle that might be?

DR. MATHEWS: Brian, I think that would depend on the extent to which we want to pursue this body of work after the mandate at hand. We're trying to dispatch this to comply with the statutory deadline of March 15th. So if there are lingering issues or additional items we want to

pursue, we could have that discussion. But the short answer is not before we end up publishing this material.

DR. DeBUSK: One other question. I had two here. In the mandate, the mandate reads that we're supposed to report, I think it is, any incentives for opioid versus non-opioid use. And I like the fact that we focused on the cost. I mean, that is the obvious one, the cost incentive. But what about the effect on length of stay or on patient satisfaction? I would think those might be incentives, too, that we would want to explore. I realize that would require chart review, and none of this is available currently. I get all that. But I was going to ask, is cost the only incentive that we're going to explore to meet this deadline?

DR. MATHEWS: That is the only one that we contemplated in the conduct of the work thus far.

DR. DeBUSK: Even though the mandate is somewhat open-ended, any incentive versus any financial incentive.

DR. MATHEWS: That is true, but the financial incentives seem to be the most pressing, and to get into things like efficacy or patient satisfaction, we start getting into very idiosyncratic issues that do invoke chart

review and things like that.

I would also point out that we were given a fairly limited amount of time in which to conduct this work. I think the final legislation was passed in October-ish. We were given a heads-up a couple of months before then, and so we started on this work. But it's not a lot of time to do an extremely comprehensive scope, and so we focused on the aspect that seemed to be of most relevance to us and do the Congress.

DR. DeBUSK: Okay. When I saw the chapter, the one lingering thought or the one that really stood out was length of stay because I thought if these opioids are perhaps getting them out of the hospital sooner or more confidently -- and even if we can't collect that data, that might be something we want to mention. That it's hard to measure.

DR. MATHEWS: We will talk when we get back, but I think it is something that we could at least acknowledge as an additional incentive that we didn't deal with at length in the analysis.

DR. CHRISTIANSON: Marge.

MS. MARJORIE GINSBURG: Two questions or

comments.

The first one, is there any tracking of discharge meds? I didn't see any reference in the report, but if one is interested in finding out how the opioid epidemic gets started, I would imagine that looking at discharge meds from the hospital would be an important piece.

I don't know. Are discharge meds under Part A or Part D?

MS. PODULKA: They get switched to Part D. So even if you take something, say, in the emergency department, they can't send you home with something that gets charged to Part D.

Specifically, we're trying to scope everything down to be responsive and meet the mandate, and the mandate is focused on A and B, which includes the discharge meds.

MS. MARJORIE GINSBURG: Okay.

My second comment -- and I confess my husband works for the Medical Board of California and does review of bad doctors, a lot of opioid cases. So I asked him to look it over.

This may not be anything we can do because if CMS is already doing it.

So, in the report itself on page 1, it talks about the things that CMS is tracking, and one was prescriptions of opioids from four or more prescribers and four or more pharmacies. And based on a whole lot of reviews he's done, he has never seen anybody with four or more and thinks that should be reduced to three.

Also, it says four or more prescribers. I think that should be changed to "practices" because often you might have nurse practitioners working under a physician. So you might end up with more prescribers than you actually have practices.

Anyway, I don't know what the status is of CMS doing this review, and I wonder if you could mention that and whether it's too late for any comments on that.

MS. PODULKA: CMS has actually just newly rolled out some refinements to the Part D tracking program, and I can't remember specifically if the four was one of the ones that changed most recently or not.

Basically, they've implemented a lot more requirements and more tracking efforts and changed some of the criteria. It's just gotten started, and so sometimes when that happens, we like to see what the effect is before

we comment again.

DR. CROSSON: Amy.

MS. BRICKER: Similar to where I thought Marge might be going was around -- so the concern is someone has started on an opioid -- I think this is the concern. Someone started on an opioid in the hospital and then maintained and then becomes addicted to the opioid they were started on.

So I'm wondering. Is there a role that retail pharmacy could play in tracking of the initiation of the drug?

Again, I know you mentioned we could hook in A and B or hospitals could hook into what's been established in D. Then we have a complete picture of the patient and the prescribing of the opioid. When the discharge prescription is written, there are additional questions about when was the patient started, what was the patient started on, what was the patient started for. I don't know. Just additional information.

I fear if we're trying to build an infrastructure for every hospital in America, we'll never get there. So can we hook into what's already established?

MS. PODULKA: So this would contemplate having -- tell me if I'm getting this wrong, though -- having a prescriber who writes a prescription that would then be filled under Part D to include information about what that prescriber knows the patient did while in the hospital.

MS. BRICKER: Just an idea because --

MS. PODULKA: Yeah.

MS. BRICKER: -- everyone that has D has A and B, so some way to then just tie this together in some sort of historical context because where the breakdown occurs is that you can leverage pharmacy benefit managers for all of the Part D information in the universe, but A and B, to your point you were making very well in the chapter, we just don't have this level of insight on the drug level in the hospital.

So given the health crisis, can we shift sort of the protocol to ensure that when you're dispensing a script, you have to get that information if it's on discharge, for instance?

MS. PODULKA: It's something we could definitely add a discussion and explore.

Totally off the top of my head, I think it's

intriguing. I'm sure there might be some limitations if the discharge is different from the team or something, but definitely worth considering. Thank you.

DR. GRABOWSKI: I like the idea, Amy, and another part of this is those individuals discharged from the hospital to a skilled nursing facility would be through a long-term care pharmacy under the Part A. I'm just thinking how, just in general, post-acute would play into this, and then do you want to bring in the long-term care pharmacies as well to be a part of this?

Thanks.

DR. CROSSON: Jonathan.

DR. JAFFERY: Two quick questions, but actually, before that, also to Amy's question, maybe one way you could think about it, without having -- well, perhaps if a beneficiary had a first-time fill for an opioid linked very closely to a hospitalization discharge, to a discharge, you might be able to get around trying to link some other things, if that makes sense.

So if somebody's first fill comes within a week of being discharge, that might be an indication at least of what happened at the inpatient stay.

But my questions, in terms of bullet point 2, if we were to require hospitals to report this in Part A and Part B, would we be missing any MA beneficiaries? That would be one question.

MS. PODULKA: For the MA beneficiaries, we might need to capture this information through encounter data, which we'll be discussing later this spring --

DR. JAFFERY: Yeah.

MS. PODULKA: -- which has its own issues, but since we're missing exact claims there, we would either have a mechanism for the prescribers under MA to report summary or claim-type information or report it as encounter data to the plan to translate to Medicare.

DR. JAFFERY: Okay. So maybe a couple extra barriers there too for that.

The other question, do all states currently have functioning PDMPs, and if so, is there any precedent or opportunity to tie into those?

MS. PODULKA: Forty-nine states do. One additional state is in the process, but doesn't have a complete one.

PDMPs do have a role to play, but right now, in

addition to some other technical limitations, the hospital inpatient pharmacies aren't required to report to the state PDMPs, so they're kind of facing the same blind spot that Medicare is.

DR. JAFFERY: I guess I'm wondering if we could move in the direction of that be the requirement because PDMPs seem to be functioning. At least in Wisconsin, they're functioning, functioning pretty well.

MS. PODULKA: It could be a requirement. I'm not sure that we're the right body to --

DR. JAFFERY: Yeah.

MS. PODULKA: Yeah.

DR. CROSSON: Okay. Seeing no further questions, we'll proceed to Round 2.

Jon is going to start us off.

DR. PERLIN: First, Jennifer, let me thank you very much for a thoughtful response to this congressional mandate.

It's interesting that just this week, the National Safety Foundation identified opioid use disorder as the number one preventable cause of death in the United States, and that's quite a statement. That supersedes car

accidents and everything else, so obviously, this is a crisis.

I think the data are that too many of these late-term consequences start with exposure to opioids in clinical settings, including the hospital.

We also know at a very fundamental level that the dose and duration of opioids contribute to the propensity to later dependence.

In terms of the questions that we were asked, the description of payment is factual, and I appreciate the very thoughtful outline of that. I think on a financial basis, the data that you outlined suggest that there are no dollar incentives that drive to a particular use of one versus the other.

But I think there are two points here worth noting. First, I think the overwhelming evidence in prescribing generally is that bad prescribing isn't driven by cost sensitivity. In fact, it's just the opposite. That the history of bad prescribing, be it overuse of antibiotics, for example, is done with incredible insensitivity to cost. So I think that's further evidence that that's probably not the key component of choice there.

I think Brian and others point, that there may be other incentives at work, I think are particularly important. Ironically, it may be that opioids, depending on the circumstance, can either shorten your life, then, and certain non-steroidals and/or other agents can shorten your life.

I think the other issue is to really get at the question that I think is behind the nominal question, is how do we improve prescribing and reduce bad or avoidable outcomes and unintended consequences.

When you factor in the unintended consequences, some of the approaches now to avoiding opioids made themselves have additional liabilities. First, at a sort of social, financial level, some of them are very expensive. They're like preparations of drugs, that they're long-acting forms and things that are dirt cheap, that put in a particular preparation are literally four to five orders of magnitude more expensive. That's obviously problematic.

Second, the substitutions of some of the analgesics, opioids in particular, by other things that aren't necessarily analgesics can lead to unintended

consequences. For example, some of the drugs that might be used for nausea or a headache actually are in the category of atypical antipsychotics and can cause lifelong complications like Tardive dyskinesia and the like. So these are not necessarily good outcomes either, and so don't want to inadvertently drive other problems.

So let me just dissect a couple of pieces first, and I'll offer some comments on each of the categories. What about the question of requiring prescription drug events reporting by hospitals? I would offer that the question is what are the relevant outcomes, and do they occur within the window of hospitalization? I think the issue here is are you creating a situation in which there are long-term dependence or complications that derive from that, and so the window of insight into those events may not necessarily be during the hospitalization, just that I mention the dose and duration are predictors.

So I just note that that's relevant on part two, which is require hospitals to report on prescribed drugs on Part A and Part B claims. I would offer that is actually going to be quite burdensome. We mentioned the limitations for MA patients in terms of a lack of structure at the

outset.

But here's the other problem. It may not be the best relevant data. It may neither be the best data in terms of in-hospital data because it's inadequately clinical, and it may be the wrong window of time because you're really looking for the propensity to a later liability.

Third -- and I feel a little guilty about this one in terms of incorporate opioid use disorder into CMS's hospital-acquired conditions program. I think in theory, that's a great idea. I think in theory, it is because I have to be consistent with myself. Authors Mike Schlosser, Ravi Chari, and Jon Perlin posted a blog to Health Affairs on considering opioid use disorder as a late-occurring complication.

And it was really meant to spark debate about dose and duration and alternatives to opioid therapy in hospital, and while in the social sense, we need to be paying attention to that in a sort of practicable time limited sense, it's probably not operational for the reasons I have mentioned.

So let me just dive down into a couple of other

comments in each of these areas. First, it may not be beyond the scope to comment on achieving best prescribing and reduction of opioids through programs that we want hospitals to do, alternatives to opioid therapy at emergency departments, or ALTO, as how some of these programs are named. Enhanced surgical recovery programs are programs that systematically reduce the need for larger doses of opioids and can be beneficial.

In the area of incentives, I would note that beyond the question of length of stay, which may go in either direction on both opioid and non-opioid classes of drugs, while the Patient Experience Survey, or HCAHPs, has been changed from questions that really implied an absolute elimination of pain, there are still discussions of pain. And I think further education is needed in the provider community because that still operates, if not an explicit, certainly an implicit incentive toward use of maximal pain therapy.

Second, you had noted in the chapter, which is really so well written -- and thank you for that -- the need for prescribing guidelines. One of the problems in adoption of prescribing guidelines is the variation. I am

pleased to report further progress from the National Academy of Medicine. I mentioned the Action Collaborative that's bringing together professional and provider organizations in both care and addiction.

But under the aegis of that and in collaboration, the FDA is actually promulgating new prescribing guidelines for pain management, suggests that that be identified as a benchmark when they're published later this year for appropriate use.

There are incentives against the use of certain agents that may have less opioid addiction liability. Buprenorphine, for example, requires additional education. Ironically, other agents that have been implicated in addiction do not, and that may fall under the aegis of incentives.

Finally, let me just close with some other suggestions on how to get at the best possible data, best outcomes. I think the thread of conversation and the round of clarifying questions about the use of Part D for discharge prescriptions is really a good telegraph into whether a patient is going home with a high dose of opioids, whether they're going home with a dose of opioids

that they didn't have prior to hospitalization. They think that could be potentially reconciled pre- and post-hospital, and in the context of the indications, the patient has certain diagnoses, as particular prescription may make more sense than some of the other diagnoses. So think about -- toward answering Congress' inquiry, a direction there may be of some benefit.

In terms of the events tracking, there may be some hospital data in terms of rescue drug use for overdoses. That's bene discussed in the clinical literature.

We now have ubiquitous electronic record system. I would encourage the use of the clinical systems, as the administrative systems really don't have the sensitivity to articulate what the context was in which particular choices of cocktails, opioids were used. And there still is a very appropriate role -- and the shortage of certain opioids for surgical other procedures.

There is in the clarifying round the question that Jonathan and others raised about the utility of the prescription drug monitoring programs, and with the increased requirements for e-prescribing, the ability to

ping the PDMP, even inpatient might be something that could be encouraged. So that prescriptions aren't started if one had indication that a particular patient was at risk for overuse or had different sorts of opioid prescription history.

Finally, the use of other technologies may be of merit. The FDA has sponsored the use of the Sentinel programs. The Sentinel has a database of the actual drugs that are used during hospitalization. That may provide a basis for surveillance -- I'm getting further afield -- chain of custody of all opioids. Distribute the literature aka blockchain may be a way of tracking opioids throughout the entire cycle.

So I hope those comments are helpful and again commend for a terrific chapter and then back to the question's factual response on the payments, that's there. The incentives, probably not financial. There may be stronger incentives related to experience, maybe some implicit incentives related to finance and tracking.

I don't think the administrative systems offer the best data in terms of trying to force Part B into the hospital, but the post-hospitalization Part D may offer the

highest utility.

Thanks so much.

DR. CROSSON: Thank you, Jon. Very comprehensive. I was particularly impressed with your ability to debate with yourself, and win.

Further comments for Jennifer? I see Jonathan, Amy.

Jonathan.

DR. JAFFERY: All right. I hadn't raised my hand.

DR. CROSSON: Oh. Not your hand. Was that Kathy's hand?

MS. BUTO: It was.

DR. JAFFERY: Go ahead.

MS. BUTO: It was my hand but I was disguised as Jonathan.

DR. CROSSON: You just snuck it up under his shoulder or what?

MS. BUTO: Sorry about that.

So I really want to just endorse a lot of what Jon was saying about prescribing guidelines and using not financial incentives so much or data requirements to try to

get at the issue of really the long-term dependency on opioids by patients post hospital discharge. I think using Part D as a way to track those prescriptions longer term would be a good way to go at it without adding new requirements.

I'm also wondering -- and this is really out of ignorance -- whether we can look at either MA or MA and ACOs, which are intended to try to manage or coordinate care across the continuum as a way to get at some of the data on opioids and use of prescribing guidelines, and find a way to provide incentives within that structure. And this may not be the only issue. But I realize that the argument against that is you don't want to develop too many sort of site-specific or entity-specific requirements that then take you far afield from making comparable assessments across fee-for-service and managed care.

But I just feel like that we ought to be, in those entities, able to track more of this kind of issue, which is longer-term dependency on opioids and other issues that cut across provider settings.

DR. CROSSON: Thank you, Kathy. Amy.

DR. BRICKER: I'm going to go a little bit of a

different angle for just a moment. So I was thinking about a couple of things. One, my own personal experience and, one, just the crisis that this country is in relative to opioid misuse.

There is never a conversation in the hospital about your care plan relative to pain management, from my experience. I've had surgery. I've had children. No one has ever said to me, "We're going to discharge you. You're going to be in the recovery room on morphine." There's never been that explicit sort of explanation of the drugs that are going to be administered.

Why I think this is important is within the number of people that will likely enter our health system, our hospitals, our ERs, that have struggled with opioid addiction, who absolutely fear being reintroduced to an opioid, it's incredible.

So is there a way for us to require the screening of, have you ever, you know, had an opioid-related addiction or have you ever sought treatment for, or some sort of screening? We put on the walls of hospital beds "this is a fall-risk," right, so take care. We don't say "this patient has struggled with an opioid so don't give

them one," or this patient doesn't ever want one if we can, at all costs, not give them one, you know, all other treatment options should be sought.

So maybe it's not practical, but I think we've got to figure out a way to support people that are coming out of recovery, and when they're at the hospital thinking that they're getting the best care that's available to them it not be price, it not be cost, but it be about the health and well-being of that patient and us ensuring that we're doing the best that we can by them.

DR. CROSSON: It's interesting because, actually, I thought where you were going to go was requiring informed consent, which, of course, is done for procedures.

DR. BRICKER: Similar. I think that's exactly what I'm suggesting.

DR. CROSSON: Jon has a comment.

DR. PERLIN: Yeah, just briefly on this point. Great comments, Amy. In that legislation, if I'm not mistaken, it includes a requirement, at least annually, Medicare beneficiaries be screened for opioid use disorder. My only qualm with that screening is that it should be broadly for any substance use disorder. Putting that

aside, I think your thoughts are really well taken about a care plan discussion.

DR. CROSSON: Okay. Did I see anybody else?

Now -- yes, Karen.

DR. DeSALVO: I'm sorry. I was trying to find that there was some legislation based on a death that happened just in that circumstance, a woman named Jessica Grubb, who had an addiction disorder, and when she was admitted they failed to ask and she subsequently died.

So I just want to relate also to the demand side of the equation. I want to add on to what Amy is saying, because I think, first, as we've described, it's a very complex scenario in the hospital setting about whether someone gets prescribed and then actually takes opioids for pain, and that may happen sometimes in the middle of the night without a lot of forethought because somebody is awake and you want them to sleep, et cetera. So many hospitals are taking matters into their own hands and they're leveraging their pharmacies as the gatekeeper to it. And I don't know if there's an opportunity, Jennifer, for pharmacy data to inform some of this, if it's so outside of the sphere. But that's a way that they're

trying to track not just prescribing but actual administration of drugs to folks.

So the demand side may be something to consider if there's still time, before we send the report to Congress, which is are there ways that the Medicare program could better inform beneficiaries at the time -- required at the time of admission to the hospital, during hospitalization, on discharge, at the time of enrollment in Medicare, just to increase awareness that there are multiple ways to manage pain, that there's good science around addition, even short-term treatment with opioids can lead to addiction, because that education would probably help empower them even further than they've already been.

DR. CROSSON: Thank you, Karen. Bruce.

MR. PYENSON: I think this is a fascinating topic and this group is so smart and interested, but I'm worried about whether this is best venue or whether MedPAC has the means to contribute to this beyond the many other federal organizations and private organizations that are addressing the topic.

So I just have a concern about that. As we go forward, we had a fairly specific charter to address on

payment issues, and wonderful discussion but I'm uncomfortable going too far out without having a full view of what the CDC is doing, or what other organizations are doing on this issue, with some of the topics.

DR. CROSSON: So, Bruce, that's a good point, and just let me sort of be clear. Given the specificity of the mandate, as you point out, and also the time frame to get this report done, we have stopped short of, and will stop short of trying to adjudicate, you know, what's the best solution, you know, to the tracking or even interdiction of inappropriate use in the hospital. But I think it is within the mandate, and it is the intention, given the time frame that we have, to mention ideas that have come up through the staff or that have come up through the Commission discussion. And I think that's the intent.

MS. MARJORIE GINSBURG: Is the point you're making, Bruce, is we can present ideas but we don't want to own it? Or is this report going to make any reference to what our future role might or might not be?

DR. CROSSON: At the moment, no. We're fulfilling a mandate right now. That doesn't mean that based on other internal or external pressures that we might

not come back to this issue. But this is circumscribed at the moment.

Okay. Thank you. It was a very good discussion, Jennifer. Thank you for this work. Very important stuff.

We are now finished with this morning's discussion. We now have an opportunity for a public comment period. If there are any of our guests who wish to make a public comment please come up to the microphone, line up, and I'll give you an opportunity in a second. I just want to see who is there.

[Pause.]

DR. CROSSON: So this is an opportunity to make a public comment on matters before the Commission this morning. We would remind you that there are other opportunities to interface with MedPAC staff, both online and in person.

As you come to the microphone please identify yourself and any organization that you're affiliated with, and we would ask you to limit your remarks to two minutes. When this light returns, the two minutes will have expired.

Thank you.

MR. BLACKMAN: Good morning. Test. Good

morning. My name is Scott Blackman. I'm an associate of Jerry Stringham at Medical Technology Partners, a Bethesda, Maryland, consulting firm.

There is a problem with the benefit design in federal programs. Some opioid pain mitigation technologies have no benefit category where they can be reimbursed by government insurers. An example of this flaw in the system is noninvasive vagus nerve stimulators. The Pain Management Best Practices Interagency Task Force, which was required to be formed by CARA, indicated in their draft report that, quote, "There are now multiple Level 1 studies and multiple Level 2 studies demonstrating that noninvasive vagus nerve stimulation can be effective in ameliorating pain in various types of cluster headaches and migraines. These therapies provide an electric field to the brain, cranial nerves, or peripheral nerves without actually requiring a surgical procedure or implant."

Unfortunately, noninvasive neuromodulation technologies, which are self-administered, do not meet any current benefit category definitions, including medical, drug, or DME.

We would like MedPAC to propose a minor change in

the definition of a Part D drug so that non-opioid technologies like this could be covered for patients under government programs, should the program administrators deem that they meet the reasonable and necessary criteria for coverage. Without some legislative change, there is no pathway for coverage for technologies like this, and opioids will be prescribed for many of these patients.

I have some legally prepared draft legislation and would ask MedPAC to recommend its enactment.

Thank you.

DR. CROSSON: Thank you for your comment.

MS. DORSEY: Good morning. DeChone Dorsey and I'm representing AvaMed, a medical device association. And I wanted to raise for the Commission one of the concerns we have related to opioid alternative device payments, namely something that wasn't brought out in today's discussion related to language in Section 6082 of the support bill, where it speaks to non-opioid alternatives which, to our understanding, could also include devices.

So we support consideration of payment and coverage policies that reduce bias in selecting the devices used to treat chronic and acute pain. In some cases, this

may mean paying separately for opioid alternative technologies and in others it may mean simply paying more to address inadequate payments.

While these changes are important, we would ask the Commission and others to consider payment revisions that do not force patients to choose between a potentially addictive opioid and a non-opioid alternative device due to financial concerns, by promulgating policies that maintain the same copay for both types of treatments.

Thank you.

DR. CROSSON: Thank you for your comment.

MR. INGOGLIA: Hi. Good morning. My name is Chuck Ingoglia. I'm the Executive Director of the Partnership for Part D Access. And I'd like to talk a little bit this morning about an issue that the Commission has discussed before, mainly Medicare's six protected classes. And this issue is especially relevant today as the Commission, in 2016, made recommendations on the protected classes that have been incorporated into a proposed rule that was recently released by CMS.

Our partnership represents patients from all over the six relevant classes, and we've been curious to --

there's been a lot of discussion that the six protected classes prevent management of the drugs within these classes, and so we commissioned Avalere to take a look at this. And despite the statutory requirements that all drugs in the protected classes be covered, the analysis conducted by Avalere, based on 2016 Part D claims data, showed that, on average, just 67 percent of available drugs from protected classes are actually being covered, and just 60 percent of brand drugs.

Also, contrary to the notion that plans are limited in their ability to manage utilization, the data shows that plans consistently use prior authorization, step therapy, and tiering to encourage the use of lower-cost drugs. In fact, Avalere found that 39 percent of medications in the protected classes are subject to some form of medication management, and the data also show that 91 percent of prescriptions filled within the Part D program are for generic products.

We believe the data compiled by Avalere calls into the question the MedPAC recommendations to eliminate coverage for certain classes of medications within the protected classes, as well as the administration's recently

proposed change to the policy.

On behalf of the patient communities who rely on the protected class policies, we ask you to consider this data and to rescind your previous recommendation.

Thank you.

DR. CROSSON: Thank you for your comment. Seeing no further guests at the microphone we are adjourned until 1:15.

[Whereupon, at 11:54 a.m., the meeting was recessed, to reconvene at 1:15 p.m. this same day.]

AFTERNOON SESSION

[1:15 p.m.]

DR. CROSSON: Okay. I think we can sit down and get going now. For the benefit of our guests, this is the portion of our meeting in January, actually it is the portion of our year where the Commission votes on recommendations primarily to the Congress for updates to various portions of the Medicare provider world for fiscal year 2020.

For those of you who were not present at our December meeting or have been here before, we will have two sorts of presentations and votes based upon the December discussion to the extent that the draft recommendation that was presented at that time was broadly accepted by the Commission. We'll have short presentations and proceed without debate to vote.

In the case where the Commissioners had a prolonged discussion and in many cases asked for more information to be presented, the presentation will be longer. There will be a discussion and then the vote following that.

So we're going to proceed with the first

presentation, which is on the update to hospital inpatient and outpatient payments, as well as a discussion about a way of rewarding hospital performance. And Stephanie, Ledia, and Jeff are here, and Stephanie has got that look in her eye like she's going to start.

MS. CAMERON: Good afternoon. We are back today to continue our discussion of the adequacy of Medicare payments to short-term acute-care hospitals and review our work in redesigning Medicare's hospital quality incentive programs. We will provide you with a draft recommendation for hospital quality reporting and updating the hospital payment rates for 2020.

To start with our assessment of hospital payment adequacy, as you'll recall, using MedPAC's common framework we examine beneficiaries' access to care, providers' access to capital, and the quality of care provided in hospitals. We also examine hospital payments and costs, including Medicare and efficient provider margins for 2017, and we project an aggregate Medicare margin for 2019.

As we discussed in December and included in your mailing materials, the draft update recommendation would affect about $190 billion in Medicare fee-for-service

spending. This includes $118.6 billion in inpatient payments and about $65.5 billion in outpatient payments. Forty-seven hundred hospitals account for about 10 million inpatient admissions and about 2 million outpatient visits.

To summarize our payment adequacy findings that we provided in detail last month and also, again, included in your mailing materials, access to care is good. Use has increased since 2016, and there is excess hospital capacity in aggregate.

Access to capital remains strong with close to record-high all-payer margins and high levels of bond issuance.

At the same time, quality metrics are improving, with mortality rates declining and patient experience improving.

Medicare margins were negative 9.9 percent in 2017, and if current law holds, we would expect slightly more negative Medicare margins in 2019 compared with 2017, even for the relatively efficient providers.

Based on the payment adequacy analysis, the draft recommendation seeks to balance several imperatives. This includes: maintaining pressure on providers to constrain

costs to improve long-term program sustainability, minimizing differences in payment rates across sites of care consistent with our site-neutral work, moving Medicare payments toward the cost of efficiently providing high-quality care, and rewarding high-performing hospitals. Clearly there are tensions between these objectives that require a careful balance in the draft recommendation.

The draft recommendation thus includes two parts: first, providing acute-care hospitals with a substantial payment update, relative to prior years; and, second, provide additional funds to hospitals for their performance under the hospital value incentive program which Ledia will now discuss.

MS. TABOR: The Commission contends that Medicare payments should not be made without considering the quality of care delivered to beneficiaries and has recently formalized a set of principles for quality measurement in the Medicare program.

Based on these principles, in our June 2018 report to the Congress we examined the potential to create a single outcomes-focused, quality-based payment program for hospitals -- that is, the hospital value incentive

program, or HVIP. The HVIP links payment to quality of care to reward hospitals for providing high-quality care to beneficiaries.

Last month, the Commission discussed recommending to the Congress to implement the HVIP with increased payments from the difference between the Commission's update recommendation for acute-care hospitals and the amount specified in current law. This approach rewards hospitals providing higher-quality care, as opposed to all hospitals.

The HVIP design and modeling I'll review today includes the enhanced HVIP payments that are part of the draft recommendation you'll review at the end of the presentation.

Over the past cycle and a half, the Commission has overall supported the HVIP and asked that we continue to move forward with a recommendation to the Congress. As some of the Commissioners have described, the devil will be in the details of how policymakers implement the HVIP, but in general, the HVIP should align with the Commission's principles for quality measurement.

As illustrated on the left-hand side of the

slide, the HVIP would combine the current HRRP, VBP, and HACRP into one program, and eliminate the IQRP which is an obsolete pay-for-reporting program. Two of these programs reduce hospital payments for poor performance with design elements that do not align with the Commission's principles. Removing these two programs would increase payments to hospitals by about a billion dollars in aggregate. Instead, the new and improved payment program would increase or decrease hospital payments using the design elements described on the right-hand side of the slide.

The HVIP would incorporate population-based outcome, patient experience and value measures. We modeled the HVIP using five existing, all-condition quality measure domains: readmissions, mortality, spending, patient experience, and hospital-acquired conditions (or infection rates).

Per the Commission's principles, the HVIP would translate quality measure performance to payment using clear, prospectively set performance standards. The HVIP also accounts for differences in provider populations through peer grouping.

Similar to the current VBP, the HVIP would redistribute a pool of dollars to hospitals based on their performance.

I'll briefly review the scoring methodology we used to model the HVIP, starting with how measure performance is converted to HVIP points.

One of the Commission's principles is that Medicare quality programs should reward providers based on clear and prospectively set performance targets. So hospitals will know ahead of time what performance they need to achieve on each measure to receive HVIP points and payments.

In our HVIP modeling, hospitals earn points for their performance on quality metrics based on a continuous scale, starting at zero points and up to ten points.

Medicare can define the performance scale using different methods. For our modeling we set the scale along a broad distribution of historical data so that most entities have the opportunity to earn credit for their performance. A hospital's total HVIP score is the average of all of its points across the five measure domains.

We accounted for differences in the social risk

factors of different hospital patient populations through peer grouping as opposed to adjusting measure results because adjusting measure results can mask disparities in clinical performances.

In peer grouping, to convert HVIP points to payment adjustments, we use the same performance-to-points scale across all groups, but each peer group has its own pool of dollars and has its own multiplier, which is the "percentage adjustment to payment per HVIP point." Like the performance-to-points scale from the previous slide, each peer group's payment multiplier is prospectively set and known by hospitals.

We modeled the HVIP where quality-based payments are distributed to hospitals within ten peer groups. Each peer group has about the same number of hospitals, and those hospitals have about the same share of Medicare patients that are fully dual-eligible beneficiaries.

In our model, the hospitals in the group serving more dual-eligible beneficiaries have a larger percentage increase in payments per HVIP point, so those hospitals receive a larger adjustment to their points for higher performance.

Each peer group has an enhanced pool of dollars which is distributed to hospitals within the peer group based on the HVIP points each hospital earns.

The pool of dollars will be made up of two sources. First, the HVIP would be built on a withhold amount from each of the hospitals in the peer group. The VBP currently uses a 2 percent total base payment withhold, but the Commission has also discussed transitioning or beginning with a 5 percent withhold amount.

The second source for the pool of dollars is part of the current law payment update. For modeling the HVIP, we assumed that 0.8 percent of the total hospital payment update, which applies to both inpatient and outpatient, would be added to the HVIP pool. This 0.8 percent roughly translates to a little more than 1 percent of inpatient spending.

So for the chapter, we modeled hospital performance using a pool of dollars based on a 2 percent withhold and 1 percent of total base inpatient spending (or a 3 percent pool), as well as a 5 percent withhold and 1 percent of total base spending (or a 6 percent pool).

Using either a 3 percent or 6 percent pool of

dollars in our modeling, the vast majority of hospitals would receive more than their withhold because the pool of dollars is enhanced by a portion of the hospital payment update. Also, our HVIP modeling scores hospitals using a continuous performance-to-points scale based on almost the entire distribution of performance, so each hospital has the potential to earn some points and be rewarded. Policymakers can define the HVIP performance scale using different methods, for example, around a desired value, which can change the distribution of hospitals being rewarded.

Compared with the existing programs, the HVIP we modeled enhances payment adjustments for hospitals serving more fully dual-eligible beneficiaries. Also, relatively efficient providers receive more of a reward from the HVIP compared with other hospitals.

So, in summary, consistent with the Commission's principles, the HVIP links payment to quality of care to reward providers for offering high-quality care. It also rewards hospitals that efficiently deliver higher-quality care.

The HVIP is simpler than the current four

overlapping programs. It uses a small set of population-based outcome, patient experience, and value measures that encourage providers to collaborate across the delivery system.

Finally, the HVIP reduces the differences in payment adjustments between groups of providers serving populations with different social risk factors.

I'll now turn it back to Stephanie to discuss the recommendation.

MS. CAMERON: Beneficiaries maintained good access to care and providers continued to have strong access to capital, while quality improvement continued, despite negative Medicare margins for most providers. Given this, the draft recommendation provides the following program improvements.

First, the HVIP eliminates the complexity of overlapping program requirements, focuses on outcomes, and promotes coordination of care.

Second, the program accounts for differences in the social risk of hospitals' patient population through peer grouping.

Third, because the current readmissions and

hospital-acquired infection programs are eliminated, hospital payments would increase and payments to relatively efficient providers would also increase.

And, fourth, the update recommendation balances the need to maintain access to care while maintaining fiscal pressure on hospitals to control their costs, with the expectation that margins will begin to increase over time.

With that, the draft recommendation reads:

Congress should replace Medicare's current hospital quality programs with a new hospital value incentive program (HVIP) that:

Includes a small set of population-based outcome, patient experience, and value measures;

Scores all hospitals based on the same absolute and prospectively set performance targets;

Accounts for differences in patient's social risk factors by distributing payment adjustments through peer grouping;

And, for 2020, update the 2019 base payment rate for acute-care hospitals by 2 percent.

The difference between the update recommendation

and the amount specified in current law should be used to increase payments in a new HVIP.

The recommended update of 2 percent with an increase in quality incentive payments would result in total hospital payments that are equal to current law. However, eliminating the current readmissions and hospital-acquired conditions programs would remove penalties from hospital payment rates and thus increase spending by between $750 million and $2 billion in 2020 and by between $5 to $10 billion over five years.

We expect the recommendation to reduce providers' burden and, relative to current law, makes adjustments more equitable among hospitals that serve populations with different social risk factors.

To provide context for the draft recommendation, the left-hand column of the slide reflects current law. As you can see, the estimated update for inpatient and outpatient rates for 2020 would be 2.8 percent if the current estimates of the market basket and productivity remain at the current estimated levels. Note that the 2020 current law update is expected to be the highest in a decade as this is the first year since 2010 that hospitals

have not received an additional downward adjustment to the update factor, as specified in law. The right-hand side of this slide reflects the draft recommendation where the update would be 2 percent, then an additional 0.8 percent from the HVIP, and an addition 0.5 percent from the elimination of the current readmissions and hospital-acquired condition program. This results in an increase in the Medicare payment rates to hospitals of 3.3 percent for fiscal year 2020.

And with that, I turn it back to Jay.

DR. CROSSON: Thank you. Stephanie, good work. Long time coming. I thank Ledia and Jeff as well.

We're now open for clarifying questions. Paul.

DR. PAUL GINSBURG: You know, given that you have a precise estimate there of what the draft recommendation will do as far as payment rates, how does that reconcile with the range between 750 million and 2 billion in the additional payments to hospitals? Or what's the basis of that range?

MS. CAMERON: So the basis of that range comes from the elimination of the current quality penalty programs. We send our recommendations to the Congressional

Budget Office, and they provide us with those buckets. We estimated kind of, you know, the fee-for-service effect to be close to $1 billion, but that is the range that we were provided with. And that comes from the 0.5 percent.

MS. TABOR: I'd say there is a range because the HAC reduction program takes away 1 percent from the lowest-performing quarter of hospitals. So it depends what that 1 percent like what group of hospitals are actually taking from, and that's true for the readmissions program, too, which takes 3 percent from lowest-performing hospitals. So which hospitals are which could vary by year.

DR. CROSSON: Is everybody clear on that? There are standard ranges that we use, so if the number roughly falls into a standard range, we use the standard range.

Okay. Other clarifying questions? Warner.

MR. THOMAS: Just two quick questions, and, once again, I apologize. I missed the presentation you did last month.

First of all, in the materials that were provided, there's still a 0.5 percent productivity reduction. Is that correct?

MS. CAMERON: Yes. That's the current estimate.

That could change as the proposed and final rules for fiscal year 2020 come out. CMS uses the most recent estimates at that time. Today the most recent estimate is that 0.5.

MR. THOMAS: Was there any thought given to proposing to reduce that or eliminate it given the continued trend you see in the efficient hospital and total inpatient margin?

DR. STENSLAND: Current law has the productivity adjustment, but our recommendations for several years haven't had a productivity adjustment. We have just said the update should be X, and I think the discussion last December was saying, given where we're at with all these indicators, we should have a bigger increase in payments in aggregate than the current law of 2.8. And that's how we got down to this 3.3 percent increase in payments, which is, you know, much bigger than anything that's happened in recent years.

DR. CROSSON: So, in effect, Warner, what was done is what you asked. What we have is what you asked.

MR. THOMAS: Yeah. I mean, I guess by eliminating the current penalties, but did you think about

or do you know how many entities or organizations would be impacted? I mean, some do not have the deducts on readmission and whatnot, and you would think there would probably be efficient hospitals that you reference. So they wouldn't necessarily get a pickup with the elimination of those programs, or would they? I mean, I'm making assumptions.

DR. STENSLAND: If you don't have any quality penalties against you now, you will not get a pickup when those are eliminated, but you will benefit from the HVIP because we're putting new money into HVIP.

MR. THOMAS: The 0.8.

DR. STENSLAND: The 0.8 plus the up to 5 percent in the HVIP. So you could have 5.8 percent in the HVIP, which would then be redistributed, and those that do well no quality would get a disproportionate share of those dollars because the HVIP is a pool of money where you take a little bit from everybody and you distribute to the good performers.

MR. THOMAS: Through that withhold?

DR. STENSLAND: Yes.

So the good performers are going to do better

under the HVIP.

DR. MATHEWS: The withhold and the 0.8.

DR. CROSSON: Brian.

DR. DeBUSK: Thank you for a really well-written chapter and a great presentation as well.

I was going to ask about page 35 of the reading materials. You cited some studies about this notion that creating fiscal pressure constrains costs, and I noticed you had a number of studies that you cited, some of them as recently as 2017. It made a really compelling argument. I've heard this, the cost shift argument versus the fiscal constraint argument. It made a really compelling argument for the fiscal constraint argument and seemed to debunk the cost-shifting argument.

Is there a similar body of literature out there? I mean, if we wanted to make the opposite argument, are there a set of articles we could use that are sort of in the equal and opposite direction here, or is this being presented to us as largely settled research now? That the fiscal constraint argument has won out over the cost-shifting argument?

DR. STENSLAND: There was one recent cost-shift

paper -- and I can't remember -- that came out recently arguing that there was some cost shift.

But for a long time, most of the economics literature has suggested that there isn't a cost-shift effect. Most of the economics literature has said that basically it kind of comes down to the providers would rather have the money go to them than stay with the insurance company, and so if they can get a higher rate, they generally will like that.

DR. DeBUSK: So it's largely settled research now, at least in the opinion of this Commission?

DR. STENSLAND: I think so. You can ask everybody else around the table. I don't know if everybody would agree, but I think at least the literature is kind of going in that way. Maybe David would have comments on that too.

DR. GRABOWSKI: I agree with Jeff here that most of the economic research on this topic is sort of debunked, but cost-shifting stories, I'm not a big believer in that. I know Jon sort of touched on this as well earlier.

DR. DeBUSK: Okay, great.

Then the second question I had, these relatively

efficient hospitals -- and I think David actually mentioned this in our last public meeting, we set up a screener that includes things like cost, and then on the next page, on page 38, we report, lo and behold, these efficient hospitals have lower costs. Well, they were screened on having lower costs. It's a circular reference.

I was sort of critical of that. David, I think you were the one who mentioned that in the last public meeting.

When I got my reading materials, I was playing with something. If you look at your screener and you just assume by random chance, these 2,151 hospitals are going to fall in a spectrum.

Statistically speaking, 476 of them should qualify, if these were just random variables based on your screen, and in practice, we only get, I want to say, 291 that qualify.

I'm really warming up to the screener. I mean, I really like what you're doing here, but I think in future work -- I'm thinking through. Have we looked at the deviation from the statistical expectations of what we should see from this group?

For example, if we said, well, we screened on cost, we would expect them to be 8 percent lower, and they're not 8 percent lower. They're 13 percent lower. Have we looked at the statistics around the bias that we've introduced into our screener?

Perhaps the longest Round 1 question ever. Sorry about that.

DR. STENSLAND: Not recently.

We could do something like that. It would be somewhat complicated because the screener says you can't be bad on any of these things in any of the prior three years.

What we do that's differently from a lot of the other analysis you'll see that will come out in kind of the more popular press and they'll say these are the best hospitals or the most efficient hospitals -- and they'll look for the hospitals in 2018, which they say are the most efficient. They'll look at 2018 costs and say these are the most efficient hospitals.

That's not what we do. We say, well, let's look at who looks good from '14 to '16, and if they looked good in '14 to '16, we'll call them the efficient group. And then we'll look at their 2017 costs. So the costs that

we're judging them on are from a year that are different from the costs that we screen them on in order to avoid them getting into the good group just by random variation.

So if they were in that good group just by random variation and there wasn't any serial correlation, you would expect them in the next year not to be anything different from the average, but that's not what we find. So the whole idea is to screen on one set of years and then look at the performance in a different set of years that's separate.

DR. DeBUSK: So is this a relatively stable group of 291 hospitals, then? Do the members change that much from year to year?

DR. STENSLAND: I would call it relatively stable, but there are definitely people that are going to go in and out because you only need one bad year to go out.

So if you're a hospital and you close a wing one year and so you write off all that expense for that wing, you're not going to make it in the efficient group just for that one thing that you did in that one year.

We're not really trying to be definitive of saying this exact group is the best hospitals. We're just

trying to say that if you do operate relatively efficiently, what kind of indicator do we have in terms of what kind of margins you would end up with?

DR. DeBUSK: Okay.

And with Warner's observation -- I guess it was a year ago -- that the relatively efficient providers had slipped into negative margins, do we have any way of assessing? Does HVIP fix that? Is it close? Have we modeled it?

DR. STENSLAND: I think what we expect to happen is their margins have been going down, and we think between the total increase in money that we have going in of 3.3 percent, we think it will start moving their margins back up, maybe not up to zero for the efficient providers, but they should be moving upward, start moving upward in 2020 because that's when this would take effect.

In terms of the HVIP, the HVIP dollars, we're redistributing all these dollars, and the top performers, the efficient providers are going to do better under the redistribution because they just tend to have mortality, lower readmission. They do better on HVIP. So they do better on that, but they're also the ones, as Warner put it

out, that aren't going to gain as much from the elimination of the current penalties because these efficient providers are also the ones that aren't getting so much of the current penalties that we're eliminating. So, on net, they do a little bit better, but it's not a huge movement for the efficient providers. So that makes sense.

DR. MATHEWS: Brian, if I could just add one thing to what Jeff said -- and I agree completely with everything that he just recited, but to your initial point about whether or not there is something of a tautology here and that we're identifying low-cost providers and -- or relatively low-cost providers and relatively high-quality providers and calling them efficient and then we say, lo and behold, they happen to be relatively low cost and relatively high quality, there's a little bit of that.

But the main point of the exercise is to demonstrate the range of performance and to sort of scope out what we can expect in a best-case scenario, even under current levels of Medicare payments.

So this is saying that within the 4,000 hospitals, the 2,100, whichever composes our base group for this analysis, that there is a subset that can, indeed,

perform X percent better on quality and with Y percent lower cost, relative to other hospitals, even at current levels of Medicare payments.

DR. DeBUSK: Again, we're really warmed up to this concept because, at first, I had dismissed it as a circular reference, and I get it now.

DR. MATHEWS: Yeah.

DR. DeBUSK: That as long as you're looking at how they deviate versus the statistical expected value, then you've got something.

It would be interesting to see how this group stratifies by SES too, though, just to make sure they're not all rich.

DR. CROSSON: Did I saw Jaewon? Then Pat and Bruce.

DR. RYU: Yeah. I just had a confirming question as far as how this impacts ACO benchmarking. I think the benchmarking is always normalized for payment updates. Is that right? But given that you're changing the HVIP with the peer grouping, if you move to a regional benchmark, the mix of what kinds of peer-group hospitals are in your region, now that payment update changes.

So I'm just wondering how that would impact, or have we thought that through?

DR. STENSLAND: Yeah. The dollars will be -- the relative benchmarks for each of the region will reflect these things. So you'll have a higher benchmark, to a degree, in the regions, where they're getting more HVIP payments.

But all the ACOs, the payments that they are going to be giving to the hospitals are all going to be higher. So the benchmarks and the payments, they'll synchronize, so there won't be any ill effects.

DR. CROSSON: Pat.

MS. WANG: You went through this in December, but can you again just talk about cash flow and revenue certainty in this?

So this is the recommendation for 2020. If I'm a hospital and I'm budgeting, I know I'm getting 2 percent. When is my performance on HVIP known to me? Is what's being recommended for 2020 based on a past period but under a new formulation? Do you know what I'm saying? It's like, How do I know how much money I'm actually going to have?

MS. TABOR: I'll start off.

So with the HVIP, as far as having these clear, absolutely, prospectively set performance targets, Congress and CMS would have to act pretty fast to get this implemented in a way that gives hospitals enough time to know what their targets are and what their payment adjustment would be before it's implemented.

MS. WANG: So the new HVIP would be perspective, but a hospital wouldn't know how they would perform until after the measurement period is completed, right? What are they getting paid until an actual HVIP award is calculated?

DR. STENSLAND: Yeah. You would know what your payments are at the start of the year, but what your payments are at the start of the year would be based on some prior year's performance under the HVIP.

So you're kind of thinking, "I'm coming up to this Year X," and CMS would say, "To reach whatever HVIP performance number of points are, you're going to have to score this big in this coming year." So you know how much you have to score to get a certain number of points and then have a certain adjustment in your payments, but that adjustment in your payments will happen in a future year.

So there's kind of like two things that are looking forward. You're looking forward in the short range to say how well do I have to score to get a certain number of points, and then you'll know once I get those points in this year, then in a future year that will affect my payments.

So they'll know their payments at the beginning of the year. They'll know their rates.

MS. WANG: But for startups, since this is a recommendation for 2020, there will be a lag in that certainty until the new HVIP program catches up. Yeah?

MS. TABOR: There would be, but I guess we'll just have to use more historical data.

But the way we kind of played it out, again, if Congress and CMS acted fast, this could be implemented by 2020. But it would have to be done fast.

DR. CROSSON: Bruce.

DR. PYENSON: A related question. The withhold could be administered on a prospective basis, so everybody would have a 2 percent or 5 percent lower payment for the year. And that would flow into some future year distribution.

MS. TABOR: That's right.

The VBP currently functions this way. It uses what 2 percent of prospective spending is and applies it to all the claims going forward for that year.

DR. PYENSON: Great. Thanks.

Now, I wonder if you could talk a little bit about the 2 percent versus the 5 percent relative to the fluctuations that you see in hospitals' revenue or margin, anyway. Is that consistent with the year-to-year fluctuations?

I'm trying to get a sense of whether this is a risk and fluctuations of the sort that hospitals often see, or is this remarkable?

DR. STENSLAND: One thing to remember is we're talking about 2 percent or 5 percent of the inpatient pool only, so maybe this is like a 1 to 3 percent, equivalent to a 1 to 3 percent shift in your margin. And that is something that we see happening fairly often.

But I think this is enough money for the hospitals to take seriously. For lots of hospitals, 2 percent of inpatient is still serious money. We could look at our hospital people, and they'll tell you.

DR. PYENSON: Just a follow-up question on that, if I could. I noticed the draft recommendation doesn't use the 2 or 5 percent on the withhold. I'm curious. Would that be decided outside the recommendation? I'm curious why we didn't do that.

DR. MATHEWS: Yeah. I think the last time we talked about this, there was no clear consensus among the Commissioners as to what the right level was. There was a discussion of 2. There was a discussion of 5. There was a discussion of starting at 2 and moving to 5. So we've left the bold-faced recommendation language a little ambiguous, but we would lay this out in the supporting narrative and rationale underneath the recommendation. You could do it this way; you could do it that way. Here's what some of the impacts might look like.

DR. CROSSON: Dana.

DR. SAFRAN: Thanks.

Just a terrific chapter and a great presentation.

I just want to go back to where Pat was going and make sure I understand. Let's say we're in the scenario you describe. Congress moves quickly. This gets implemented. It starts in 2020. Can you just talk us

through if I'm a hospital, what I understand on January 1st, 2020, about my performance, about my payment for this year, and about my incentives for performance to enhance my payment for 2021?

MS. TABOR: So we include this as part of the normal rulemaking process. Like this summer when inpatient IPPS rules come out, CMS could put in place or release, "Here the targets that you need to meet. Here's the performance adjustment. Here's the list of all the hospitals and which peer group you're in."

And then that would be implemented into final law that fall, affecting that fall's fiscal year payment.

DR. CROSSON: Paul.

DR. PAUL GINSBURG: A question. I think this is a great system, and it will hopefully incent even better performance by hospitals.

So what happens if the performance improvement is greater than what's envisioned? Do we wind up paying the hospitals more and saying it was worth it because quality is better, or does it somehow -- sets it budget-neutral?

MS. TABOR: That's a great point. So the way that it is defined, again, since it is a prospective

system, is that if hospitals do perform better, Medicare will end up paying more.

But one thing that we do touch on in the paper is that CMS should regularly monitor what these targets are, and if one year there is a lot more improvement than was anticipated, they can revise the targets the following year. So there is kind of a checks-and-balance system on this.

MS. CAMERON: And I think the flip side is also true. If they don't hit the performance targets, then less would be paid out. So the goal is for budget neutrality. The expected value there is zero, but it could go on either side of that equation, depending on performance.

DR. CROSSON: Jaewon.

DR. RYU: I just wanted to follow up on the earlier question on timing and mechanics of how this would go. So if it got implemented on the timeline that you would set, the payment would hit that next prospective year, but it would be based on quality measurement that would be performance year two years ago, correct? So that would still be retro. The payment would be.

So, in some respect, you'd have a period of a

couple years before a hospital could really do anything to change what they would be getting paid under the new HVIP.

MS. TABOR: That's correct.

But one thing I will say is that we selected measures that hospitals have been paid on. We're changing how they're paid on it and trying to make it a little more fair and to drive improvement, but these are not brand-new topics for hospitals.

DR. CROSSON: Okay. I saw a half a hand. Oh, Round 2.

So we'll move into the discussion period. Put up the recommendations up there. So we are on the path to vote. What I'd like to do is ask those of you who want to make comments to do it in the context of the recommendation, support and not support; if so, reasons why, as we traditionally do.

Warner, you're up.

MR. THOMAS: So, directionally, I think the HVIP is a good program. I guess I -- it just comments to me, and I'm not sure what it will go and the specificity behind this, because obviously more details need to be worked out. But I do think having some flexibility, if you need to

change a measure out, would be important, because obviously things evolve over time.

I also question whether cost is a quality measure, but we can probably debate that one the rest of the day, so it's just really a comment.

I think a comment that Jim made earlier, that, you know, the 0.8 is new money being put in, but it's really not new money. It's taking dollars from the update factor and reassigning it. So, you know -- and I think that's fine, but it's not necessarily, you know, new dollars that are tied to specifically this program. It's taking dollars that, statutorily, we were recommending. We're just allocating it in a different fashion versus just giving folks an update. And I just worry about that, given the information in the chapter of the trend of how Medicare payments are doing versus, you know, inflation factors and input factors that go into hospitals, such as drug pricing, labor pricing, et cetera.

So I think that the concept, moving this direction, is a good one. I'm just concerned about taking pieces of the update factor versus, you know, maybe we take the 0.5 percent that's a deduct and add that back, you

know, versus taking something that's the update factor and reallocating it in a different way.

So it's not necessarily I'm against the proposal, but I also think doing this for 2020 seems quick, just given how we deal with other issues. This seems like it's a pretty quick move. So not that it can't be done, but I'm not sure actually that CMS could move quick enough to get this put in place, going to Jaewon's comment that you're going to be dealing with a lot of historical data, and will hospitals really be able to make an impact in that short a period of time, almost most are tracking all these measures anyway. It's just that are the clear about what the baseline is kind of going into a new program like this.

DR. CROSSON: Comments. Paul.

DR. PAUL GINSBURG: Actually, I interpreted it differently, Warner. I interpreted this as yet the 0.8 is going into the HVIP, but also the elimination of the current quality penalties. That, to me, is, in a sense, an extra half percentage point increase in the update in the aggregate. So this is not just current law. This is really current law plus 0.5, from my perspective.

MR. THOMAS: Yeah, I don't disagree with that,

but I think Jim's point was but the new money, the 0.8 is new money. That's really not new money. That's part of the updates being reallocated differently. And I get that, you know, reduction of the -- or elimination of these reductions, I think that that's fine. And once again, I think hospitals should have to earn the dollars. There's no doubt about that. I also look at -- if you look at the performance of what's happening in this category, especially as you compare it to the rest of the categories we have that we evaluate, that we're going to be talking about the rest of the afternoon, you know, I think we just need to really be mindful of that when we're making these types of changes.

DR. CROSSON: Further comments. Bruce.

MR. PYENSON: I want to comment the authors for this. I think the tiering was really well done and I support the recommendation.

I'm hoping we might be able to get a consensus on recommending an aggressive withhold, because I think what we have here is right, it creates the right incentives, it has the right protections, so why not be aggressive with recommendation for an attention-getting withhold.

DR. CROSSON: So let me hear other responses to that. Dana.

DR. SAFRAN: So I'm really excited about this program, and understanding Warner's point that this does involve moving pretty fast. I guess I think that's appropriate in this case because we're removing some programs and complexity that really aren't producing so much value and are in the way. We're adding, you know, the social risk factor stratification that, you know, I think really solves problems that folks have been pretty vocal about. And it's really good for beneficiaries and I think better for providers.

So I think there's a lot here that really is an enormous step forward and good model for both Medicare and other payers, in terms of how to structure value-based payment, and I'd love to see us move it quickly.

DR. CROSSON: Jon.

DR. PERLIN: Let me begin by thanking the group for really thoughtful work. I want to really associate with Warner's comment. I like it directionally. As always, the devil is in the details, and particularly if you're looking at an operating environment.

The way the cash flow plays out, to Pat's point, I think is tremendously important, obviously, if there's a lag. And the problem with the lag is that it decouples the actual improvement from the reimbursement for the improvement, by necessity. And so these are the things that would hope we pay attention to as we figure out what the implementation characteristics are.

So if you look at the five measure domains, we had some discussion earlier today about the challenges of readmission measures, generally. And, you know, we talked through socioeconomic circumstances that there may be difficulties for placement, and some of that gets evened out, perhaps, in the dual-eligible stratification by band. That's the theory.

But that can operate sort of like the challenge with mortality, that may be insensitive to that particular banding. So, for example, the hospital is a referral hospital. Even if it's in an upper band it actually may get patients from hospitals with much more complex patients, complex socioeconomic circumstances, that have one trajectory, and that trajectory is unfortunately going to be death or advanced complex disease that could lead to

remission, my point being that it may be less amenable to the management than possible.

The spending per Medicare beneficiary is -- you know, I'm not sure what it is. It's an index but it's not a quality measure and it may or may not be, for those reasons, controllable. Measures generally that have been in these buckets have suffered from the challenges of clustering, and I think part of our guidance will have to be that there's decompression. Otherwise, you can both win and lose with virtually the same performance on that.

And in terms of the final measure, the hospital-acquired conditions, we've had discussion, we had discussion last time about these being extremely, fortunately, rare events, but in order to have enough data to have statistical validity we go further back.

The comment was made that in terms of linking the actual performance with the reimbursement schedule that you would sort of weight that nearer, but either way it's still driving while taking information from the rear-view mirror.

So I think this is laudable but I think we really have to pay attention to the components of each of the measures, and step away from some of the pratfalls that

we're already aware of, in the context of support for the general direction and the involvement of that.

The second is that I agree with Warner as well and Pat, in the sense that we have data in our own report that shows that, you know, we've got a 9.9 aggregate Medicare margin -- negative 9.9 percent aggregate Medicare margin, and anticipating negative 11 percent this year. And so I think as this goes forward -- I see heads nodding as well -- that there has to be a vehicle to fund this that is different than the vehicle of updates to control for cost of labor and cost of supplies, et cetera. So got support on this, but I think the onus is on us, and ultimately CMS, to finesse that implementation along those lines. Thanks.

DR. CROSSON: Just a quick comment, Jon. I mean, you've identified some of the natural problems in doing any kind of quality assessment. The only point I'd add is that the mortality is risk-adjusted. Now it may not be risk-adjusted adequately but it is risk-adjusted.

DR. PERLIN: I mean as Lisa Iezonni wrote many years ago, that's 20 percent of the variation, but there are some systematic complexities. I'm a strong endorser

here of measures, of the buckets measurement, but, you know, need to really get to the evidence base for which measures -- the statistical means to actually differentiate appropriately. Thanks.

DR. CROSSON: Further comments.

Seeing none, we will proceed to the vote. All Commissioners in favor of the recommendation please raise your hands.

[Show of hands.]

DR. CROSSON: All opposed.

[No response.]

DR. CROSSON: Abstentions.

[No response.]

DR. CROSSON: The recommendation passes unanimously.

Stephanie, Ledia, Jeff, thank you for this work and all the work that has preceded it. It's really excellent. Thank you very much.

[Pause.]

DR. CROSSON: Okay. We're now going to proceed to the second update recommendation. That's on payment to physicians and other health professionals, and we have

additional recommendations relating to the payment of advanced practice registered nurses and physician assistants. Ariel, Brian, and Kate are here. Ariel, it looks like you're going to begin.

MR. WINTER: Good afternoon. As Jay said, I will discuss the payment adequacy assessment for physician and other health professional services and present the draft update recommendation for your vote.

Then Brian will present two draft recommendations on payment policies for advanced practice registered nurses and physician assistants, which you will also be voting on. You saw all three of these draft recommendations last month.

We'd like to thank Kevin Hayes, Carolyn San Soucie, and Emma Achola for their help with this work.

We discussed our assessment of payment adequacy extensively at the December meeting, so today I will be focusing on highlighting some key points. There are more details in your mailing paper.

First, some background on this sector. Medicare pays for services provided by physicians and other health professionals using a fee schedule. Total spending for

these services was about $69 billion in 2017, or 14 percent of fee-for-service spending.

Nine hundred eight-five thousand clinicians billed Medicare in 2017. Under current law, there will be no update to the fee schedule conversion factor for 2020. But there is a 5 percent incentive payment for certain clinician participants in Advanced Alternative Payment Models.

We received several comments from Commissioners at the December meeting, which we have addressed in the paper. In addition, we have updated some of the numbers in the paper.

I do want to focus on one issue that Kathy raised at the December meeting, which is how we calculate changes in the volume of clinician services. Volume growth is a function of two things: changes in the number of services, such as the number of imaging tests; and changes in the intensity or complexity of services, as measured by RVUs, or relative value units. For example, the substitution of a CT scan for a plain X-ray represents an increase in intensity.

This table shows each factor separately. From

2016 to 2017, across all fee schedule services, which is the top row, the number of services per beneficiary grew by 1.3 percent, and intensity per beneficiary increased by 0.3 percent. The sum of these variables gives us the change in volume per beneficiary of 1.6 percent.

The rest of the table includes examples of service categories that had relatively large changes in intensity. For example, the second row is the category of major vascular procedures. There was no change in the number of services per beneficiary, but intensity per beneficiary grew by 9.5 percent. So all of the volume growth was related to an increase in intensity.

This was because certain vascular procedures with relatively high RVUs had rapid growth in the number of services, and there was a corresponding decrease in the number of procedures with lower RVUs.

To summarize our analysis, payments appear to be adequate. Access indicators are generally stable. Our annual telephone survey indicates that beneficiaries have comparable or slightly better access to clinician services than privately insured individuals ages 50 to 64. The share of providers enrolled in Medicare's participating

provider program remains high, and the number of clinicians billing Medicare per beneficiary is stable.

Quality is indeterminate; the ratio of Medicare's payment rates to private PPO rates did not change; and there was an increase in the volume of services.

So the draft update recommendation reads: For calendar year 2020, the Congress should increase the calendar year 2019 Medicare payment rates for physician and other health professional services by the amount specified in current law.

In terms of implications, there would be no change in spending compared with current law, and this should maintain beneficiaries' access to care and providers' willingness and ability to furnish care.

And now I'll hand things over to Brian.

MR. O'DONNELL: So, switching gears a bit, I'll now discuss Medicare's payment policies for NPs and PAs. The Commission discussed this topic in depth in October and December. What follows today is a brief summary of the materials discussed in those meetings.

NPs are the largest subgroup of APRNs and are registered nurses who have additional training, most

commonly a master's degree.

Similarly, PAs must graduate from a PA educational program, which is generally a post-baccalaureate master's.

The number of NPs and PAs billing Medicare has increased rapidly over the last several years.

For example, from 2010 to 2017, the number of NPs that billed the Medicare program increased from approximately 52,000 to 130,000, an average annual increase of 14 percent.

In addition to their growing number, NPs and PAs increasingly practice in specialties other than primary care.

The result of these two trends is that NPs and PAs perform a larger number and a greater variety of services for Medicare beneficiaries than in the past.

NP and PA services can be billed in two different ways under Medicare.

They can be billed directly. Under this option, NP and PA services are billed under their own NPIs, and Medicare pays 85 percent of fee schedule rates.

The same services can also be billed under

Medicare's "incident to" rules. In this case, NP and PA services are billed under a physician's NPI, and Medicare pays 100 percent of fee schedule rates.

In your mailing materials, we walk through a list of potential motivations to eliminate "incident to" billing for NPs and PAs, and it's worth noting a few here.

At a very basic level, "incident to" billing limits transparency by obscuring policymakers' knowledge of who is actually providing care for Medicare beneficiaries.

"Incident to" billing could also inhibit accurate valuation of fee schedule services and increase Medicare and beneficiary spending.

It's also worth noting that eliminating "incident to" billing would not affect the services NPs and PAs can perform. Even if "incident to" billing were eliminated, the decision about what services these clinicians can perform would continue to be the province of states and the physicians with whom they practice.

Given these issues with "incident to," the first draft recommendation related to APRNs and PAs reads: The Congress should require APRNs and PAs to bill the Medicare program directly, eliminating "incident to" billing for

services they provide.

In terms of implications for spending, the draft recommendation is expected to reduce program spending between $50 million and $250 million over one year and between $1 billion and $5 billion over five years compared with current law.

The draft recommendation would also reduce beneficiaries' financial liabilities and is not expected to adversely affect their access to care.

In terms of effects on providers, revenues for some practices that employ APRNs and PAs would decline.

In addition, APRN and PA services would be billed under their own NPIs instead of physicians' NPIs, which would improve Medicare's data on who furnishes care to beneficiaries.

The next issue to discuss is the specialties in which NPs and PAs practice.

NPs and PAs have historically been concentrated in primary care. However, they increasingly practice outside of primary care, in specialties such as dermatology and orthopedics. Recent estimates suggest that only half of NPs and around a quarter of PAs practice in primary

care.

Despite the variety of specialties in which they practice, Medicare has limited specialty information for these clinicians. For instance, Medicare groups all NPs into one specialty.

This lack of specialty information can create issues, such as limiting Medicare's ability to target resources towards areas of concern, such as primary care, and inhibits the operation of programs that rely on identifying primary care providers.

Given these issues, the next draft recommendation reads: The Secretary should refine Medicare's specialty designations for APRNs and PAs.

The draft recommendation is not expected to substantially affect program spending, beneficiaries' access to care or financial liabilities, or provider revenues.

This last slide summarizes the three draft recommendations that Ariel, Kate, and I discussed today.

With that, we look forward to your comments, and I turn it back to Jay.

DR. CROSSON: Thank you. Very clear.

I think for purposes of efficiency and also based on my memory of a reasonable degree of consensus here, we'll take all of these recommendations together, both in terms of Round 1 and Round 2. So clarifying questions? Marge.

MS. MARJORIE GINSBURG: I think this is a clarifying question. One of the arguments made for getting rid of the "incident to" is that it was sort of mucking up the information about who do we attribute this service to in terms of checking for quality of care and things like that. Isn't there a way of changing -- or is there a way of changing the recording so you're actually separating out the provider who provided the care from the billing for that particular care? Maybe I'll throw this all together. The reason I say that is I'm a little concerned about doing away with the "incident to" for primary care providers, and the reason is solely a financial one. We're all struggling with how do we maintain adequate income for primary care physicians, and if they're possibly making a little money by hiring NPs to do the work and that's fattening their pocketbook a little bit, that may not necessarily be a bad thing. So I'm sorry, I sort of have two comments here.

The first one is: Isn't there a way of separating out who's providing the service from how the service is being billed?

MS. BLONIARZ: Sure, you could do that. You could have like a performing provider, rendering provider, billing provider, have it be all separate, and have the payment amount attached to one of the other categories.

MR. WINTER: The other thing I would say is that -- so one of the arguments we make is that if you're looking to kind of put money into primary care, this is a really inefficient way to do it, because a lot of them practice outside of primary care. But I think putting our two recommendations together, we're saying, okay, we're getting rid of "incident to," but we're also allowing the program to identify, let's say, NPs that work in primary care. So that if in the future the program wanted to put money into primary care more accurately, it could do so.

DR. CROSSON: Other questions?

[No response.]

DR. CROSSON: We'll move on then to comments, again, directed towards the slide, comments of support, lack of support, for any or all of the recommendations?

[No response.]

DR. CROSSON: Seeing no comments -- and I think, again, for purposes of efficiency, since there doesn't appear to be a significant amount of debate, we'll take all of the recommendations together. So all Commissioners in favor of the recommendations, please signify by raising your hand?

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: The recommendations collectively pass unanimously. Thank you, Ariel, Kate, and Brian, for excellent work again.

[Pause.]

DR. CROSSON: Now we're going to proceed into the part of the afternoon where we do update recommendations and voting based on expedited presentations and expedited voting. And we've got Dan and Zach here. Three of you?

Okay. Kim, are you just visiting or are you --

MS. NEUMAN: No. Hospice will be next.

DR. CROSSON: Oh, wait a minute. Did I mess up something here?

DR. MATHEWS: No. You're good.

DR. CROSSON: Yeah. Wait a minute. Oh, we're doing both? Hang on. Sorry. Sorry. Oh, and hospice. All right. Sorry about that.

Yes, well, getting back to it, Dan, are you going to present the ASC recommendation?

MR. ZABINSKI: I am.

All right. At the December 2018 meeting, we presented update information for ambulatory surgical centers and provided draft recommendations. In your updated draft chapter we have added text in response to Commissioner comments from the December meeting. For Sue, we added text about the rate at which rural beneficiaries receive care in ASCs. Bruce, we added a discussion about which services covered under the ASC payment system are often provide in physician offices. Dana, we added text that the measures in the ASC quality reporting program should be synchronized with the measures in the hospital outpatient quality reporting program. And for Kathy we added discussion about developing new quality measures that

rely on specialty-specific clinical guidelines to assess the appropriateness of specific services provided in ASCs.

Facts about ASCs in 2017, are that Medicare payments to ASCs were nearly $4.6 billion, the number of Medicare-certified ASCs was about 5,600, and 3.4 million fee-for-service beneficiaries were served in ASCs.

We find that beneficiaries' access to ASC services is improving. In 2017, we found a volume per fee-for-service beneficiary increased 1.7 percent, the number of fee-for-service beneficiaries served increased by 0.4 percent, and the number of ASCs increased by 2.4 percent. In addition, Medicare payments per fee-for-service beneficiary increased by a healthy 7.7 percent.

The growth in the number of ASCs suggests that the access to capital is good. Also, there has been a fair amount of acquisitions and partnerships with ASCs by hospital groups and other health care companies, which requires access to capital.

The measures of payment adequacy showed slight improvement from 2013 through 2016, but issues with the quality measures remain. We believe that CMS should add more claims-based outcomes measures, and we are concerned

about CMS's decision to delay use of the CAHPS-based patient experience measures.

Finally, a limitation of our analysis is that we cannot assess margins or other cost-based measures because ASCs don't submit cost data. Even though the Commission has recommended on several occasions that these data should be submitted.

So for the Commission's consideration today we have the following draft recommendation: The Congress should eliminate the calendar year 2020 update to the conversion factor for ambulatory surgical centers.

Given our findings of payment adequacy and our stated goals, eliminating the update is warranted. This is consistent with our general position of recommending updates only when needed. The implication of this recommendation for the Medicare program is that it would decrease spending relative to current law by $50 million to $250 million in the first year and by less than $1 billion over five years.

We anticipate this recommendation having no effect on beneficiaries' access to ASC services or providers' willingness or ability to furnish those

services.

In a second draft recommendation, we have that the Secretary should require ambulatory surgical centers to report cost data.

The importance of this recommendation is that the Commission has recommended this policy several times. In contrast, CMS has implemented a policy of replacing the CPI-U as the basis for updating ASC conversion factor with the usually higher hospital market basket for a five-year period, without a firm commitment to collecting cost data from ASCs.

Collecting cost data, as Medicare does for other providers, would improve the accuracy of the ASC payment system. The Secretary could limit the burden on ASCs by using a streamlined system of cost submission. Implementing this recommendation would not change Medicare program spending. We also anticipate no effect on beneficiaries. However, ASCs would incur some added administrative costs.

Now Kim will cover hospice.

DR. CROSSON: Yeah, if I'd ask you to hold, I mean, I think -- I'd like to do one at a time, if we could. Sorry.

So based on the judgment we made in December about the relative degree of support here and the decision to use expedited voting, I would invite questions or comments specifically on the changes that were delineated, or the additions that were delineated in the beginning of the presentation.

[No response.]

Seeing none, we will proceed to vote and we'll vote on both recommendations simultaneous.

All in favor of draft recommendation 1 and 2 please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed.

[No response.]

DR. CROSSON: Abstentions.

[No response.]

DR. CROSSON: Seeing none, both pass unanimously.

Okay. Sorry, Kim. Now we can -- yeah.

MS. NEUMAN: Good afternoon. I'm going to review indicators of hospice payment adequacy that we discussed at the December meeting and that's described in detail in your mailing materials.

We revised the materials based on your December conversation. For example, Jonathan, we added information on hospice days by level of care and hospice provider characteristics. David, we added the issue of higher margins among providers treating patients in nursing facilities and assisted living facilities.

So a few key facts about hospice. In 2017, about 1.5 million Medicare beneficiaries used hospice services, including more than half of beneficiaries that died that year. Nearly 4,500 Medicare hospice providers furnished services to those beneficiaries, and Medicare paid those hospices about $17.9 billion.

So now we'll look at our indicators of payment adequacy which are strong. The supply of hospice providers continues to grow, increasing about 2.4 percent in 2017. For-profit providers account entirely for the net growth in the number of providers.

Hospice use also increased. The share of Medicare decedents using hospice exceeded 50 percent for the first time in 2017. The number of hospice users, number of hospice days, and average length of stay among decedents also increased. Marginal profit in 2016 was 14 percent,

which suggests providers have an incentive to accept new Medicare patients.

Quality data are available and scores are high, but there is concern that the process measures are topped out. In terms of access to capital, the continued growth in the number of providers suggests that capital is accessible.

So this brings us to margins, and as you will recall, margin estimates assume cap overpayments are fully returned to the government and exclude non-reimbursable bereavement and volunteer costs. For 2016, we estimate an aggregate Medicare margin of 10.9 percent. For 2019, we project an aggregate Medicare margin of 10.1 percent.

On the basis of these positive payment adequacy indicators, we have the draft recommendation, which reads: For 2020, Congress should reduce the fiscal year 2019 Medicare base payment rates for hospice providers by 2 percent.

The implications of this recommendation are a decrease in spending relative to the statutory update of between $750 million and $2 billion over one year and between $5 billion and $10 billion over five years.

In terms of implications for providers and beneficiaries, given the margin in the industry and our other payment adequacy indicators, we anticipate that the aggregate level of payments could be reduced by 2 percent in 2020 and would still be sufficient to cover providers' costs. So this draft recommendation is not expected to have an adverse impact on beneficiaries' access to care.

Consistent with the Commission's principle that it is incumbent on Medicare to maintain financial pressure on providers to constrain costs, this draft recommendation would increase financial pressure on providers but it is not expected to affect their willingness or ability to care for beneficiaries.

So with that I'll turn it back to Jay.

DR. CROSSON: Thank you, Kim. Before we proceed with voting I want to correct the record. The previous recommendation was not passed unanimously. A Commissioner was absent. Sixteen members voted in the affirmative, one will be recorded as not voting.

We will proceed to vote on the draft recommendation for hospice services. All Commissioners in favor of the recommendation please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed.

[No response.]

MS. MARJORIE GINSBURG: I was talking.

DR. CROSSON: Okay. Abstentions, other than that.

[No response.]

So we have 16 votes in the affirmative and one talking, which I will count as an affirmative. Thanks very much.

Thank you, Kim.

[Pause.]

DR. CROSSON: Just to be clear, Carol, you're going to present the SNF one, and then we're going to rotate presenters; is that right?

DR. CARTER: Yes.

DR. CROSSON: Okay. Sorry.

DR. CARTER: Are we ready?

DR. CROSSON: We're ready.

DR. CARTER: Okay.

In this block of presentations, we'll consider the adequacy of payments for thee PAC settings: skilled

nursing facilities, home health agencies, and inpatient rehabilitation facilities. We discussed the full information for each setting in December, and you have the complete papers. So each of these presentations will be short. I'll start with the analysis of Medicare's payments to SNFs.

In 2017 there were about 15,000 providers that furnished services to 2.3 million beneficiaries. About 4 percent of fee-for-service beneficiaries used SNF services. Medicare spending on fee-for-service totaled $28.4 billion.

Our analysis of the adequacy of payments found that indicators are mostly positive. In 2017, supply was steady. Even though covered admissions and days decreased between '16 and '17, these trends are consistent with the decline in inpatient hospital stays that were three days or longer, which is required for Medicare coverage, and with expanded MA enrollment and alternative payment models, which are likely to use fewer SNF services. The marginal profit, an indicator of the financial incentive to treat Medicare beneficiaries, was 19.1 percent.

Quality performance was mixed, with small changes from 2016.

Access to capital is adequate and expected to remain so. Medicare remains the providers' preferred payer.

In terms of payments and costs, the Medicare margin for 2017 was 11.2 percent, and this was the eighteenth year in a row that the average was above 10 percent.

For efficient providers, those with relatively low cost and high quality, the average Medicare margin was 18 percent, further evidence that Medicare overpays for SNF care. We project the 2019 margin to be 10 percent.

The Commission's analysis of payment adequacy often considers revisions to the payment system that would improve its accuracy and equity. CMS is poised to implement a revised PPS that will base payments on patient characteristics, not the amount of therapy furnished.

The revised design is consistent with MedPAC's recommendations for a SNF PPS and the PAC PPS. The changes are likely to prompt many providers to revise their mix of cases and cost structures, which would change the relative costs of different types of stays and indicate the need for the relative weights to be recalibrated.

In considering how payments should change for 2020, there are two takeaways. First, the SNF PPS continues to favor the provision of therapy and needs to be revised. Further, to keep payments and costs aligned, the relative weights of the case-mix groups should be updated annually.

Second, the level of payments is too high, given the costs of treating beneficiaries.

The first draft recommendation reads: "The Secretary should proceed to revise the skilled nursing facility prospective payment system in fiscal year 2020 and should annually recalibrate the relative weights of the case-mix groups to maintain alignment of payments and costs."

In terms of implications, relative to current law, this recommendation would not change program spending. The recommendation is budget-neutral to the current level of spending.

For beneficiaries and providers, a revised PPS will increase the equity of Medicare's payments for all case types and help ensure access for all beneficiaries, including those with medically complex conditions. We do

not expect the recommendation to affect providers' willingness or ability to care for Medicare beneficiaries.

Turning to the level of spending, the second draft recommendation reads: "The Congress should eliminate the fiscal year 2020 update to the Medicare base payment rates for skilled nursing facilities."

In terms of implications, spending would decrease relative to current law by between $750 million and $2 billion for fiscal year 2020 and between $5 billion and $10 billion over five years.

For the beneficiary and provider, "Given the high level of Medicare's payments, we do not expect adverse impacts on beneficiaries. Providers should continue to be willing and able to treat beneficiaries."

Now I'll turn the voting over to Jay and put up both recommendations.

DR. CROSSON: Thank you, Carol.

Based again on our discussion in December and the decision to proceed to expedited voting, I'll now ask for a vote on these recommendations together.

You have the recommendations before you. All Commissioners voting in favor of the recommendations,

please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: Seeing none, the recommendations passed unanimously.

Thank you, Carol.

[Pause.]

DR. CROSSON: Okay. Evan, are you going to take us through the update for home health?

MR. CHRISTMAN: Yes.

Good afternoon. We're going to look at home health next. As Carol mentioned, we had a longer presentation, going to summarize a longer presentation we presented in December, and you also have the paper that includes some revisions you requested. Please let me know if you have any questions about the revisions.

As a reminder, Medicare spent $17.7 billion on home health services in 2017. There were over 11,800 agencies, and the program provided about 6.3 million

episodes to 3.4 million beneficiaries. And about 8.8 fee-for-service beneficiaries used home health in 2017.

As you may recall, our indicators for home health were mostly positive. Beneficiaries have good access to care. The number of agencies has declined slightly, and the number of episodes declined slightly in 2017. But both remain relatively high, and the marginal profit in 2017 was 17.5 percent, indicating that home health agencies have an incentive to serve Medicare beneficiaries.

For quality measures, we saw trends consistent with earlier years. The rates of hospitalization and emergency department use were unchanged.

The functional measures showed improvement in 2017, but as we discussed in December and note in the paper, agency coding practices may contribute to this trend.

Access to capital is adequate. The all-payer margins in 2017 were 4.5 percent, and the financial performance of this sector under Medicare is strong. And these are the highest margins of any fee-for-service provider you've seen this cycle.

Home health agencies had Medicare margins of 15.2

percent in 2017, and we project margins of 16 percent in 2019. The median margin for the efficient provider in 2016 was 24 percent.

Based on these findings, we offer the following draft recommendation. The recommendation reads: "For 2020, the Congress should reduce the calendar year 2019 Medicare base payment rate for home health agencies by 5 percent."

The impact of this change would be to lower spending by $750 million to $2 billion in 2020 and 5- to $10 billion over five years.

The impact to beneficiaries should be limited, and we do not expect it to affect beneficiary access to care, and it should not affect provider willing to serve beneficiaries.

This completes my presentation.

DR. CROSSON: Thank you, Evan.

We'll now invite comments or questions on any of the Commissioner-requested changes to the text.

[No response.]

DR. CROSSON: Seeing none, we'll proceed to the vote. The recommendation is before you. All Commissioners

in favor of the recommendation, please signify by raising your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: The recommendation passes unanimously.

Thank you, Evan.

I would point out parenthetically here, we've made this point in general. I think after these last two presentations, it's important to note that the recommendation we made for acute care hospitals increases -- if it's adopted, increases Medicare payment. It's more than made up for -- or would be more than made up for by our recommendations here in a number of post-acute care settings.

Okay. Craig and --

MR. LISK: All right. What?

DR. CROSSON: Craig and Dana are here to talk about an update to IRFs.

MR. LISK: Okay. Good afternoon.

So, last month, the Commission discussed the findings from our update analysis of inpatient rehabilitation facilities, and we will review those findings briefly and then present the draft recommendation for your consideration.

Just as a reminder, here is a bit of background information on inpatient rehab facilities.

In 2017, Medicare spent $7.9 billion on care provided in about 1,180 IRFs nationwide, most of which were hospital-based units that are part of acute care hospitals.

There were about 380,000 fee-for-service beneficiary IRF stays in 2017, but because freestanding IRFs tend to be larger and have higher occupancy rates, slightly more than half of all cases are in freestanding facilities. Slightly less than 1 percent of fee-for-service Medicare beneficiaries had an IRF stay in 2017.

Overall, our indicators of payment adequacy are positive.

Let's start with access. Overall, capacity appears adequate to meet demand. While we saw a slight decrease in the number of IRFs in 2017, the total bed

supply actually increased slightly.

The average IRF occupancy rate was 65 percent, indicating that capacity was more than adequate to handle current demand for services. The number of IRF discharges per fee-for-service beneficiary did fall 2.4 percent in 2017 from 2016, however, but we see strong marginal profits for both freestanding and hospital-based IRFs, indicating that IRFs have an incentive to take more Medicare beneficiaries that qualify for IRF-level care.

To assess quality of care in IRFs, we looked at discharges to the community and to SNFs and readmissions to the acute care hospitals. We also looked at measures of improvement of motor function and cognition. We have seen slight improvement in all of these measures since 2012.

We then considered access to capital. Hospital-based IRFs have good access to capital through their parent institutions. Large chains also have very good access to capital. We were not able to determine the ability of other freestanding facilities to raise capital, however.

All payer margins, though, in freestanding IRFs were robust, 10.4 percent in 2017.

Finally, we looked at payments and costs.

Payments have been rising faster than costs on average over the past five years, leading to a health Medicare aggregate margin in 2017 of 13.8 percent. We expect the cost growth is likely to exceed payment growth in 2018 and 2019, and so we've projected that the aggregate margin will fall to 11.6 percent in 2019.

In 2020, IRF-based payment rates are slated to increase by 2.7 percent, and so we lead to the draft recommendation, which reads: "For 2020, Congress should reduce the fiscal year 2019 Medicare-based payment rate for inpatient rehabilitation facilities by 5 percent."

The implication for spending is it would decrease Medicare spending by between $250 million and $500 million in fiscal year 2020, and by between $5 billion and $10 billion over five years.

For the implications on beneficiaries and providers, we anticipate no adverse effect on Medicare beneficiaries' access to care. The recommendation, though, may increase financial pressure on some providers.

So that concludes our presentation, and we'll turn it back to Jay.

DR. CROSSON: Thank you, Craig.

Based on our discussion in December and our decision to go to expedited voting in January, we have the draft recommendation before us. All Commissioners in favor of the draft recommendation, please raise your hands.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: Seeing none, the recommendation passes unanimously.

Thank you, Craig and Dana.

[Pause.]

DR. CROSSON: Okay. We'll now return to the regular order. We're going to have a discussion of the recommendation for updating payments to long-term care hospitals. Commissioners should note that this recommendation is slightly different than the one we discussed in December.

Stephanie?

MS. CAMERON: Thank you. Good afternoon. Today we are here to discuss how payments to LTCHs should be

updated for fiscal year 2020. We will be reviewing our full analysis today because, as you'll recall from December, the Commission was concerned about the adequacy of Medicare payments for this sector and the Chairman's draft recommendation.

Based on your feedback, our review of the payment adequacy indicators, and to ensure equitability with other sectors, we will be presenting a revised draft recommendation at the end of my presentation.

However, before I go on, I'd like to note a few other changes in your mailing materials based on your feedback in December.

Kathy and Marge, we added a discussion regarding LTCH use compared with other PAC use following discharge from an acute-care hospital.

Jonathan and David, we provided additional detail regarding the use of ICU days as a proxy for defining the chronically critically ill.

And, Kathy, we added a new table and discussion in response to your questions about LTCH mortality.

Today I start by summarizing some background information that was included in your mailing materials.

To qualify as an LTCH under Medicare, a facility must meet Medicare's conditions of participation for acute-care hospitals and have an average length of stay for certain Medicare cases of greater than 25 days.

Medicare spent $4.5 billion for about 116,000 LTCH cases. These cases are expensive with an average payment per case of about $38,000. Given the high cost of LTCH care, the Commission has sought to understand the level of care and cases most appropriate for this sector.

However, MedPAC, other researchers, and policymakers have struggled with how to define the patients most appropriate for LTCH care over the past several decades. LTCH medical staff, administrators, and case managers have been unable to reach consensus on describing patients most appropriate for LTCH care during conversations with the Commission.

The literature describes the chronically critically ill as patients with multiple-body system failures; requiring heavy ICU use; being ventilator dependent with major co-morbidities; multiple organ failures; or with septicemia and other complex infections. Research has found that ICU days are an indicator of case

complexity and are readily available in administrative data.

With that in mind, in 2014 the Commission recommended that standard LTCH payment rates be paid only for LTCH patients who meet certain criteria at the point of transfer from an acute-care hospital. Such cases should be those that spent eight or more days in an ICU or received mechanical ventilation for 96 hours or more. The Commission recommended that Medicare pay for all other cases admitted to LTCHs using an IPPS-based payment rate.

The Pathway for SGR Reform Act of 2013 established a dual-payment rate structure. Cases meeting the criteria, those preceded by an acute-care hospital discharge that either spent three or more days in the ICU of the referring acute-care hospital or received prolonged mechanical ventilation in the LTCH are paid under the LTCH PPS and will be the focus of a lot of the analysis I will walk through. The policy began in fiscal year 2016 and, until 2020, cases that do not meet the criteria are paid a rate equal to 50 percent of the site-neutral rate and 50 percent of the much higher standard LTCH payment rate.

I will now turn to the question of how payments

to LTCHs should be updated for fiscal year 2020. To determine the update recommendation, we will review payment adequacy using our established framework.

While we apply our established framework in the same manner for LTCHs, we expect substantial changes from the implementation of the dual-payment rate structure given the financial disincentive for LTCHs to continue taking Medicare beneficiaries not meeting the criteria. Because of the reduction in payment, the extent to which LTCHs are able to alter their admission patterns toward cases meeting the criteria determines facilities' financial performance under Medicare.

Because some LTCHs have dramatically altered their admission patterns in response to the policy consistent with the goals of the dual-payment rate structure, some of our analyses focus on LTCHs with more than 85 percent of their cases meeting the criteria. I will specify when we consider this subset of providers during this presentation.

With that, we have no direct indicators of beneficiaries' access to needed LTCH services, so we focus on changes in use, capacity, and occupancy. Starting with

use, the number of LTCH cases declined starting in 2012. The volume of cases meeting the criteria decreased slightly from 2012 to 2015. Starting in 2016, the volume of cases meeting the criteria increased, as expected by the implementation of the dual-payment rate structure.

In contrast, cases not meeting the criteria declined more rapidly from 2015 to 2017 compared with THE prior years. As a result, the share of LTCH discharges meeting the criteria has increased since 2012. Just over half of LTCH cases met the criteria prior to the implementation of the dual-payment rate structure; however, this share increased to about 64 percent in 2017.

Moving to other indicators of access, supply has decreased since 2012, and we expect addition reductions in 2018. Occupancy has decreased by about two percentage points from 2016 to 2017; however, despite these trends, Medicare marginal profit remains strong. Therefore, we contend that LTCHs have a financial incentive to increase their occupancy rates with Medicare beneficiaries who meet the criteria.

Now, quality. Not unexpectedly, given differences in patient severity, unadjusted rates of LTCH

readmissions and morality varied depending on whether or not the case met the criteria, but were stable over time. In 2017, for cases meeting the criteria, 10 percent were readmitted to the acute-care hospital directly from the LTCH, 16 percent died in the LTCH, and another 13 percent died within 30 days of discharge from the LTCH. This means that, combined, close to 40 percent of LTCH cases meeting the criteria in 2017 were readmitted or died within 30 days of LTCH discharge. By comparison, cases not meeting the criteria have lower rates of readmission and mortality.

We have begun to provide information for several outcomes measures reported publicly by CMS that we discussed in December and were included in your mailing materials. As you'll recall, these measures have not been in place long enough for a time-series analysis, and we will continue to monitor them.

Moving now to access to capital, access to capital allows LTCHs to maintain and modernize their facilities; however, given the last decade of policies that have limited industry growth, which include moratoria on new facilities and the implementation of the dual-payment rate structure, the availability of capital is limited

across the industry.

LTCHs' access to capital also depends on their all-payer profitability which was 0.2 percent in 2017 down from 3.1 percent in 2016 resulting from reduced payments for cases not meeting the criteria. LTCHs with more than 85 percent of their Medicare cases meeting the criteria had an aggregate all-payer margin of 4.2 percent in 2017.

In 2017, the aggregate Medicare margin fell to negative 2.2 percent down from 3.9 percent in 2016. However, the aggregate Medicare margin for LTCHs with more than 85 percent of Medicare cases meeting the criteria was 4.6 percent, indicating that facilities with a high share of these cases can have positive financial performance under Medicare.

We project that the 2017 Medicare margin for LTCHs with a high share of cases meeting the criteria will decline in 2019. Our projection of the LTCH margin for fiscal year 2019 focuses on LTCHs with more than 85 percent of their Medicare cases meeting the criteria. We expect significant changes in LTCHs' costs as the dual-payment rate structure is fully implemented and LTCHs continue to increase their Medicare admissions toward cases that meet

the criteria.

However, once an LTCH has reached a threshold of Medicare cases that meet the criteria, we expect changes in cost will become increasingly stable and reflect cost growth levels consistent with those prior to 2016. Using these historical levels of cost growth, we project a 1.2 percent Medicare margin for LTCHs with a high share of cases meeting the criteria for 2019.

In sum, measures of beneficiary access, quality of care, and the industry's access to capital are mixed as is expected from an industry in flux. Focusing on financial performance under Medicare, we project that the 2019 margin for LTCHs with a high share of cases meeting the criteria will be 1.2 percent, down from 4.6 percent in 2017.

As I mentioned, the Chairman's draft recommendation presented in November was for no update to LTCH payment rates; however, based on concerns about payment adequacy and equity with other sectors, we re-evaluated our indicators and, given the trends we observed for LTCHs, focused on cases meeting the criteria.

The revised draft recommendation reads: For

2020, the Secretary should increase the fiscal year 2019 base payment rates for long-term care hospitals by 2 percent.

A 2 percent update for 2020 will decrease federal program spending relative to the expected regulatory update of 2.8 percent by less than $50 million in 2020 and by less than $1 billion over 5 years.

We anticipate that LTCHs can continue to provide Medicare beneficiaries who meet the criteria with access to safe and effective care.

And, with that, I turn it back to Jay.

DR. CROSSON: Thank you, Stephanie.

We'll proceed to clarifying questions. Yes, Jonathan, and then Warner.

DR. JAFFERY: Thanks, Stephanie. This is a great report on the updates. Just a quick question. In the mailing materials on page 23 in the table, you have Table 11-5, which gives the different kinds of readmission rates and in-LTCH mortality and three-day post-discharge for a number of conditions. I wonder if we have the ability to dig a little deeper on that in the future around some other factors. Age comes to mind, and other co-morbidities. It

seems like there's a real opportunity for understanding a little bit better prognoses in some of these situations. So just a thought for a future -- unless you know some of those things off the top of your head.

MS. CAMERON: Absolutely. I think, you know, for a long time we have been providing unadjusted measures and unadjusted rates because for quite some times LTCHs did not have an assessment instrument that allowed for risk adjustment. The LTCH care database has now been used, and assessment data is becoming increasingly available in this sector. So I think as we move forward, we will be able to certainly start thinking about better risk adjustments for this population and see kind of how we can incorporate that data. I think starting with age is certainly a possibility.

If you'll recall, there is a much higher share of Medicare beneficiaries in LTCHs that are under 65. So, you know, that's actually kind of an interesting difference from the other post-acute-care settings where some of these younger patients are actually very, very sick. And so, you know, we can certainly look at some of these by those factors, and it will be interesting to see what we find in

the future.

DR. JAFFERY: Thank you.

DR. CROSSON: Warner.

MR. THOMAS: This may be more of a question for Jim. When we look at all-payer margins, are we -- is that cash flow? Is that operating income? Are we excluding any expenses? Is it pre-taxing -- like what exactly are we looking at when we look at all-payer income?

DR. MATHEWS: Yeah. So we look at overall net profit margins here, if I'm getting this right, and we only take into account Medicare allowable costs, which vary by sector. So earlier this afternoon Kim mentioned that with respect to calculation of hospice margins, there are a couple of cost categories that we do not consider in our Medicare margin. And, similarly, when we are going to talk about ESRD, there are cost categories that we exclude for this purpose.

MR. THOMAS: I mean, so are there -- it may be just interesting to know what is -- I mean, I have no idea like what would be excluded or how material that is just on a go-forward -- I mean, it's not necessarily related just to LTCH, but just in general, how material is it? Is it a

half a percent? Is it multiple percent? Just so we understand.

DR. MATHEWS: In hospice where there are distinct categories, we do quantify --

MR. THOMAS: Right.

DR. MATHEWS: -- the impact on margins of including versus excluding those costs. I don't think in the LTCH sector we are dealing with the same issue of Medicare allowable costs the way we are in these couple of other --

MR. THOMAS: What about in other areas? In all the disciplines we've looked at, I mean, would there be excluded costs that would not be in the all-payer margin numbers?

DR. CROSSON: I thought -- I may be wrong, but I thought when we were dealing with hospice bereavement costs, we were talking about something around 1 percent.

MR. THOMAS: Okay.

DR. CROSSON: Is that right? Something like that.

MR. THOMAS: But consistently in other categories we've approved during the day today, I mean, the same sort

of thing, there would be excluded costs that are outside of the all-payer margin. Is that correct?

MS. CAMERON: No. For the all-payer margin, we're looking at a total revenue calculation and a total cost calculation that comes into the hospital. So I think what Jim was speaking to was the Medicare margin. The all-payer margin, we're looking at the cost reports at the bottom line, what costs have gone out and what revenues have come in.

MR. THOMAS: So there's no excluded costs or revenue. So if you're looking at proprietary, it would include -- it would be pre-tax or post-tax or -- I'm just trying to us what the --

DR. STENSLAND: There's a schedule in the cost report where they're just supposed to take the information from your audited financial statement and just stick it on there.

MR. THOMAS: Okay.

DR. STENSLAND: So it's going to include everything on there. You might -- but it's supposed to be at the individual hospital level.

MR. THOMAS: I got it.

DR. STENSLAND: So you could have an individual hospital level that has its profit and cost, and then you have it's owned by a system and you wouldn't always include all like the system's taxes and things.

MR. THOMAS: What about in the other areas like home health and, you know, rehab and others? The same sort of thing?

DR. STENSLAND: I'm not familiar with those cost reports, but I'm assuming it's the same thing.

DR. CROSSON: Other clarifying questions?

[No response.]

DR. CROSSON: Let's put the recommendation -- it is up. We'll now have discussion of the recommendation. In favor, or opposed, other ideas? Kathy.

MS. BUTO: So I'm in favor of the recommendation, and I think it was a good discussion that led us to this point. It must have led to some pretty good staff discussions that led to this revised recommendation.

I wanted to just mention something that -- to me, LTCHs are almost like the poster child for this issue that has been rattling around in my brain about PAC, unified PAC, and directionally going forward, and that is that I

think we've tended to think of unified PAC as sort of the place we're going and we have to deal with issues like different criteria for entering those facilities or for being a patient who qualifies for service in that facility or whatever, or even in home health. And I've been struggling with how do we reconcile those differences and standards, and in a unified PAC, are we going to get to a place where you have just a standard set of conditions of participation.

The LTCH presentation kind of brought home to me that there truly are some patients that won't easily fit into other sites of care. And so what I'm thinking of -- and this is a longer discussion -- is that, yes, we can achieve a greater degree of equity and comparability and site-neutral payment based on clinical characteristics of patients, but there may be patients like ventilator-dependent patients, patients with long ICU stays and so on who somehow in this unified PAC we want to make sure we're not discouraging care, specialized care for those kinds of individuals. And I think that helps us also address the issue of different standards for institutions or for programs within institutions to deal with these different

kinds of patients. And I know the staff has been thinking of different ways to address this, but I just wanted to get that out there because I think we tend to think of, you know, our eventual path leading us to a much more unified system, but this one brings home to me that there really are some patients who -- and I'm not historically a great fan of LTCHs. I think I was part of the group that recommended we just eliminate the category when I was at CMS. But I do think it's important to recognize that, as we move forward, there be some way to address both the differences in the criteria to qualify, and it may help us with all these different things like three-day prior hospitalization and long ICU stays and stuff like that, and also to recognize that patients need different things.

So I just wanted to get that out there.

DR. CROSSON: Carol, would you care to comment, or is it fine? And then we'll go to Brian.

DR. CARTER: So the way I would think about this is to make sure in the risk adjustment model, we have indicators of things that we think are really important for identifying really high-cost patients.

So, for example, you might want to include an

indicator for ventilator patients, so that they pull enough of the payments towards them, or severe wounds or ICU lengths of stay of eight or more days or severity level No. 4. So all those things are going to be pulling in resources, resource requirements to those patients, and the payments for those patients would go up. So that's on the payment side, making sure that we're directing our dollars towards patients we think have high-care needs.

On the other side, we've talked about having regulatory requirements that are patient condition-specific. So instead of licensing by shingle on the door, it would be licensing by the types of patients you're opting to treat.

So for ventilator cases, for example, you might pull in requirements that some of which might be current LTCH requirements. I don't know. We're going through that.

You might have minimum staffing levels. You might have certain training requirements. It's not just what are the care needs, but what are the staffing and equipment needs to take care of patients? Ventilator patients and severe wound cases are, for example, patients

where it's not just that you have the right equipment, but you need to have staffing that's adequately trained.

So I think of like ventilator cases and patients that really meet the LTCH requirements as having -- trying to identify who those patients are and having requirements that meet them, so that's how we're thinking about it. Does that help?

MS. BUTO: That helps.

You and I talked also about stroke patients and IRFs and things like that.

DR. CARTER: Yes, that's right.

MS. BUTO: Again, SNFs might be able to treat stroke patients just as effectively, but the issue whether there should be certain criteria associated with that --

DR. CARTER: Right. I mean, sometimes Stephanie and I talk about maybe LTCHs. We want to think of them as almost regional referral centers for certain types of cases, and that might be a useful model.

DR. CROSSON: Okay. Thank you, Carol.

Brian, and then I saw Jon and Paul and Jaewon.

DR. DeBUSK: To Kathy's point, I do think the unified -- the PAC PPS does fix a lot of issues with the

prospective payment. But I do think as we build that or recalibrate that model -- and, Carol, this is sort of a technical, I guess, question/comment combined -- when we go to calibrate that model, you're going to have 2.3 million SNF stays. Then you're calibrating the same model with 116,000 LTCH visits.

The contribution of the LTCH to this regression model that we're going to do is beyond negligible. I mean, it's probably two or three orders of magnitude beyond negligible.

So one of the concerns would be to make sure that the LTCH cases that are these true high cost, I mean these long-term mechanical ventilation cases or you hear about these stories about beneficiaries who are going to be there for six months, we're going to have to figure out a way to make sure that their costs don't get completely run over in the model.

And just like we had that dichotomous variable that made a home health adjustment, we may have to have a lingering or at least a transitioning dichotomous variable that accounts for the fact that some of these LTCH cases are just fundamentally different and more expensive.

And I do love your idea, Carol, of different levels of certification too. That's complementary because what we may want to do is let the dichotomous variable relate to the level of certification that the facility has, not just the fact that this happens to be an LTCH and something else happens to be a SNF.

So I think, Kathy, you and I are directionally going in the same direction. I just don't want the LTCHs to get completely run over in the calibration.

DR. CROSSON: Jonathan.

DR. JAFFERY: Yeah. Thanks.

This actually also builds on that a little bit. I made some comments about this in December, but when we think about the unified PAC PPS, I think about the IRFs and the SNFs and the home health as being a pretty clear continuum, and I do like the idea of trying to base it on what the patient needs are.

But I still wonder if LTCHs, the level of care for patients who go to LTCHs is actually close to acute care hospitals than these other areas.

Even adding to Brian's point about how it's such a small number, that it's going to get kind of swamped up

by all the SNF and other stays and home health stays, how you account for that. I just wonder if we should be thinking about is there a unified PAC PPS for those three other areas and that LTCHs are somehow close to acute care hospitals.

Then the other comment I want to make, again, I appreciate the update and the history on the ICU stay in the report. So maybe I'm not getting it or maybe I'm just perseverating a bit, but it seems to me that showing that this prolonged ICU stay is a proxy for LTCH-level intensive resource needs isn't exactly the same as saying that patients who had a long ICU stay are going to benefit from an LTCH stay.

It seems like we've come to the point where we've talked about mechanical ventilation as being sort of the specialty care that an LTCH provides. In fact, that's what sort of drove the recommendation to include that as a criteria, an LTCH criteria.

So if that's really the specialty that they have, it's not clear to me why we don't just talk about prolonged mechanical ventilation as the criteria because I'm not seeing a lot of evidence that patients with other complex

needs benefit from their LTCH stay.

MS. CAMERON: Some of the quality data is still new. With the evolution of this quality data, I am hopeful that in the future, perhaps we can provide more comparisons to the extent that you're discussing.

There will be some vent weaning and some ventilator-associated quality metrics coming online that I hope we'll be able to talk about in the next couple years. Hopefully, those will provide some value.

I do just want to circle back. In terms of thinking about some of these populations within the PPS, Carol mentioned ventilator, and as we dig deeper on how we define ventilator in the post-acute care setting and compare it across, what we're finding is well upward of -- well over 95 percent of beneficiaries who receive an invasive mechanical ventilation in a post-acute care setting are in fact in LTCHs.

And I think as our analysis is updated and as we are better able to refine invasive versus non-invasive vents because they're two very different things, as many of you are well aware, when we look at those invasive vents, the vast, vast majority of them in the post-acute care

setting are in LTCH, and therefore, the model will calibrate appropriately to reflect primarily LTCH costs for that category, which will far outweigh other PAC provider costs.

So, Brian, you're absolutely right with your example of the 2.3 million SNF relative to the 116,000 LTCH. When we look at this very small category, it is so heavily weighted LTCH that we are finding that's what's carrying that predictive cost in the model.

DR. CROSSON: Okay. Paul? Pass.

Jaewon.

DR. RYU: Just on the unified PAC PPS, I thought -- and I may not be remembering this right, but from one of our earlier discussions in the fall when we talked about LTCH, there were markets where LTCHs has never been very present, and somehow the care got absorbed through the other categories. I just think as we delve deeper into that discussion, it may be informative to look at those markets around how did that happen, how did they get absorbed, and what was it about the cost structure of whether it was the SNFs or wherever?

The care got met somehow. It's not clear to me

how because I agree with Kathy and Brian and others. There's clearly a subset of patients where the category makes sense. So I'm curious how those markets address that and what happened to the care because the need clearly couldn't have gone away, but what happened? I think that would be an informative exercise.

MS. CAMERON: Do you want me to respond to that?

DR. CROSSON: Are you going to answer?

MS. CAMERON: So I think as we look at different markets, there are a few things, and one is even when we look at markets across the country, there is an LTCH available to a vast majority of Medicare beneficiaries within about 90 miles.

Now, that's not all beneficiaries, but for certain beneficiaries who are willing to travel for their needs, they do travel.

Although the median travel distance, I believe, is between 15 and 20 miles, the range is huge. That's a median, and it's a very, very large range.

We have found in some of our work that especially for things like ventilator-associated conditions, those people are more willing to travel, and for those that do

travel outside of their market area for an LTCH, it's more likely for a ventilator issue.

Because of the numbers and because these patients other than the vent are so difficult to define, it's very hard to see them and tease them out of the data on a market basis. Many of these beneficiaries have very long lengths of stay in the acute care hospital, and I think some of our hospital people we spoke with during our site visits have spoken about the long, long length of stay.

Some folks in New York were citing 180-day lengths of stay in their acute care hospital, but finding the folks who are longer than the average, 5.3-day average length of day, they could stay 30 days in the acute care hospital. And that might mimic more of their length of stay in the LTCH, and it's very difficult to tease out.

So I think LTCHs are unevenly distributed throughout the country, but they are often in markets with a critical population mass. And that represents a vast majority of Medicare beneficiaries, at least within kind of an hour-and-a-half travel area. To the extent that those folks are able to get to an LTCH, I think they do use it.

There are SNFs, not a lot, but there are SNFs

that do provide that care. And we spoke with markets like that who do have some SNFs that provide this care.

Now, I think that's still fairly rare in the industry. SNF payment is changing, and one of the parts of that payment change, we don't expect it to happen overnight. But will SNFs over time be able to increase their staffing capital in such a way that could support this population? There needs to be a critical mass of patients on vent for a facility to pay for a respiratory therapist and have these physicians do rounds more frequently. So a one- or two-off patient at a SNF is not going to carry that threshold.

So there are a lot of dynamics changing here, and when we've looked at it, that's what we've found.

DR. CROSSON: Thank you.

Jon.

DR. PERLIN: Right on this point, there's that triangulating between Jaewon's comments and Jonathan's earlier about the similarity perhaps more to certain hospitalized than SNF patients.

Self-service research may already be done, but I knew you were really skirting to it -- is that if you look

at those areas without SNFs within X number of miles or X number of hours of drive time, it would seem that one potentially calibrating population would be those extreme outlier ventilated patients with excessively long lengths of stay.

And that may help with Brian's point about the asymmetry of the groups in terms of modeling out that group of patients.

DR. CROSSON: Do you have a comment, Brian?

DR. DeBUSK: On that, that may be one of the reasons.

Actually, last week, I exchanged some emails with Jim. We were speculating -- or I was speculating. One of the reasons we were having some trouble separating out these, teasing apart these populations is there may be some LTCH patients that are legitimate PAC patients and will be well addressed by the PAC PPS.

There may be some outliers that are really just levels of MS-DRGs that we don't currently account for.

I mean, it would be interesting to see if you could take the IPPS, selectively add a few severity levels to some existing DRGs to accommodate for those, peel those

patients off, and then let the balance of them go into the PAC PPS, because I was looking at the ventilator, the patients within the ventilator criteria. It's only like 19,000 Medicare discharges out of 116,000. So the vent isn't quite the bright white line that we were looking for.

And when you think about this whole definition of CIRCADIAN and three days in ICU, I mean, it starts to sound a little bit like a poor man's grouper. In the IPPS, we've solved that with the DRG grouper.

And so, again, I do wonder if some of those cases that Kathy was mentioning earlier, they may be better fit by adding a couple of MS-DRGs on the high end of the severity.

MS. BUTO: Didn't we recommend some increase to the outlier payments for hospitals to account for some -- in some kind of combined policy, I think last year in our paper?

MS. CAMERON: That's right.

Many of these patients -- and when we talk about this, I'm mainly focused on the patients that kind of meet the criteria because I think the way the patients are defined, those that don't meet the criteria are likely to

be those that could be seen at other post-acute care settings.

Maybe kind of what's your definition and what you're thinking about as, they're more able to be treated in a SNF or in another post-acute care setting.

But when we think about the patients meeting the criteria, those patients are extremely expensive, whether they're treated in an LTCH or -- and they're very costly, I should say. They are very costly to treat, whether it's in an LTCH or in an acute-care hospital.

Many of these patients are financial losers for the hospital, regardless of whether they end up getting an outlier payment, and so part of our March 2014 recommendation was -- in addition to putting this in place in the LTCH, was to provide the additional money from the LTCHs to the acute care hospital in the form of an outlier pool that addresses the financial losses that hospitals are taking on this type of patient because they're not typically profitable.

DR. CROSSON: Okay. Thank you, Stephanie.

I think we are ready to proceed with the vote. So the draft recommendation is before you. It's amended

from December. All Commissioners in favor of the draft recommended, please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: Passes unanimously.

Thank you very much, Stephanie.

We'll move on to the final presentation for the day.

[Pause.]

DR. CROSSON: Okay. Our final presentation for the day is going to be on the update for outpatient dialysis services. Nancy and Andy are here, and take it away.

MS. RAY: Good afternoon. Today's presentation on assessing the payment adequacy of outpatient dialysis services consists of three sections. First, we will answer some questions raised during the December meeting. Recall during last month's session, Commissioners asked for additional information to help in their deliberation of the

draft update recommendation. Then I will summarize the indicators of payment adequacy that we reviewed in December. Lastly, I will present the draft update recommendation.

So as background, in 2017, there were about 394,000 Medicare fee-for-service dialysis beneficiaries treated at approximately 7,000 facilities. Total Medicare fee-for-service spending was about $11.4 billion for outpatient dialysis services.

So now I'm going to move to answer some of the questions raised during the December meeting.

Bruce, in 2017, fee-for-service Medicare accounted for roughly 45 percent of revenues, according to public SEC filings and our preliminary analysis of cost reports.

Jonathan, we have added additional discussion about the use of chronic kidney disease care coordination and patient education efforts, and some of these have been sponsored by payers in addition to providers.

Kathy and others, we have added additional discussion about CMS's revision to the transitional drug add-on payment adjustment, including our strong objection

to the policy. In addition, the broader issue of drug pass-throughs is on the list of items that we will discuss tomorrow during the drug session.

Jon and others, we have added additional discussion about how CMS adjusts payment in the dialysis PPS for rural and low-volume facilities and our concern that these adjustments are not well-targeted for low-volume and isolated facilities.

Now let's review the payment adequacy analysis. The indicators assessing adequacy are generally positive, and you have seen all of this material in December.

Regarding access, there is a net increase of about 250 facilities between 2016 and 2017. Our analysis suggests that there were few facility closures in 2016, and the few beneficiaries who were affected were able to obtain care elsewhere.

Regarding capacity, the growth in dialysis treatment stations has exceeded the growth in the number of fee-for-service dialysis beneficiaries between 2016 and 2017.

Looking at volume changes, between 2016 and 2017 the growth in the number of dialysis fee-for-service

beneficiaries and Medicare-covered treatments remained steady. The 17 percent marginal profit suggests that providers have a financial incentive to continue to serve Medicare beneficiaries.

So here are trends in quality that we discussed lath month. Between 2012 and 2017, mortality admissions per beneficiary and the percent of hospitalized beneficiaries with a readmission are trending down. The percent of dialysis beneficiaries using home dialysis, which is associated with improved quality of life and patient satisfaction, has increased. These are all good trends. On the other hand, the percent of dialysis beneficiaries with at least one ED visit has increased between 2012 and 2017.

Regarding access to capital, indicators suggest it is robust. An increasing number of facilities are for profit and freestanding, and private capital appears to be available to the large and smaller-sized multi-facility organizations.

Moving to our analysis of payments and costs, in 2017, the Medicare margin is -1.1 percent. The Medicare margin is higher for high-volume facilities compared to

low-volume facilities. That is, the margin increases as total treatments increase. The lower Medicare margin for rural facilities is related to treatment volume. Rural facilities are on average smaller than urban ones.

So the factors that the 2019 projection accounts for include the statutory payment increases in 2018 and 2019; regulatory changes by CMS that are expected to increase total payments in both years; and the small estimated reduction in total payments due to the ESRD Quality Incentive Program in both years.

Based on these factors, the 2019 projected Medicare margin is -0.4 percent, a small increase from the 2017 margin.

Here are the policy changes in 2020 that will affect spending. I'd like to highlight the third item. As discussed earlier, CMS will begin to pay facilities separately under its revised TDAPA policy for all new dialysis drugs without any offset to the PPS base payment rate. We expect this will increase Medicare payments to dialysis facilities.

So here is a quick summary of the payment adequacy findings. Access to care indicators are

favorable. Quality is improving for some measures. However, the 2019 Medicare margin is projected at -0.4 percent.

So here is the draft recommendation: For calendar year 2020 the Congress should update the calendar year 2019 Medicare ESRD PPS base rate by the amount determined in current law.

In terms of spending implications, this draft recommendation has no effect on spending relative to current law. Regarding implications for beneficiaries and providers, we anticipate that beneficiaries will continue to have good access to care, and we also expect providers' continued willingness to furnish care.

With that we turn it back to Jay.

DR. CROSSON: Thank you, Nancy. We will take clarifying questions. I see Brian, Jon, and Dana.

DR. DeBUSK: The -- and I think this was Bruce's question earlier and I'm sure I can produce it in the materials, but what percentage of their treatments go to Medicare fee-for-service beneficiaries?

MS. RAY: It's roughly 60 percent. So 60 percent of all treatments are fee-for-service treatments, and

roughly 45 percent of total revenues is from fee-for-service.

DR. DeBUSK: Okay. So there are about 60 percent -- I'm just trying to do a back-of-the-envelope calculation. I think in the materials we said their all-payer margin was maybe 20 percent.

MS. RAY: Right. It's about 20 percent. And I just want to -- that the 45 percent and 60 percent, those are averages and it could vary from facility to facility.

DR. DeBUSK: Okay. I agree it's an aggregate. I was just trying to back into what it would take to get a 20 percent -- you know, if 60 percent or more of your business is at zero margin, effectively -- you know, zero -- what do you need to be -- would that mean commercial rates are $550, $600 a treatment? I'm just trying to think of how you get to 20 percent if 60 percent of your business is sitting at zero.

DR. CROSSON: You charge a lot.

DR. DeBUSK: Well, that's what I'm saying. No, no, I'm with you. I'm thinking the non-Medicare treatments are going to be 20 percent more. They're going to have to be 100 percent more. I mean, are we talking roughly 100

percent?

DR. JOHNSON: We don't have an exact number but it's in that ballpark, and the type of math you're doing makes sense.

DR. DeBUSK: Okay.

DR. CROSSON: I recently reviewed, or in the process of reviewing a paper that suggests that your estimate is correct.

DR. DeBUSK: Okay. Thank you.

DR. CROSSON: Other questions? We've got Jon.

DR. CHRISTIANSON: In your presentation you noted that there was an increasing proportion of dialysis beneficiaries using the ER, and it's increasing but it's not huge.

MS. RAY: It's not huge but there is a modest increase.

DR. CHRISTIANSON: So my question is, does that come predominantly from home- versus facility-based, or did you look at that?

MS. RAY: I have not looked at that.

DR. CHRISTIANSON: Okay.

DR. CROSSON: Dana.

DR. SAFRAN: I forgot I had my hand up before.

DR. CROSSON: You did, didn't you?

DR. SAFRAN: I did. Yeah.

DR. CROSSON: It's late but go ahead.

DR. SAFRAN: I'm curious, how does the thinking about home dialysis get factored into our thinking about payment rates for facilities, including, you know, the desire, if we have one, to motivate the use of home dialysis where it's appropriate, since it's so much better quality of life and convenient and all that? So how does that fit together with this?

MS. RAY: So when CMS developed the PPS, and it was implemented in 2011, one of the issues was whether to pay -- have a separate payment for home dialysis or include home dialysis with in-center. And the decision that CMS made at that time, based on cost report data, was to not have a separate adjustment for home dialysis, because, histo4ically, home dialysis costs were less than in-center costs.

DR. SAFRAN: So if I'm a provider I will get paid the same regardless of the setting.

MS. RAY: For patients over the age of 18, that's

correct.

DR. SAFRAN: Thank you.

DR. CROSSON: Kathy.

MS. BUTO: So as I'm reading this, Nancy, the transitional drug add-on payment adjustment is completely administrative. In other words, it's not dictated per se, this policy, by statute, or is it part of the statute on the PPS?

MS. RAY: So in some law passed, I think it was in PAMA perhaps, instructed the agency to develop regulations on how new drugs would be paid for under the PPS. And so the agency did that and they finalized that in 2016, I think.

MS. BUTO: Yeah.

MS. RAY: And those regulations -- based -- what those regulations said was, well, if you have a new drug and if it fits any of the existing dialysis drug categories, we're going to just put it right into the bundle.

MS. BUTO: Right. They changed that in this latest decision.

MS. RAY: Right. That's correct.

MS. BUTO: That's the change.

MS. RAY: Yes.

MS. BUTO: But even the original interpretation was their interpretation. They could have said all new drugs are covered under the bundle and we'll recalibrate the rates accordingly, from time to time.

MS. RAY: That's correct.

MS. BUTO: Okay. I just wanted to be clear on that.

DR. CROSSON: Okay. Seeing no further questions, you have the recommendation before you. We will proceed to comments, support, oppose, other comments with respect to the recommendation.

[No response.]

DR. CROSSON: Seeing none, I'd ask for a vote on the recommendation. All Commissioners in favor of the recommendation before you raise your hand.

[Show of hands.]

DR. CROSSON: All those opposed.

[No response.]

DR. CROSSON: Abstentions.

[No response.]

DR. CROSSON: The recommendation passes unanimously.

DR. CROSSON: Thank you, Andy. Thank you, Nancy.

We have come to the end of this day, and it's now time for a public comment period. If there are any members, any of our guests who wish to make a public comment please proceed to the microphone. Just wait for my instructions for one second, if you would.

I'll just make a note that there are other mechanisms to provide information to the Commission, through the staff, either online or in person, that this is an opportunity. We'd ask you to state your name and any organization you're affiliated with, and please limit your comments to two minutes. When this light returns, that's two minutes. Thanks.

MS. DREW: Good afternoon. My name is Lauren Drew, and I am the senior manager of advocacy and state relations at NHPCO, the National Hospice and Palliative Care Organization. On behalf of our president and CEO, Edo Banach, I respectfully submit comments on the MedPAC Chair's recommendation to Congress that you reduce fiscal year 2020 Medicare base payment rates for hospice by 2

percent.

The National Hospice and Palliative Care Organization is the oldest and largest nonprofit membership organization representing hospice and palliative care programs and professionals. We represent almost 4,000 unique programs nationwide.

The organization is committed to improving serious illness and end-of-life care and expanding access to hospice and palliative care with the goal of profoundly enhancing quality of life for the seriously ill, the dying, and their loved ones.

We believe we bear a special responsibility both to ensure that the Medicare hospice benefit is available to all Americans and that it continues to deliver the value that patients, their families, and all taxpayers deserve.

It is for that reason that we are deeply concerned about the Chair's recommendation and look forward to discussing opportunities to strengthen the hospice program and ensure adequate hospice reimbursement.

NHPCO's value agenda is designed to achieve a seamless delivery model from patient diagnosis through family bereavement. Featuring common-sense reforms for

person-centered care, our agenda is designed to advance patient choice and access to care, particularly in underresourced areas; improve provider education and training; enhance accountability; and improve program integrity.

Importantly, our vision also unified hospice and palliative care, including their payment systems, under a single person-centered care umbrella for enhanced transparency and predictability. We look forward to meeting with Dr. Jim Mathews, Kim Neuman, and staff at our scheduled meeting later this month. We are excited to share our improved data analytics capabilities and to receive your valuable perspective on our work.

We look forward to offering our assistance to MedPAC in their important role in advising Congress.

Thank you.

DR. CROSSON: Thank you for your comments.

Seeing no one else at the microphone, today's session is concluded. We will reconvene tomorrow at 8:30. Thanks, everybody, for the work.

[Whereupon, at 3:45 p.m., the meeting was recessed, to reconvene at 8:30 a.m. on Friday, January 18,

1 2019.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Friday, January 18, 2019
8:30 a.m.

COMMISSIONERS PRESENT:

FRANCIS J. CROSSON, MD, Chair
JON B. CHRISTIANSON, PhD, Vice Chair
AMY BRICKER, RPh
KATHY BUTO, MPA
BRIAN DeBUSK, PhD
KAREN DeSALVO, MD, MPH, Msc
MARJORIE GINSBURG, BSN, MPH
PAUL GINSBURG, PhD
DAVID GRABOWSKI, PhD
JONATHAN JAFFERY, MD, MS, MMM
JONATHAN PERLIN, MD, PhD, MSHA
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P R O C E E D I N G S

[8:30 a.m.]

DR. CROSSON: Okay. We can be seated and get going. Welcome to the Friday morning session.

It comes as no particular surprise that the country is wrestling with the problem of increasing drug costs taking place now in the popular literature as well as, of course, with policymakers and in Congress and in the administration. This Commission has been working on this issue for some time. We intend to continue to do that, and so today's presentation is intended to be a review of the recommendations and ideas that have come out of this Commission in recent years, as well as a discussion -- a presentation and discussion among the Commissioners about priorities for continued and future work of the Commission.

Today we have Kim and Nancy and Rachel and Shinobu in the bull pen to help us think through these issues, and, Kim, it looks like you are going to start out.

MS. NEUMAN: Good morning. So today's session focuses on Medicare policy concerning drugs and biologics. As you know, Medicare spending on these products is substantial. In 2017, Medicare and enrollees paid Part D

plans $94 billion, and Medicare fee-for-service spending on Part B drugs, including cost sharing, was $32 billion.

As Jay mentioned, today we're going to explore potential future policy directions to address concerns about growth in drug prices and Medicare spending. This session is in response to Commissioners' requests to take a broad look at Medicare drug policy, starting with the Commission's past work, and then outlining a variety of ideas offered by others that could be explored.

As we'll discuss, work is already underway on several specific topics for spring presentations that will be potentially included in the June 2019 report. We hope that today's session will spark discussion about which additional ideas you're interested in exploring further and help set priorities for our research agenda going into the fall and beyond.

This next slide provides an outline of the presentation. We'll briefly discuss the scope of the presentation and then, as I mentioned, discuss the Commission's past recommendations, other ideas the Commission has explored but not moved forward on to date, work planned for the spring, and then other ideas in the

environment that we could consider exploring further. Since there are many policy ideas in the environment, this presentation will by necessity be relatively high level, but we aim to give you enough descriptive information so that you can set initial priorities.

Clearly, there are a number of policies beyond Medicare that have important implications for drug prices, but since these areas are outside of MedPAC's purview, this presentation won't be covering them. Examples include: government funding of research and development by NIH; patent policy and the FTC's anticompetitiveness enforcement policy; FDA policies concerning drug approval, exclusivity, and interchangeability; aspects of Medicaid drug policy, such as best price; tax credits and tax incentives for research and development; and state pharmacy law, such as those governing pharmacists' substitution of interchangeable products.

So now turning to the Commission's past recommendation, first we have Part B. As you'll recall, Medicare Part B covers drugs that are infused or injected by physicians and outpatient hospitals as well as a few pharmacy-supplied drugs. Medicare pays the average sales

price plus 6 percent for most Part B-covered products.

In June 2017, the Commission made a three-part recommendation to improve payment for Part B drugs. The first part consisted of four policies aimed at improving the ASP payment system. I'll highlight two.

One requires drug manufacturers to pay Medicare a rebate when ASP for their drug grows faster than an inflation benchmark.

Another would pay innovator biologics and biosimilars the same rate under a consolidated billing code to promote price competition.

The second part of the recommendation was the development of a drug value program, or DVP, which would be a voluntary market-based alternative to the ASP payment system in which physicians and outpatient hospitals could choose to enroll. Medicare would contract with a small number of DVP vendors to negotiate prices for Part B drugs, and these vendors could use tools such as a formulary and, for some drugs, binding arbitration.

The third part of the recommendation was reducing the 6 percent add-on under the ASP payment system to encourage DVP enrollment.

Next is Part D. As you know, Medicare Part D covers drugs dispensed as pharmacies. Medicare pays Part D plans using a combination of capitated payments based on plan bids and reinsurance subsidies. In June 2016 and March 2018, the Commission made recommendations to address concerns over rising drug prices and Part D spending.

To increase plans' incentives to manage spending on high-cost drugs, the recommendations would lower the reinsurance Medicare pays from 80 percent to 20 percent of catastrophic spending while simultaneously increasing capitated payments. At the same time, the recommendation would give plan sponsors greater flexibility to use formulary tools, strengthening their negotiating leverage.

Other parts of the Commission's recommendation would modify cost sharing for low-income subsidy beneficiaries to improve incentives for use of generics and biosimilars. The recommendation would also eliminate cost sharing above the out-of-pocket threshold, increasing insurance protection in the catastrophic phase of the benefit.

This next slide highlights some other past drug recommendations the Commission has made. I won't go into a

lot of detail now, but we'd be happy to discuss on question. These include: a 2016 recommendation to reduce the Part B drugs' dispensing and supplying fees paid to pharmacies for inhalation drugs and certain oral drugs to rates similar to those of other payers.

In 2007, out of concern that there is not enough credible, empirically based information on the comparative effectiveness of alternative treatments, the Commission recommended Congress charge an independent entity with sponsoring research on the comparative effectiveness of health care services, including drugs, and disseminate that information.

In 2007, the Commission also recommended moving coverage of new preventive vaccines from Part D to Part B to facilitate easier access in physician offices. Also in 2007, the Commission recommended the Secretary clarify average sales price reporting requirements for drugs that are subject to bundled price concessions.

Over the years, the Commission has discussed several other strategies aimed at increasing the value of Medicare spending for drugs and biologics. The Commission has not pursued recommendations in these areas to date, but

the issues could be revisited depending upon interest.

The first relates to coverage with evidence development, or CED. Under CED, Medicare links the coverage of an item or service to the collection of clinical evidence. Although Medicare applies CED in the national coverage determination process, some researchers argue that Medicare's use of CED has been limited.

We have also discussed several policies that are based on comparative clinical effectiveness research, which compares the clinical effectiveness of two or more treatment options for the same condition.

The first three noted on the slide -- least costly alternative, Pearson-Bach, and combined billing codes -- are all variants of reference pricing where the amount Medicare pays for products with similar health effects are based on a benchmark such as the lowest-cost comparable alternative or the average cost.

The fourth approach is cost-effectiveness analysis, which starts with information on comparative clinical effectiveness and compares the incremental cost in dollars of one intervention to another in creating one unit of health outcome. There's increasing interest by

commercial payers in using such information in determining a drug's value.

Because cancer drugs account for a large share of Part B drug spending, the Commission has also discussed several approaches to improve the efficiency of oncology care. Approaches discussed include oncology medical home, bundling, and accountable care organizations, which are all approaches to increasing provider accountability. We've also discussed oncology clinical pathways which are evidence-based protocols that some providers and commercial payers use.

Finally, there is the ASP hybrid model. In June 2016, we modeled a policy option that changes part of the 6 percent add-on to a flat fee.

DR. SCHMIDT: In the spring, we plan to discuss the issues on this slide and, as Kim said, potentially include them in our June report. For now I'll just describe these briefly.

Kim just mentioned some variations of reference pricing. It's a general approach that could be used in Part B or Part D in which a purchaser or payer sets a maximum amount that it will reimburse for therapeutically

similar drugs. Reference prices can be based on a payer's own pricing data, but under a second approach, the reference price could be based on prices from other countries.

Under binding arbitration, two parties would agree to accept the verdict of a neutral third party over a drug's price. As Kim mentioned, the Commission's 2017 Part B drug recommendation included binding arbitration as a tool in the drug value program. In spring, we'll explore using it more broadly for Part B drugs.

Yesterday we talked about how in Part D brand manufacturers provide a large price discount in the coverage gap. This lowers enrollee costs but also reduces incentives to manage benefits. We'll come back this spring to discuss a way to restructure the discount in a way that may address this concern.

Finally, some enrollees take high-priced specialty drugs that have few therapeutic alternatives. For those patients, Part D cost sharing can also be high and may affect their adherence. We plan to discuss some approaches for addressing this.

Over the next few slides, I'll describe some

policy ideas that stakeholders, academics, policymakers, and others have raised to address drug prices and spending but that the Commission hasn't yet formally considered. Although we don't have estimates of savings for many of these, we've tried to use the information we have to put the ones that we expect to have the biggest effect towards the top.

So the first idea relates to excluding new drugs from coverage or formulary at launch. Launch prices of new drugs have been rising steadily. Part B providers and Part D plan sponsors have little or no ability to negotiate price concessions for a new drug that doesn't have competitors. Excluding a new expensive medication until there is more real-world evidence about its clinical effectiveness could allow room to negotiate more competitive pricing. Some PBMs are already using this approach for commercial clients.

Next on the list is Medicaid-like rebates in Medicare. So the Medicaid drug rebate has two components: a flat percentage rebate and an inflation rebate. One or both of those approaches could be used in Medicare. If used in Part D, a Medicaid-like rebate could apply to dual

eligibles and others who receive the low-income subsidy. They account for about 30 percent of enrollment and 50 percent of spending.

In 2006, the duals were moved from Medicaid to Part D's low-income subsidy program. Estimates by government agencies suggest that the average rebates negotiated by private plans in Part D tend to be lower than the mandated ones under Medicaid. With the Medicaid-like approach, manufacturers would pay Medicare the difference between the rebates required under Medicaid and the amounts negotiated by Part D plan sponsors. The Congressional Budget Office estimates that the flat percentage and inflation rebates combined would save $154 billion over ten years in Part D.

In 2013, OIG recommended that CMS explore the effect of applying a Medicaid-like rebate to Part B drugs. The Commission has recommended an inflation rebate for Part B drugs, but has not considered a flat rebate. If applied in either B or D, the Medicaid-like approach would generate savings. However, it could also lead to increased launch prices for new products. To the extent that occurs, the savings to Medicare from the rebate would decline over

time.

In recent years, manufacturers, payers, and PBMs have entered into outcomes-based agreements that link a drug's payment to measures intended to reflect patient outcomes. These can sometimes be complex to implement and can have high administrative costs. A key issue is how to define a clinically relevant outcome that is observable in a reasonable time period.

Control over outcomes data and a data analysis can be sticking points in these agreements. Stakeholders have said that best price reporting requirements can be an impediment. Some payers have questioned whether the approach can really achieve sizable reductions in price. However, other payers like the approach, and the number of outcomes-based contracts is increasing, particularly in drug classes that have competing therapies.

Indication-specific pricing has been promoted by experts such as oncologist Peter Bach and is used by PBMs for some commercial clients. This approach stems from the common situation where the FDA approves a drug for an initial indication and then the drug receives subsequent approvals for additional indications. Rather than paying

one flat amount for any use of the drug under indication-specific pricing, a PBM might negotiate a lower payment for those indications for which the drug is relatively less effective.

Proponents of the approach contend it can expand access by lowering prices. Critics argue that the approach primarily serves to expand manufacturer profits and would only expand access for lower-value uses of a drug.

Proponents of direct price negotiations believe that with the federal government's large purchasing power, Medicare could obtain prices from manufacturers that are lower than we see today, particularly for drugs that have no competitors. Opponents of this idea contend that in Part D private plan sponsors are already negotiating for prices and provide access to a wide range of medications.

The effectiveness of government negotiations would depend on the specific authority given to the Secretary, such as whether he could establish a formulary, exclude certain drugs, or set prices directly. Even if the Secretary was given authority to establish a formulary or use other tools, it may be difficult to exercise that authority in the presence of strong resistance from

stakeholders, including patients and manufacturers.

Commercial plan sponsors often try to dispense high-cost specialty drugs through an exclusive network of specialty pharmacies. Many of the largest insurers and PBMs own specialty pharmacies, and some encourage their clients to dispense exclusively through that company.

In Part D, plan sponsors cannot set up a narrower network of specialty pharmacies because, under law, plans are subject to the any willing pharmacy provision. Proponents of exclusive networks believe that the approach can provide greater negotiating leverage and lower prices from drug manufacturers. Critics question whether more concentrated delivery by fewer pharmacies could lead to a less competitive specialty pharmacy market.

One approach would be to periodically compete contracts to dispense specialty drugs for Part D beneficiaries in part or all of the country, as the Department of Defense does for TRICARE. However, smaller pharmacies and other organizations that today dispense specialty drugs would oppose limits on their ability to share in the revenues of this growing part of the market.

Some manufacturers offer coupons to commercially

insured patients to reduce patients' cost-sharing liability. Manufacturer coupons are not considered as discounts for the purposes of calculating a product's ASP. If coupons were considered discounts, Medicare ASP+6 payment rates would be lower. For example, GAO estimated that the ASP of 18 drugs would be on average seven-tenths of a percent lower if coupons were counted in the calculation.

Some stakeholders have expressed interest in moving drugs from Part B to Part D as a way to apply pharmacy management tools to Part B drugs. Shifting drugs from Part B to Part D could increase or decrease a beneficiary's out-of-pocket costs, depending in part on whether the beneficiary has Medigap, other supplemental insurance, or Part D.

Part B covers a few pharmacy-supplied drugs that may be relatively easy to provide under Part D, but moving provider-administered drugs, which account for most Part B spending, would be complex and may not necessarily lead to lower prices.

The final idea I'll present is a manufacturer rebate for wasted drugs. Infusion drugs are often sold in

a single-use vial that's intended for one patient, with any leftover drug discarded. Peter Bach and colleagues found that some manufacturers offer products in limited vial sizes that are not well matched to patient dosing, which leads to waste and higher revenues for the manufacturer.

Bach suggests one potential approach to address this could be to require manufacturers to pay a rebate for wasted drugs. The magnitude of savings from this idea relative to the administrative costs is unclear.

So that concludes our laundry list of ideas, and we're looking forward to your feedback, your questions, your suggestions, whether we've missed something important, and we look forward to your discussion.

DR. CROSSON: Thank you, Rachel, Kim.

We'll now take clarifying questions on the presentation. I see Amy and Paul. Amy?

MS. BRICKER: On the idea of accounting for coupons in the ASP calculation, what did you say the savings was estimated to be?

DR. SCHMIDT: It was seven-tenths of a percent.

MS. BRICKER: That seems really, really, really low.

MS. NEUMAN: So GAO had data from a sample for 18 drugs, and what they found was that there were five that had an effect greater than one percentage point, and the rest, the other 13, were below. And so on average, you get to that 0.7 number. But, clearly, there's differences across products.

MS. BRICKER: So these are just the Part B drugs where you looked at this?

MS. NEUMAN: Yes, it's just Part B.

MS. BRICKER: Okay. So was something done similar on the D side?

DR. SCHMIDT: Not that I'm aware of, no.

MS. BRICKER: Something to consider. I'll do that maybe next round. Thank you.

DR. CROSSON: Paul.

DR. PAUL GINSBURG: You know, as far as moving drugs from Part B to Part D, do you have a sense of magnitude of dollars where this might be an administratively feasible thing to consider? In a sense, are people just talking about it with being very few opportunities to actually do it effectively? Or is this something substantial?

DR. SCHMIDT: So there is a paper that just came out, and Jay and Jon actually wrote a commentary that goes alongside it. But I'm not sure that's going to directly answer your question. The ones that are administratively easy, no, I haven't seen an estimate as to the magnitude of that spending. The particular paper that just came out was trying to measure overall movement from B to D, and it estimated that savings, but it was using an approach where it was applying some average rebates that are observable to WAC, and one could question some of those assumptions.

DR. CROSSON: Jon.

DR. CHRISTIANSON: The reference pricing suggestion or topic, does that come from the experience of Germany or other countries; and if so, what has been their experience?

MS. RAY: So, in March, we plan to come back to you in greater depth to discuss reference pricing, when the payer does it, using the payer's own pricing data as well as international reference pricing. We do plan to include a case study about Germany, where a part of their system is based on reference pricing.

DR. CROSSON: Kathy and then Bruce.

MS. BUTO: Do we have sort of magnitude, high, medium, low kind of sense of which ones of these proposals have the biggest impact on spending? Have you done some of that thinking? Are they kind of rank ordered according to that belief that some will have a bigger impact than others?

DR. SCHMIDT: Right. There's a whole lot of uncertainty, and it depends a lot on implementation details and things like that, of course.

So we did try and rank order them where there was an estimate out there; for example, the Medicaid-like rebates, we could hang our hat on a CBO estimate, that sort of thing.

We put excluding at launch at the top just because it seems like that could be very huge.

MS. BUTO: That would be very huge.

DR. SCHMIDT: Right.

Unfortunately, there aren't detailed estimates for a lot of these, and as I said, a lot depends on the details of how it would be implemented.

DR. CROSSON: Bruce.

DR. PYENSON: In the international comparison of

prices, I wonder if you could look at the comparison of the intermediaries that exist in the U.S. that, my understanding don't exist elsewhere in the same level, so the distribution in the intermediary, because I suspect it's not just about we're very different from the rest of the world and not just in prices, but in how we distribute, how we move things around. Do you have any visibility into that?

MS. RAY: We can certainly try to take a look at that between now and when we come back to you in March. I think that's an interesting point.

DR. CROSSON: Yes, Karen.

DR. DeSALVO: Thank you all so much.

To this point about laundry list, which I appreciate how much you all have been trying to grab new ideas, I want to build no what Kathy said and ask about whether you've been able to also rank according to impact on beneficiary for their out-of-pocket cost changes.

Related to that, I wondered about whether there's an equity issue built into some of this or an inequity issue. Maybe you can help me understand if that is a concern or not; in other words, if you're a low-income

subsidy beneficiary, it seems like sometimes there's maybe not a differential impact on your out-of-pocket but on your access to some drugs that might be of best evidence to treat the condition you have. Think about, in the Medicaid world, something like hepatitis C medications. Sometimes we've created this artificial barrier based on the payment methods, so two things in there, but both about impact on beneficiary as we think about ranking.

DR. SCHMIDT: Again, I think it's hard to rank because there's so much in the details of the parameters of how you choose to implement something. It's pretty complicated.

Moving drugs from B to D issue, for example, might actually benefit low-income subsidy folks or people who qualify for the low-income subsidy, so long as they have Part D, to the extent that a lot of the cost sharing would be covered if they didn't come from having a Medigap and then they moved to LIS coverage, for example.

In other situations, yes, potentially access could be denied. An exclusion at launch, for example, that would not only affect low-income subsidy but perhaps others as well.

Reference pricing, it's the same sort of idea. The individual will be paying for the difference between the price level that's set by the payer or plan, and it would set a reimbursement rate. If the price is higher, then the patient would be picking that up, and that could be an access problem for low-income subsidy.

Each one of these is pretty complicated, and it would be hard to, I think, rank order them, both in terms of -- we wouldn't necessarily have the same rank, I should say, in terms of program savings versus effects on beneficiaries.

DR. CROSSON: Warner.

MR. THOMAS: First of all, thanks for the ideas and appreciate the great work done here.

Just a couple of questions. I'm just not sure what data is or is not available to us as we kind of go through this analysis.

Is it possible to take a market basket, say take the top 100 drugs that is in Part D or Part B, and look at those drugs over a period of time to see what has been the -- not just the utilization, because obviously when you're looking at total cost, you look at utilization and price,

but to look at the price change over a period of time, three, five, or more years for top drugs that are utilized by those programs and maybe looking at brand and generic because I think historically we thought generic is a much better alternative. But I think more recently, we're seeing a lot of escalation there.

Is that something that's possible? I don't know what data is available to us.

DR. SCHMIDT: Yeah. In fact, other organizations have put out publications along those lines. I know OIG has, for example, and I think CBO has done some similar sort of work. If you're interested in seeing that, we could present some of that to you.

MR. THOMAS: I guess what I'm trying to get at is one of the things that wasn't -- I mean, one of the things I know we bandied around is just this idea of a -- we did the ASP, moved it from 6 to 3, but the idea of an inflationary cap. And I guess my question is, Would that even matter? Would that have an impact? The only way to maybe understand that is to look back and see if you had a cap over a period of time, what impact may that have had? Obviously, it doesn't impact a launch price, but it may

impact increases on a go-forward basis. So that is something that is potentially feasible.

My second question, maybe it's building off of Bruce's comment.

I'm sorry?

MS. NEUMAN: I just wanted to add one clarification. In the 2017 recommendation, the Commission did recommend an inflation cap for Part B drugs, and so that would, going forward, if it were implemented, keep payments at an inflation benchmark and not higher. So we don't have a specific estimate because that whole recommendation was scored by CBO, but it is part of what the Commission recommended.

MR. THOMAS: Right. Thank you. I appreciate that.

I guess my thing is could we make it broader. Could it have a broader impact across multiple areas?

The second comment -- I think it's maybe building off of Bruce's comment -- or question -- is just this idea of looking at a comparison of a -- we're looking at domestic pricing for ASP, really just doing a straight comparison internationally and just see can we buy drug,

see what that change would be, maybe for the same market basket, if we looked at the top 100 or top 50 or top 250. Is that data available or not available?

MS. NEUMAN: So the Department put out a study where they looked at the prices in the U.S. versus other countries and came up with estimates of what they thought the differential is, so that's something we could come back to you on with more information.

MR. THOMAS: And did they do that on a group of drugs, on specific drugs?

MS. NEUMAN: Specific drugs, yeah, where they thought they had good data, and it was Part B. It wasn't D.

MR. THOMAS: Okay. And is it possible to look at that for Part D as well? Because I think we get this --

DR. SCHMIDT: That gets more complicated.

MR. THOMAS: What's that?

DR. SCHMIDT: It's hard to observe the Part D drugs directly without knowing the rebate information.

MR. THOMAS: I got it.

DR. CROSSON: Okay. Further questions?

Marge.

MS. MARJORIE GINSBURG: Warner brought up a topic that I was interested in, and that is the comparison to international, what other countries do, and of course, we've always heard that those with universal or almost universal health care have much better control of their drug costs.

So my question is how much we know about what -- the specifics of what other countries do and whether they apply certain processes like reference pricing or is it simply a matter, they tell the drug company, "This is how much we're going to pay. Take it or leave it." So do they simply set a ceiling of what they're going to pay for certain drugs, or do they actually utilize certain mechanisms for making that determination?

MS. RAY: So that will vary from country to country. In March, we were going to come back and just give you a feel for a couple of countries, just to give you several case studies. As I said, one we were planning on coming back to you with is Germany.

DR. CROSSON: Warner.

MR. THOMAS: I just had another question, and I think it's maybe building off of Karen's comment.

The idea of beneficiary out-of-pocket -- and, once again, maybe we had this data and we've looked at it. We've looked at a lot of data. So just the escalation of beneficiary out-of-pocket in any of the programs, Part B, Part D, over a period of time, do we have good information around that, that sort of situation, about how that has changed over the past three years, five years, et cetera, as far as what they have to pay out of pocket?

DR. SCHMIDT: I can speak to D because we have claims information, so we could come back with estimates.

But, generally, I think in D, so much of the population has moved towards generic, so out-of-pocket for many of those folks, zero, low co-pays. It's a pretty nice deal. The problem is with the specialty drugs, the small percentage of the D enrollees who are on those. That's where they're facing co-insurance and on very, very high prices. So that's where the burden lies for there.

DR. CROSSON: Karen and then Dana.

DR. DeSALVO: I had a reference pricing question. You had mentioned somewhere of TRICARE as a model, and I don't remember where that was in the list. But it made me think about the VA. So is there a domestic reference

pricing opportunity or some reason why we're not able to use VA as an example?

DR. SCHMIDT: Well, with VA, there's statutory rebates, and they negotiate some additional rebates. They have an ability with their prescribers to move market share pretty strongly. There's more consensus among prescribing, I would say. So those are two big reasons why they get such good prices.

I think an objection that would come up to using VA as a reference price is probably associated with the statutory rebates. It's by law. That's not to say we shouldn't go there. That's your decision, but that's an objection that would arise. It's demanding by law, a rebate. But other options we've brought to the table do the same thing.

DR. CROSSON: Dana.

DR. SAFRAN: Yeah, two things.

One, back to the issue we were talking about a little bit yesterday on cost-related non-adherence. I don't have a clear understanding, so I just wanted to get one, of whether there are direct data, meaning beneficiary-reported data over time on cost-related non-adherence to

medications, or if not, hearing you talk about our ability to use the claims data to get at some of the issues we've been talking about so far did start me thinking about some of the indirect ways that cost-related non-adherence has been attempted. It's tricky with claims data, but that's my first question: Do we have a way to measure what's happening with respect to cost-related non-adherence as we're moving around cost sharing and access?

DR. SCHMIDT: I'd have to think about whether -- on just beneficiary-reported adherence, whether there's something that's reliable we could turn to there or some other kind of clinical thing that would show up in data that's readily accessible to us.

The other sorts of measures that are commonly used for adherence, yes. That's, I think, possible to look at those.

DR. SAFRAN: Because I think looking at that over time would be extremely valuable for this issue that we're immersed in and staying immersed in for the foreseeable future.

The other thing, I just wanted to come back to this international comparison in Part D because I heard

your answer to Warner's question about whether we could do something like that for D and sort of the challenges of doing that with rebate. It just seems like we should -- maybe this is a Round 2. It just seems like we shouldn't be stopped, like we should make a best effort to see what could be done there. That line of inquiry seems quite important, and if that's the barrier, then I just wonder if there's a way we can come at it.

DR. SCHMIDT: There were a couple of suggestions yesterday for how to look at some brand-name drugs that have been priced at a net level rather than inclusive rebates. So it would be for a limited number of drugs, but that's one way to get to it.

DR. CROSSON: Pat.

MS. WANG: The next time that we have this conversation, would it be possible for you to do, sort of in one place, a description of an evaluation of the different types of statutory rebate programs that exist, whether it's Medicaid, the VA, 340B, their similarity, and just what the common themes are that perhaps we could identify as being the most effective?

DR. SCHMIDT: [Nodding affirmatively.]

MS. WANG: Thank you.

DR. CROSSON: Okay. Seeing no further questions, we're going to move on to the discussion.

I just want to make a couple of points. Number one, maybe it's not been brought up explicitly. Much of our work has focused on Part B an Part D. That doesn't mean that in searching for solutions, we should ignore another set of issues that Warner and other Commissioners have brought up, and that's the impact of drug prices on Part A and the impact that has on the ability of hospitals to absorb cost increases over time. To the extent that we address solutions here, we just need to keep in mind that it's not simply Part D and Part B, but Part A is an important consideration as well.

Second thing, just in terms of the conversation here, you've done a wonderful job setting the table here. This is a sumptuous buffet that we are facing here. I'm probably going to mix metaphors here because I was going to say something about boiling the ocean. But my experience with buffets in the past is that sometimes overindulgence is a risk.

I think what I'd like to do here and I think what

would be most helpful for the staff and for the Commission in general is to try to focus your remarks, as best you can, thinking about a few parameters. Relative effectiveness, for example, what's most likely to work? Even though we have some issues around quantitation, this is as judgment issue. What do you think is going to be the most likely approach or set of approaches to impact price and to some degree, in some circumstances, the issue of appropriate utilization of drugs as well?

What about feasibility? And I'm not so much thinking about enactment here because I think that's very difficult to predict in any environment, particularly at the moment, but administrative feasibility, how this would work out in the end.

The time to effect, how long would a particular approach take to actually have an impact over what is increasingly creating a sense of public concern, if not alarm?

Then the question of unintended consequences, downsides, impact on beneficiaries Karen brought up, but there are other things as well.

That's a lot to absorb, but I would ask you to

try to be as focused along those lines as you can. And I'm going to ask Kathy to begin the discussion.

MS. BUTO: Thanks, Jay, and I was going to sort of start there.

DR. CROSSON: You were going to say what I was going to say? Sorry about that.

MS. BUTO: No. Actually, what I started -- as I looked at this document, which was comprehensive, one of the things that occurred to me is it would be helpful to us to try to sort those options so that we can focus the work of all of us on those things that will have the biggest impact. So that's why I asked the question about do we know anything about magnitude of savings.

The other sorting that I thought about was new drugs versus ongoing payment discipline or pricing issues for existing drugs. So I actually think there's a lot of concern about new drug pricing, and we ought to really look at a constellation of things around that and also, then, look at the ongoing maintenance pricing issue going forward. So those are two sorts that I would try to do and then, of course, the magnitude of savings.

The operational feasibility piece, I just offer

that it was my experience that the more you get into a drug-by-drug kind of decision-making process the longer it takes and the harder it is to make a systemic impact. So, for example, one of your options is looking at the pass-through policy for outpatients. That's not a drug-by-drug approach. That is a systemic issue that definitely impacts spending and pricing and everything else. So again, I would try to figure out, not exclusively, but are there areas where we know if a policy change happened it would be pretty much an across-the-board, you know, improvement.

The other thing that is important, and this probably comes from experience also, is the extent to which a policy change can be implemented, not at the federal level, because the federal level is very susceptible and vulnerable to lobbying, congressional interference, et cetera, statutory change that stops you from doing something. So again, if we can think about, you know, where are the pressure points that would make the change actually happen, I think that's useful too.

And then I think we should consider whether the policy options we're looking at would actually stimulate higher launch prices. I think you alluded to some of

those, Rachel, in your setup. But there's some where we're pretty sure that if we took that approach that it would lead, initially, at least, to higher launch prices and then maybe diminishing returns down the road. We don't know. I think it's important to consider, also, the impact on competition and innovation amongst drug categories and individual drugs, so that's important.

One of the things that occurred to me -- and this is just back to the point about new drugs versus existing -- is in addition to policies designed to constrain, there might be policies that could be used to constrain spending for inappropriate uses that are really used more as a carrot. So, for example, there might be a combination policy where we want to delay the introduction or ability of beneficiaries to get a wide range of indications off-label, but the carrot could be if we believe that the manufacturer wants to come in and talk about, you know, more coverage with evidence development or some evidence generation process, then they have an incentive to do that and the program might benefit down the road.

So using the interest to stimulate something else, even the issue of direct negotiation, which I know is

anathema to industry, might be appealing if it meant that some breakthrough, as they define it, drug would get earlier access in the program. So there might be a willingness to negotiate in exchange for earlier access or access in certain setting. In other words, I would try to think of this as both carrots and sticks, constraints as well as incentives, to try to induce the kind of generation of information that we'd like to see. So not just ways to stop prices from rising but also how can we get a better value for the program.

And so I would just say, in the next go-around, if we could have maybe a little bit of foundational information about whether we think something is going to have an impact of a greater magnitude, whether it's operationally feasible in a relatively short period of time and whether there is a mix of things that could be both constraining but also stimulate, you know, better information, longer-term registries, whatever it is we think will provide better value to the program, I think it would be good to have that sense.

DR. CROSSON: Thank you, Kathy. Very good.

Okay. So I think we're going to have a lot of

comments. I'll start with Paul and then Brian.

DR. PAUL GINSBURG: Thanks. I think you did an excellent presentation and Kathy's comments were very wise.

I, too, kind of big-picture things that apply to a lot of this. One is that as I was listening to the different options I kept thinking about all different aspects of price discrimination, and, you know, price discrimination sometimes is a good thing, sometimes is a bad thing, and that you might want to, when you come back in March, do a few minutes' seminar for the Commission about price discrimination, because it's going to come up on a lot of the issues. And I think if we have a nuanced perspective on it I think it will be very helpful, because, really, some of these things make it easier to price discriminate and some of them make it harder to, and, you know, we need to go through that.

The other thing is that when we're in the Part B space, a lot of times there's a tendency to say, well, something won't work because of Medigap coverage. And, you know, Medigap, to me, has been something that has driven Medicare spending higher ever since the beginning of the program, but I think there were some changes, some

restrictions on Medigap benefit design, and I know this Commission has recommended it further, that we should certainly, you know, resurrect some options. If all it would take would be a change in Medigap benefit design, it would make it a viable option. We shouldn't feel constrained forever.

Getting back to the particular options, one that was new to me is the one on coupons, about, you know, using data on coupons to calculate ASP, because again, coupons are really a price discrimination approach and I think hurts the program, and I think hurts society, and we ought to do that. And I'm also particularly interested in various reference pricing approaches that we might be able to come up with.

DR. CROSSON: Thank you, Paul. Brian.

DR. DeBUSK: First of all, thank you for a really good chapter and I'm glad to see us jump into the middle of drugs.

Jay, I agree with your assessment that it is a buffet. I like that term and I was going to stick with your analogy here. You know, if you talk about the particularly attractive items on the buffet are things

we've identified before -- the DVP, for example, binding arbitration, so the baseball-style arbitration, and the restructuring of the reinsurance component of Part D. But now I'm going to take your buffet one step further, which is I think before any of these measures will be effective we need to go revisit the rebate trap, because my argument was that the rebate trap is the salmonella in the whole buffet. And here's the issue.

DR. CROSSON: I think I see where this is all going to go.

DR. DeBUSK: Well, there is an absolute necessity for fees, discounts, and rebates. I mean, you guys probably understand it as well or better than I do. There is a place. You have to have that vehicle. But not all fees, discounts, and rebates are created the same. Some are used for legitimate purposes and some are used in very predatory and punitive ways.

And, for example, if I'm buying -- I'll just get specific -- if I'm buying $10 million of something and someone comes to me and says, "Hey, you're a great customer. I want you to have a 25 percent rebate," well, I may buy $9 million next year, I may buy $11 million the

next year, but I know I'm getting a proportional 25 percent rebate on those purchase. That's very different than a rebate -- when I'm buying $10 million of something and someone says the moment you shift one dollar away from that $10 million purchase I'm taking $2.5 million away from you.

These disproportional rebates, these punitive rebates are fundamentally different than legitimate fees, discounts, and rebates that are proportional to the value and volume of products sold. And I don't think it's our place to go in and say, "Let's ban all these punitive rebates." But they certainly shouldn't enjoy safe harbor protection either. Right now all of these predatory tactics enjoy safe harbor protection under the fees, discounts, and rebates rule, and I do think it would be within our purview to dig into the rebate, revisit the rebate trap again, and try to identify these disproportionate rebates, and try to put together good policy on how to address them.

DR. CROSSON: Thank you. Further comments? Amy.

DR. BRICKER: So there's so much here, and I think it does warrant a lot of time for the Commission to spend to really attempt to get this right. It's really

easy to grab one thread and pull it, but, of course, this is very complicated.

I mentioned yesterday that I thought we'd seen some success in Part D from a total spend -- the numbers are still big and I'm not willing to debate whether or not the number is a good number -- but we did see trend flatten, year over year, '16 to '17. So in total spend, that's a good sign. It's not escalating. But I do think that it warrants us revisiting who is the winner and who is the loser in the way that it's designed today -- whether or not we've got the right incentives in place for plan sponsors, whether or not we have the right protections in place for beneficiaries.

In particular, you highlight around specialty drugs. Absolutely in favor of us ensuring that the beneficiary has a maximum out-of-pocket. That is, you know, in line with a commercial market -- nothing more than $100, nothing more than -- you guys pick the numbers, but something that would, you know, send a signal to plan sponsors that we can't shift those high-cost benefits to the beneficiaries.

I thought maybe I could just tick through some of

the things that you highlighted and just provide a reaction. I'm interested in us exploring reference pricing. It feels a little complicated but that's not a reason not to do it. So I'm interested in that. I'm not a fan of broader use of arbitration. For me, if we want to give the tools to the Part D plan sponsors, or incent Part B to actually be managed in a way similar to Part D, allow those plan sponsors to exclude products, allow plan sponsors to have leverage in a way that would essentially -- you wouldn't need arbitration if you could actually exclude products at launch. If you could demonstrate increasing leverage over a manufacturer, you don't need a binding arbitration. And furthermore, you're just essentially -- and as I spoke about it when we went through it last year or two years ago -- you're essentially negotiating as a single entity. I don't know any other way to see it. You're essentially negotiating, Medicare is negotiating for drug benefit, or drug pricing, essentially. So not a fan of that.

Otherwise, we talked a little bit about coupons, and I think, picking up on what Paul mentioned, it has led to increased pricing over time, and I appreciate the

estimate on the ASP but what if those coupon dollars would also be required to show up as rebate in Part D? There you would see a tremendous impact in overall cost. So manufacturers could be required to report their coupon dollars in the commercial market, and since Medicare beneficiaries cannot receive those coupons, by statute, then those dollars could go back to the plan sponsor, could go back to the government as the payer. So one approach for us to potentially consider.

Particular with LIS, because they don't have a disincentive to use certain brand products because of the way that the copay is structured, so again, just thinking about the consequences of coupons and the overall impact, not just it's to the, of course, Medicare benefit but what also is happening in the commercial space I think might be worth considering.

I'm a big fan of outcomes-based pricing, if we can crack that nut. Historically, what's been the issue is an anti-kickback, so if the drug becomes free then have you crossed a line? And that's been my experience that manufacturers fear that they don't want to enter into those agreements because if they have to fully refund the product

then do they have a best price issue or are they in violation of anti-kickbacks?

So things, I think, that we have to address if we're going to recommend, and also I'm a fan of indication-based pricing, because, and an example of that, I would like the group to think about is cancer products, where a drug has been approved for a certain cancer, it works really well, we see that in evidence, it commands a high price. Off-label an oncologist could use it for another type of cancer. It doesn't work as well. Same price. So manufacturers certainly, and today in the commercial world, come to the table with I'll give you a different level of pricing depending on the indication it's used.

With Kathy not in support of direct negotiation by Medicare, and in favor of exclusive specialty pharmacy networks, think about it this way. There isn't a specialty pharmacy today where you walk up and you get the specialty drug at the counter. All specialty pharmacies, be it, you know, an independent or a very large pharmacy, those products are delivered at your doorstep or at the physician's office. So this isn't about reducing access. It's about where is the best price, where can you get the

best price, and where can you get the best care?

So those two things, again, support of us exploring that and moving certain drugs from B to D, again, in support of. I would like to understand more about the manufacturer rebates for wasted drugs.

All in all, I think what we've said is we can't continue to just nibble at the edges of this problem that's continuing to, you know, the volume is continuing to increase. I think you have a group of folks here that want to take on the issues in a large way, and it's complicated but that shouldn't be the reason that we don't take it on. And to spend the time to get folks, you know, educated on what will work, what won't work, and the unintended consequences of some of these actions, I think, is really important.

So thank you and I appreciate all of the hard work on this.

DR. CROSSON: Thank you, Amy. Jonathan.

DR. JAFFERY: Yeah, thank you. This is a great array of topics.

I want to echo what Jay had said about not forgetting Part A and thinking about actually not only the

impact on prices and costs for hospitals but thinking about is there some beneficiary impact here. I'm thinking about actually some of the things we've seen in the generic world, which also is maybe not something that is deep in the list of ideas yet, but there are a couple of egregious examples of pricing increases in that space. But we're starting to see some evidence of impact on beneficiaries. There was a study out of the Cleveland Clinic recently that looked at decreased utilization of nitroprusside, a drug that launched in clinical use in 1928, so before any of us here were born, and it rose over the course of a couple of years. The average price rose from $27 to almost $900. And now they're starting to see a decreased utilization of a drug that has had a lot of clinical experience. So that's one thing.

In terms of some of the other specifics, I will just mention a few. I'm also really interested in understanding more about reference pricing and the various methods of being able to do that. I'm curious as to what you would think about the impact on beneficiaries for excluding new products at lunch, especially if there's not a lot of other alternatives, and certainly regardless of

what we think that's going to be something that comes up from advocacy groups and industry a lot.

And then the last thing I'll mention is on outcome-based pricing. I guess I'm concerned that that may not get to the issue, one big issue that's top-of-mind for a lot of folks, which is just how expensive things are at launch anyway. So, again, I want to understand more about the mechanics of that. But now that we're seeing these therapies that come out at half a million dollars or three-quarters of a million dollars, if the manufacturers are in a situation where they're being offered, or offering, or are forced to offer that outcome-based approach, is that going to -- what's the behavior there? Does that embolden them to have prices that are going to be higher or just come out with more of these really super high-priced drugs at launch?

So just a couple of thoughts. Thanks.

DR. CROSSON: Sue.

MS. THOMPSON: First of all, Amy, I want to agree with the comment you made about educating us. I mean, this is a system that is complex by design and intention, it seems, and the more we understand it, the better job we can

do. So I just want to underscore that comment.

And the second comment I want to underscore before I labor on in commentary is the call out that Jay did in his opening on round Part A and the impact this has on Part A. On a newsfeed that came across this week or last week, I read that hospitals are now stating they're reducing labor, they're reducing nursing staff in order to account for the increase in drug costs to hospitals. So after -- I can't help but connect many of our chapters, and after yesterday and the long deliberation around our update to hospitals recognizing negative -- 11 percent negative margins for hospitals in terms of Medicare margin, I mean, these all connect. And I think it's important as Commissioners for us to recognize that.

But in terms of the context for this chapter, in addition to the complexity and all the technical details that go into the formulas for pricing, we talk about the effect to the beneficiary, and we reference out-of-pocket spending, quite important. But there's a broader impact to the beneficiary in the context of health care, and it has to do with an assumption that drugs are good. And drugs do a lot of good, but not all drugs are doing good things for

our beneficiaries. And there's a broader impact to this system that I think just in terms of the context and the urgency that this group of Commissioners feels around this issue, it's important as we articulate our recommendations that it's in a broad context of there's harm created to our beneficiaries by the fact that we're not managing the profiles of our beneficiaries. And we see patients coming into our system, whether it's through the emergency department after a fall or primary care clinics that are overwhelmed and don't have time to reconcile the drug lists, of patients that are on six, seven, eight, up to twenty different prescriptions. And there's a consequence to the system for this happening, and this is all one of the unintended consequences of this assumption that drugs are good and that a pill will fix things. And I just think it's important for us to recognize there are costs well beyond those that you have identified in this chapter that go to the emergency department costs, the patient has an inpatient stay, they end up going to skilled, and then all the impact to the system and Medicare in that context. And I think that's just important for us to pull these pieces together and understand and tell our story and create that

urgency.

So just again, in terms of the context to the discussion, there's a broader cost going on here to our beneficiaries.

In terms of the recommendations, I am intrigued with better understanding what's this coupon business about and how does that weave together and what are the themes. And, likewise, I'm interested more about the Medicaid rebates and how that might have application in Medicare.

Thank you.

DR. CROSSON: Bruce.

MR. PYENSON: I want to second Brian's E. coli reference -- sorry, it was Salmonella, on the importance of the rebate trap that I don't think any of this -- any of the other suggestions will work if that's not addressed.

But I'd like to set a goal of prices deflating as a measure of success. Session after session, we're looking at increasing prices on the various chapters that we review, and in my mind, all of those represent failures for our ultimate goal of the stability of the Medicare system. A place to start is pharmaceuticals because they are commodities that are manufactured. And manufactured goods

follow Moore's law or more or less that over time -- and we've all witnessed this in our lives -- commodities become less expensive, they get produced more efficiently, and perhaps more profitably. So that should be our expectation. I believe we should start with pharmaceuticals, and if we don't get there, we haven't done our job.

One particular area that I think deserves focus is the failure in the United States of biosimilars. Biosimilars have failed here. In a number of countries, biosimilars are aggressively promoted by the national systems and are in very wide use, and various obstacles that we see in the U.S. have been resolved. Issues that are not supported by science are repeatedly brought up in the U.S., and there's a whole series -- you know, the patent estate has become a patent thicket, and a series of things that are outside our scope, but there's certainly issues inside our realm that deal with the pricing and the failure of biosimilars in Part D that we can address.

In particular, the failure of biosimilars in the U.S. I think is going to destroy the potential of personalized medicine because if we can't get efficient

production of biologic drugs on a mass scale and get that through the system and into use, we'll never be able to do that on an affordable basis for personalized medicine. So this I think is really critical for future health care and hope for solutions.

Finally, I really do like Kathy's concept of carrot and stick. I think one of the real carrots that the Medicare program has is its data. Actually, I'm not sure if that's a carrot or a stick, but the ability of using Medicare data, even claims data, as real-world data with its vast scale and longitudinal capabilities could be put to use to figure out what works and what doesn't work and really indicate why. So I think that's potentially of great value, and I suspect that innovators and manufacturers would have a keen interest in using -- in having access to that information.

DR. CROSSON: Jon.

DR. PERLIN: Let me thank the Commission for really exceptionally thoughtful work on obviously a critically important area.

I sit here thinking about the fact that our discussion is frame within this is Part D, this is Part B.

You alluded to Part A. And it makes me think of two things.

First, how might we think of this more holistically, even though we have a buffet, it's still the same meal? And, second, how would this be handled in other settings? How would this be handled in the commercial environment?

So just a couple thoughts that may offer some opportunity in terms of unification and opportunity. When we talk about the coverage with evidence determination and comparative effectiveness, really we're talking about the relative utility of certain products relative to each other. And, you know, that leads to an implication that some are, in fact, better. And the whole premise of evidence-based medicine is that at any given moment there is knowledge that suggests for a set of circumstances some agent is better.

And I think that we're going to have to think about -- and I liked Kathy's way of framing this -- how we have incentives to offer beneficiaries best at any given moment as opposed to, you know, the sort of traditional, you know, wide open platter where, in fact, we know that

there are costs -- and I think we should quantify this -- of complications of inappropriate therapy. Goodness, we talked at length about one category of that yesterday in the area of opioids.

So I think we have found an obligation to think about not only the coordination among programs in terms of acquisition and supply of medications, but in terms of the coordination between the different Medicare program elements for the beneficiary herself.

I think this notion of data is undertapped. You know, as someone who had the experience of caring predominantly for older individuals in my clinical past, I was always impressed with the number of obsolete prescriptions that were still prescribed and the number of times that those led to drug-drug interactions. One of the costs that, you know, may offer some opportunity is the cost of drug-drug interactions.

The medication reconciliation, while onerous at one degree, is obligatory and, you know, has been promulgated through the electronic health record, earlier the meaningful use, and now performance improvement program as well.

I would suspect, if we look systematically, that we would find that there are medications that beneficiaries are prescribed solely to treat the complications of other medications, and that is a cost. And Dana mentioned an incredibly important topic, which is the cost of non-adherence. We know from our own internal work that when heart failure patients return for readmission, oftentimes it was lack of access to medications as an example. That's why we're taking approaches to mitigate that. But, you know, writ larger, when beneficiaries don't have a Part D record in some window after, you know, certain categories of hospitalization, I would argue that is a telltale data trail of the cost of non-adherence leading to readmission or potentially worse, and I hope we would actually look into, you know, the relative rates of Part D encounters following obviously admissions and their association with readmission, if that health service research hasn't already been done.

Then, finally, on this theme of using the data to drive more ideal prescribing for efficiency and best outcomes for beneficiaries, it's kind of interesting that if any of us have an allergy to a medication, that is

recorded. But if something didn't work, it gets stopped, and something else is tried, only to repeat the cycle again. And while we know intellectually that at a genomic level there's probably some molecular basis for that, the problem is that that's not systematically recorded, and one of the areas that would contribute tremendously to understanding particularly in terms of tapping into personalized medicine in the future is some systematic recording of why a medication is stopped, short of an allergy, and that would help to drive, you know, better utilization as well as ultimately an understanding of the genomics of pharmacotherapy.

So I appreciate those ideas. The short message is that there are a number of utilization parameters that I think we can follow that actually would allow progress even as the table is set now. Second, the coordination amongst programs would have a rationale not only in terms of program management but in terms of the care and best care of the individual beneficiary. And, third, in an election world with the availability of data, there are data elements that can help us drive this forward. And, fourth, that the aggregate of those data drive us toward more

thoughtful prescribing practices that, as Kathy framed, could be incentivized positively or other less desirable prescribing practices discouraged.

And just a sort of asterisk on that, having had the privilege of leading the VA system, it was the two-fold -- it was not only the ability to structure the acquisition of the medication, but also to couple that with work flow that drove toward most optimal prescribing.

Thanks.

DR. CROSSON: Thank you Jon. Marge.

MS. MARJORIE GINSBURG: I just wanted to put out a greater exploration in the whole area of cost-effectiveness research. In part, I'd begin sort of thinking about what are the primary principles that are most important to us in trying to achieve lower prices. And to me, the principle that stands out most of all is the whole concept of clinical effectiveness and relative clinical effectiveness.

I was a panel member for ICER for seven or eight years, and even before it was ICER, when it was part of the Blue Shield Foundation program. So I sort of grew up with the program and, of course, anybody who is familiar with

it, you know, really came to respect it and enjoy it and appreciate the incredible amount of work that goes into being fair in determining what cost-effectiveness looks like in terms of pricing of drugs.

So I hope we can give this its due. It's very labor-intensive, and many people argue that we shouldn't be using qualities as a measurement in any fashion. But I just thought I wanted to speak from personal experience of having been a panel member on ICER, that I really became a true believer.

Thank you.

DR. CROSSON: Dana and then Warner.

DR. SAFRAN: This has been a great discussion. Just one thing to add to it, which kind of picks up on cost-effectiveness. I think I've mentioned this here before, and so I don't know whether we've explored it, but if we haven't, I think it would be good to.

Many other countries have a formal way that they require when a new drug is coming to market that there be cost-effectiveness data presented to them and that it be used in determining coverage and price. And so I've wondered, since we don't have an analogous mechanism to

something like NICE in the U.K., would it be possible to require that all data and reports that had to be submitted for approval of a therapy in other countries be reported in the U.S., too? They don't have to do additional new, different reporting, but at least to have that information on hand as drugs are being looked at has always struck me as information that could be helpful. So just an idea about exploring that if we haven't already.

DR. CROSSON: On that point?

DR. PAUL GINSBURG: I just want to mention I'm surprised that I have not heard yet in our discussion of effectiveness the fact that we have legislation that established an effectiveness agency. It's called PCORI. Many people are -- from the beginning, it was prohibited to looking at costs. I think many people have been disappointed in what it's achieved, just looking at effectiveness, and -- but in a sense -- so this is something, revisiting a major policy that has been either launched, or perhaps not launched because of the restrictions on costs. And I'm not optimistic that we could have a big impact in this area compared to some of the other areas we've talked about.

DR. CROSSON: I lost track now. Warner.

MR. THOMAS: So I think all the comments have been great. I think going back to Kathy's opening comments, I do think -- and Karen's questions earlier, I do think it would be helpful to -- whatever laundry list you come up with, or the buffet as it has been referenced, think about putting this on a 2x2 grid of, you know, from a low to high positive impact to beneficiary from a cost perspective, impact to the program, so we could understand that we are -- you know, what we're targeting and making sure that we're going down the road where at least from your perspective we feel like we could have the most impact. I think it would be helpful.

And I also like Jay's comment about what's feasible. So let's look at the cost-effectiveness or the cost impact and then the feasibility of actually what can be, you know, put into place. I know all of those are subjective, but at least we'd have a way to look at that.

You know, I think MedPAC has put a lot of ideas out there and I think tried to be very creative about how it approaches this situation. There hasn't been a lot of uptake on many of those. There's been some but not a lot.

And I think we know that there's this pressure that we see increasing drug prices and we hear the anecdotes in the news, and, you know, there's an article in the Wall Street Journal today about drug shortages, but also the fact that we see costs increasing several hundred percent.

If we're sitting here talking about a several hundred percent increase in home health pricing or hospital pricing or any of the things we talked about yesterday, we'd be like, "Are you kidding me?" I mean, how can this be? But yet we've come to almost think that this is okay or acceptable.

So I would really encourage us to be methodical and thoughtful, but also take a hard line on this. And although I don't think -- I hear the comments about direct negotiation from a government perspective to the manufacturers may not be the right way. I do think this idea of taking the suggestion that was in Part B and maybe extrapolating across all the programs, A, B, and D, of an inflationary cap would at least put some downward pressure on pricing and I think encourage manufacturers to get more creative.

I think going to Bruce's comments around Moore's

law, I mean, many of these drugs that are so old, we should see the pricing going down not up several hundred percent. And, also, maybe we should talk about or there should be some research done about how do we make it easier to get into the world of manufacturing or are there other opportunities there, because, you know, it's just not sustainable, kind of what we're talking about.

So I would encourage us to look at the idea of a cap across all the programs. I would also encourage us to think about a cap around launch price. Now, you could have a -- you could go to maybe binding arbitration if someone wanted to go over that cap. But I think this idea -- I mean, we started to hear this the other -- a couple meetings ago about million-dollar drugs, you know, for a dose, and it's just like obviously for that patient it's extremely important, but is that really feasible to the cost of health care and to our society to have million-dollar drugs going forward or drugs that are several hundred thousands dollars for treatments or for doses?

So I think we've got to start to put a cap on these things and take a harder line. We can always have an arbiter. It could be a binding arbitration, or you can

have an appeals process. But I would really encourage us to take that as a hard line.

I also think it would be interesting to understand -- we have somebody here who has a lot of experience, Jonathan, in the VA. How has the VA done on pricing? And how does that compare to what we're seeing in our own government programs, which are actually larger, you know, from a purchasing perspective? And just what are those differentials?

I've got to be honest, I don't totally understand the rebate area, and I think having more transparency around that, it seems like it does create escalation in pricing, and that there probably out to be some modification of that program to create, number one, more transparency, and for it not to be able to be used as a way to drive pricing up. If it's a way to essentially rebate so people get better deals or that beneficiaries have lower out-of-pocket costs, great. But if it's, you know, just used so we can drive the pricing up and kind of push it back in a different fashion, I don't think that that makes a lot of sense.

So I would just encourage us to take a much

harder line -- we can always back off from it, but I would encourage us to take a much harder line around this idea of escalation caps. We do this in all the other areas of the program. Maybe in Part A we ought to -- and I actually mentioned this to Jay before. Maybe we should index it to whatever increase we put in for the inpatient increase for hospitals. Maybe the drug escalation or price cap ought to be whatever the inpatient rate increase is. That would be a way to index it so that it's maybe more fair as far as how we think about purchasing in the Part A program.

So those are some ideas that I'd like to see us explore, and to not be scared by, you know, lack of R&D or shortages -- because we have shortages today, and there's virtually no control in pricing. So I think we've got to do a better job putting some caps on this and forcing this part of the industry to be a lot more creative in how they look at costs and a lot more creative in how they come to the table to be part of the solution.

DR. CROSSON: Karen, did you want to comment on that?

DR. DeSALVO: [Speaking off microphone.]

DR. CROSSON: Okay. Jaewon first, then Karen and

Amy.

DR. RYU: I was just going to comment that it seems like this topic, more than any other that we've encountered, obviously very complex, but I'm noticing that there are a lot of recommendations that we have previously made that didn't gain traction. There are three whole slides dedicated to it.

I wonder if it's got something to do with this notion of it's a buffet. There's just too much, and you don't even know where to start. So it's not even you're overeating. You're not eating at all. You're just confused and starving.

[Laughter.]

DR. RYU: So it would be helpful, at least to me, when we revisit this in March, some notion of how do you prioritize and where do we think is -- it's that notion of feasibility, but it's what can be done quickly to just take one step. If you extend the buffet, it's salad, start here. Something like that would be good.

The ones I kind of gravitate towards, the structural elements around the program and reinsurance and catastrophic versus the capitated component, kind of what

we talked about yesterday, do those seem or feel at least to have a little more immediacy to what can be done? But I'm not sure about that.

If there's some way to say instead of this, let's shrink the world and really look at this, I think that might help to get traction. It seems like we've recommended all the right things, and we could keep fine-tuning, but where do we start?

DR. CROSSON: Karen.

DR. DeSALVO: First, just to underscore the opportunity for us to do more education, I think that MedPAC is uniquely situated to have a very evidence-based frame and peel back the onion of the complexity in areas like rebate and otherwise.

I want to offer three 3's as parameters for how we can begin to determine which of the food has salmonella and which doesn't. So the first of the three 3's would be financial. The second would be impact on beneficiaries, and the third would be execution.

The first, in financial, to look at overall impact on cost, I'm thinking about Part A on price and on spend, which I believe would be different kinds of notions.

The second area, impact on beneficiaries, we've mentioned out-of-pocket, overall access, and then equity in access.

Then the third, in execution and feasibility, time to market, time to change.

I would just ask also about what's statutorily allowable right now versus what would require congressional action that will impact time and feasibility, but let us know what's the near term. That's a suggestion for some parameters that we might use to help sort and sift.

Thank you.

DR. CROSSON: Thank you, Karen.

I had Amy. Then I saw Marge and Kathy.

MS. BRICKER: Yeah. Just back on -- a couple of Commissioners have mentioned the VA. It's just worth noting that the VA is buying drug for each VA facility, and the veterans have to use the VA to get access to those drugs at those prices. So to suggest that we would use a similar model would either mean that we're going to buy drugs for every pharmacy in America and every hospital in America or that we're going to suggest that Medicare is going to have some sort of closed system, select

pharmacies, select hospitals, what have you.

Again, it sounds interesting, like why can't we just do that. We just have to understand the model that exists for deployment of those discounts, similar to a Kaiser or something else.

A point to make again, I've heard the international pricing and why has there been success in other countries relative to this. This isn't because manufacturers like those countries better. It's because, again -- if you asked the question before -- it does depend on the country, but for the majority, they just won't cover the drug. The drug just is not available. So manufacturers are forced to bring the price down to something that -- they're forced to bring down the price, period. We saw this in hep C, and they launched at a price that was three times that in developing countries here in the U.S. And it wasn't until competition that that price actually now is less than in those other countries.

We simply have to allow the market, the free market here in the U.S. If we're not going to go to a socialized system, we have to allow the free market to operate, and we get caught between fear that, oh, if we do

that, the manufacturers just will stop inventing drugs. We've not seen that. That's what folks want us to believe will be an outcome, but we have not seen that.

So, again, I'd just encourage us to think about the handcuffs that are on this system today, as we've designed it today, and take those off.

DR. CROSSON: Marge.

MS. MARJORIE GINSBURG: I personally wouldn't mind a few limits on our free market system, myself, but that's a different thing.

But as long as we're putting everything on the table, it occurred to me -- and I'm a patient advocate -- that one possible way to bring down the use of more expensive, less effective drugs is to charge patients higher co-pays.

I don't know. Perhaps others have even considered that in some fashion before, and I can't even believe I'm actually saying it. But it's one of the few things that is within our control. We talk about what's feasible, and if we can't get the drug companies to lower their prices, then we discourage take-up by telling patients they have to pay more for a drug when it doesn't

work as well.

Downside to that is that people tend to equate higher co-pays with higher quality. So we have that little problem to deal with, but I just wanted to throw this out, just to get it on the plate. Thank you. On the buffet table.

DR. CROSSON: And just to note, Marge, that is a mechanism in the commercial marketplace.

MS. MARJORIE GINSBURG: It is?

DR. CROSSON: Commercial drug coverage, yeah.

MS. MARJORIE GINSBURG: [Speaking off microphone.]

DR. CROSSON: Me too.

Kathy.

MS. BUTO: And also, Marge, higher-cost drugs do result in a higher co-insurance for beneficiaries. So I think they are feeling that, unless they've got Medigap.

MS. MARJORIE GINSBURG: [Speaking off microphone.]

MS. BUTO: Yeah. With more differential co-pays.

So I just wanted to add to Karen's three by three or whatever it was by saying I think we need to have

something on unintended consequences, and one of the ones I mentioned earlier was the potential to increase launch prices. So if a policy is going to actually cause some escalation in pricing, I think we want to be aware of that. We might think it's worth pursuing anyway, but that's something that we ought to consider.

Then I really hope that in the -- and this is going to be hard because I think we're going to be sorting through and identifying and prioritizing, but I think some granularity around feasibility is going to be important because there are these issues that I think Amy mentioned of what if you allowed Part D plans to exclude drugs, or if you want government at the federal level to do something, how feasible is that? What process would they have to follow? I think it's important for us to understand because it affects timing, and it actually affects the ability to turn around and make a revision, which I'm always concerned about.

You can maybe do the first step, but then when prices maybe go in a different direction or you want to incorporate new competitors, how do you turn around and do it again in a timely way?

So I think the feasibility is really important to make these policies work.

DR. CROSSON: Okay. Thank you, Kathy.

And I think we're going to have to wrap up.

I want to make a couple concluding remarks, basically building off of what Warner had to say a few minutes ago.

Not to oversimplify -- or actually to oversimplify, to paraphrase a former President, it's about the price. That's really what we're dealing with, and I think as we think our way through this -- and thank you again to the staff for setting this up for us -- we're going to have to think about, in addition to the parameters that have been discussed, mechanisms to directly affect the price, and then many of the other suggestions we have, do that indirectly by changing the nature of the marketplace or by various comparative effectiveness or comparative pricing schemes and the like.

A lot of the public discussion right now is about directly affecting the price through having Medicare negotiate prices. I think we understand the reason behind that. We also recognize the complexity that that would

require because it would fundamentally, in many ways, change the relationship between hospitals and drug manufacturers, change the structure of Part D.

We have recommended changing the structure of Part B, by the way.

In thinking about directly intervening on price, I would like to say that the option that we chose in Part B, which is to recommend in certain circumstances, binding arbitration, particularly winner-take-all or baseball arbitration, is one way to enforce the notion that Warner brought up, which is to intervene in extreme circumstances, either around launch prices or around inordinate escalation of price over time, caps, enforcing caps in that way.

The notion of introducing arbitration is, I think in the mind of man, a radical idea, and in the mind of others, difficult to contemplate. But from my own perspective, it's a little easier to understand how that could be inserted into the existing programs that we have and would fall well short of Medicare intervening and directly negotiating prices.

As we go through this, among the other things that we're going to discuss over the next year or so, I

think we are going to elaborate beyond our suggestion, which by the way was introduced about 10 years ago by a former Commissioner, Joe Newhouse from Harvard, of expanding the idea of binding arbitration beyond our recommendation in Part B to potentially include Part D and also Part A.

How that would work is to be determined, but I have some belief that in the end, that may turn out to be more feasible in this country than the idea of excluding new drugs from Medicare beneficiaries.

I mean, if we look at the experience over the last years with coverage with evidence determination, which is a much milder approach to exclusion, if you want to call it that, that has just simply not been able to work because, as has been mentioned, the pressure that's brought by -- in some cases, legitimate pressure that's been brought by interest groups for patients, for example.

So I do think we need to keep our eye on the ball and make sure that in our prioritization process, we are hitting at the core issue, which is price, both launch prices and inappropriate escalation of price over time.

So, with that, thank you very much, and we'll

move on to the next presentation.

[Pause.]

DR. CROSSON: Okay. Let's move on to the final presentation for the January meeting, and that's going to be part of our continuing work on accountable care organizations.

Today we're going to look at a set of analyses with respect to the performance of the MSSP ACO program.

David, it looks like you're ready to go?

MR. GLASS: Yep. Ready to start.

So good morning. In this session, we'll be discussing performance of the Medicare Shared Savings Program, or MSSP, which is the largest Medicare accountable care organization program in Medicare, and we're going to look at it from several perspectives.

I would like to thank Emma Achola for her help with this project and welcome Luis Serna. He's going to answer all of your difficult questions.

[Laughter.]

MR. GLASS: I'll begin today by giving some brief background on Medicare's ACOs and the MSSP. I'll then discuss differing estimates of MSSP performance on cost.

And we're just talking MSSP, and we're not doing quality this time, just costs.

We will look at performance from three perspectives. First, relative to the cost targets or benchmarks CMS sets for the program; then estimates from the research literature on savings relative to counterfactuals, that is, what spending would have been in the absence of MSSP ACOs. And, finally, Jeff will present the results of our new analysis of the relationship between changes in spending and assignment to ACOs. He will then present some implications and turn it over to you for discussion.

As you know, ACOs are groups of health care providers who have agreed to be held accountable for the cost and quality of care for a group of beneficiaries.

The goals of Medicare's ACO programs are to increase quality of care and patient experience, lower the growth in health care costs, and achieve care coordination at a lower administrative cost than MA plans. And ACOs that are successful are rewarded with shared savings.

There are three key concepts for ACOs that will come up throughout our discussion today. The first is

assignment. Beneficiaries have to be eligible, which means they must be in fee-for-service, not MA, and have at least one visit with an ACO physician.

The basis for assignment is the plurality of primary care services, although some of those services could be provided by specialists.

Timing can differ. Assignment can be prospective; that is, beneficiaries are assigned on claims from the prior year, thus the ACO knows which beneficiaries are assigned at the start of the year. Or assignment can be retrospective, and the ACO does not know final assignment until the end of the year, because assignment is based on claims in the current year. This distinction between prospective and retrospective assignment will be important in our discussions of findings from our analyses and their implications.

ACO models at one-sided risk have shared savings but no shared losses, and two-sided risk models have shared savings and losses.

So to create incentives for ACOs to control cost, CMS creates benchmarks. The benchmark is a function of historical and regional spending, although for the period

of analysis in this briefing, primarily historical spending.

MSSP has three tracks that differ on several parameters. The important thing to note is that Track 1 is a one-sided risk model with retrospective attribution. By the way, these tracks will all change mid 2019 according to the recent final rule, so don't get too attached to them.

First, the number of MSSP ACOs has steadily increased over the years and in 2018 reached over 500 ACOs, with over 10 million assigned beneficiaries. As I said, please note that the vast majority of ACOs are in Track 1, the green bar.

Remember, Track 1 is a one-sided risk model, with no shared losses, only shared savings.

Track 2 and track 3 ACOs are two-sided risk models, the blue and yellow bars. The first Track 2 ACOs began in 2013, and Track 3 began in 2016.

We are going to be discussing MSSP as a whole in this briefing, and for the period of our analysis, almost all the ACOs were in Track 1, with one-sided risk and retrospective assignment.

There are two basic methods to estimate MSSP

performance. The first is performance relative to benchmarks. The benchmarks or spending targets are set in advance by CMS and are designed to approximate expected spending on the beneficiaries assigned to the ACO while creating incentives for the ACOs and to further policy objectives.

For example, they might be designed to encourage ACOs to participate or further equity within or across markets. They are forward-looking, based on past experience and set in advance. Benchmarks are the pertinent estimate from the ACO's perspective because it determines if they are eligible for shared savings.

The second method is performance relative to a counterfactual. These estimates are determined after the fact. They compare the spending of the ACO beneficiaries to the actual spending for a comparison group. The intent is to determine what spending on the ACO beneficiaries would have been if the ACO program had not existed, hence the term "counterfactual."

Figuring out who is in the ACO group and who is in the comparison group is clearly important.

This approach is used in the research literature

to assess performance of the program as a whole rather than to determine which ACOs won or lost.

So we will first look at performance relative to benchmarks and then at two examples of estimates relative to counterfactuals.

Let us start by looking at CMS estimate of savings relative to the CMS-computed benchmarks. As I mentioned, this is the most pertinent estimate from the ACO's perspective because it determines if they are eligible for shared savings.

Actual spending on ACO beneficiaries was about 1.2 percent below their ACOs' benchmarks in 2017.

Shared savings payments, that is, what CMS paid ACOs over and above claims, were about 0.8 percent of benchmarks. Thus, net savings in 2017, after accounting for shared savings payments and doing some rounding, was about 0.3 percent of benchmarks.

2017 was the first year with net savings for the MSSP. There were no net savings found in earlier years; that is, aggregate shared savings payments exceeded relative savings in those years.

Dobson DeVanzo and Associates did a study for

NAACOS, which is the National Association of ACOs, on savings in the MSSP. Their analysis compared the growth in spending on beneficiaries assigned to ACOs to growth in spending for other beneficiaries in the market using an as-treated difference-in-difference study design. It adjusted spending for changes in risk scores and found gross savings of 1.1 to 1.2 percent of Medicare spending from 2013 to 2015. That is equivalent to net savings of 0.3 percent after taking into account shared savings payments through 2015.

Michael McWilliams and colleagues have been estimating MSSP performance for a number of years. In 2018, they published their findings of MSSP performance after three years. They used an intent-to-treat difference-in-difference study design. It aligns tax IDs with an ACO, and even if that ACO drops out of the program, it continues to consider that tax ID's patients as ACO patients.

In addition, they assigned beneficiaries to ACOs on a plurality of primary care office visits with a primary care physician, and that differs from CMS in that it excludes specialty visits and visits in SNFs.

The analysis found savings relative to the counterfactual. It found higher savings for physician-only ACOs than hospital ACOs; that is, ACOs with hospitals as participants. It found higher savings for older ACOs than newer ACOs and net savings in 2015 relative to the counterfactual for physician ACOs and no net savings for hospital ACOs.

However, they suggest additional savings may come from spillover; that is, savings from treating patients in Medicare fee-for-service who are not assigned to ACOs, the same way as those who are assigned to the ACO.

In sum, from each of the perspectives I have discussed, MSSP ACOs seem to be saving a few percent at best of their benchmark or expected spending, with net savings below 1 percent overall.

I have just discussed three estimates of MSSP performance, one relative to benchmarks and two relative to counterfactuals. We were interested in constructing our own counterfactual, which would be less dependent on risk adjustment, because we were concerned about the effect of coding.

So Jeff will now explain what we have found along

the way to doing that.

DR. STENSLAND: All right. So the studies David just talked about, the researchers compared spending for a cohort of beneficiaries in years prior to the ACOs forming to spending for a different cohort of beneficiaries in years after the ACOs were formed. And to adjust for changes in the makeup of the pre-ACO and post-ACO cohorts of beneficiaries, the studies risk-adjusted spending.

To complement the analysis David just talked about and to reduce the reliance on risk adjustment, we took a different approach. We chose to track a consistent cohort of individuals over time. The goal is to see how changes in spending over time are associated with changes in assignment into or out of an ACO.

We tracked specific patients who were alive from 2012 to 2016 and eligible for ACO assignment in every year. We examined how moving in and moving out of ACOs is associated with changes in spending. We compare spending growth for individuals consistently in ACOs, to those never in ACOs, and to beneficiaries who switched in and out of ACOs.

Next, I will show you some preliminary

descriptive statistics. These are only designed to look at the effect of moving in or out of the ACO. We will come back in April and discuss the implications for overall ACO savings with a propensity-matched system.

The following three tables examine the percentage point change in spending from 2012 to 2016. A negative number will be mean spending that is slower than average in the market, implying savings.

The first row looks at beneficiaries continually assigned to an ACO from 2013 to 2015. On average, those beneficiaries' spending growth was 2.3 percentage points lower than the average in their market.

The second row looks at beneficiaries continually assigned to an physician-only ACO -- the first row was hospitals -- from 2013 through 2015 had spending growth that was 5.6 percent lower than the average in their market. This finding of slower growth for physician-only ACOs relative to hospital-only ACOs is consistent with the work by McWilliams. In your paper, we described how this appears to be partially due to the nature of physician-only ACOs, but also partially due to those physician ACOs tending to form in higher-spending markets, where spending

reductions are easier.

Next, look at the third row. These are beneficiaries who were never in an ACO. We see their spending growth on average was 1.3 percent lower than the average for their market. So, so far, we're in Lake Wobegon where everyone's spending is slower than average. So which beneficiaries are growing faster than average?

Now look at the bottom row. These are beneficiaries that switched in or out of an ACO. They had spending that was 3.1 percentage points above the average in their market, and we call these the "switchers."

Next, we will look at the higher cost for these 2.2 million beneficiaries that switched in or out of and ACO in a little more detail.

So this slide decomposes the last row of the previous slide, the switchers, into three groups, all of which had higher growth than their market average.

The first row is those who switched in or out of an ACO during 2013 to 2015, and they had slightly higher than average spending growth through 2016.

The second row are beneficiaries who were assigned to a new ACO in 2016 after having never been

assigned to an ACO in prior years. They also had slightly higher growth than average.

Let's focus on the third row. These are beneficiaries who did not primarily use an ACO doctor in their market for the prior three years, even though ACOs were operating in their market. Then in 2016, they started to use an ACO doctor. One possibility is that their health status changed, and that triggered a change in doctors. We see a large jump up in their health spending, and the result is spending growth that was 16 percentage points above the average growth from 2012 to 2016.

For these MSSP beneficiaries, assignment is largely retrospective. That means that when a beneficiary switches to an ACO physician in 2016, the ACO is responsible for all of that 2016 spending, even if part of that spending occurred before an ACO doctor ever saw the patient.

Now we can also decompose the rows in the first slide that included beneficiaries assigned to the ACO in 2013, '14, and '15 according to what happened to that beneficiary in 2016.

Those who stayed in the same ACO from 2013 to

2016 had much lower spending growth than their market average, 10 percentage points less on average, 10 percentage points less. These may disproportionately be beneficiaries without a change in health status.

In contrast, the row in yellow shows beneficiaries who lost assignment to an ACO in 2016. These beneficiaries had spending growth that was 13.8 percentage points higher than average in their market. These beneficiaries had the benefit of care coordination the ACO provided during 2013, 2014, and 2015, but something happened in 2016. Most likely, they changed physicians they saw, possibly due to a change in health status.

We see a big jump in spending in 2016, after having slow growth in spending through '12 through '15. This tells us there is an association between changes in assignment and changes in spending; for example, a beneficiary may fall ill and start to use a new set of physicians. The effect of the changes in health status appear to outweigh the benefits of the care coordination provided by ACO physicians in the prior three years.

In summary, two groups of beneficiaries had very high spending growth compared to their market averages,

those who lost assignment to their ACO in 2016 and those who gained assignment to an existing ACO in 2016. Other switchers had higher than average growth as well, but those were smaller differences.

Because the spending growth is so much higher than average for these two groups, it is important whether they are assigned to the ACO when determining their shared savings. Whether they are assigned to the ACO in the switcher year will hinge on whether the ACO has prospective or retrospective assignment. So let's review those two concepts.

To review retrospective and prospective assignment, let's look at a hypothetical example of a Medicare beneficiary who first sees an ACO physician in 2016. In this hypothetical example, the ACO beneficiary has $20,000 of spending in 2016 and $30,000 of spending in 2017.

The ACO provided a plurality of care in 2016, and the beneficiary will be assigned to that ACO. But the question is, Are they assigned to that ACO for 2016 spending or for 2017 spending?

Under retrospective assignment, the patient is

assigned to the ACO in 2016. CMS retrospectively looks back at 2016 claims and then definitively determines the beneficiary should have been assigned to that ACO for 2016. The ACO would then be responsible for $20,000 of 2016 spending. The 2016 spending would be adjusted for the beneficiary's 2016 risk score, which was actually based on diagnosis through 2015. So, under retrospective assignment, the ACO will not know for sure which patient is assigned to it until 2017.

In contrast, under prospective assignment, the patient will see an ACO physician in 2016 and then have that patient assigned to them in 2017. They will be responsible for the $30,000 of spending in 2017, but that spending will be risk adjusted for diagnosis recorded by the ACO physician during the patient's 2016 visits.

A key point is that under prospective assignment, an ACO physician always has seen a patient prior to that ACO being responsible for any of that patient's spending.

So the data has the following implications. The relationship between assignment and changes in spending makes assignment algorithms important. It can result in favorable or unfavorable selection for the ACO.

ACOs may achieve favorable selection if the ACO can retain healthy beneficiaries and shift out those with declining health status.

In contrast, ACOs can face adverse selection if beneficiaries see an ACO clinician for the first time when their health status is declining.

In part, the risk to the CMS stems from allowing retrospective assignment. Under retrospective assignment, the ACO can see a partial-year spending data before deciding whether to take actions to try and retain assignment of a beneficiary.

In contrast, under prospective assignment, ACOs take responsibility for the beneficiary first and then become accountable for spending going forward.

CMS has less risk under prospective assignment, and ACOs have more opportunity to manage care. ACOs may be willing to accept prospective assignment, despite losing some ability to influence who is assigned to them.

The two key benefits of prospective assignment for ACOs are, first, ACO doctors will have seen the beneficiary before the ACO is responsible for the beneficiary's spending; and second, the ACO will know who

they are responsible for at the start of the year.

For example, think about a patient who had significant medical spending in the first half of 2016, then saw an ACO physician in the second half of 2016. Under retrospective assignment, the ACO is responsible for all 2016 spending, even if most of that spending occurred before the patient ever saw an ACO physician.

In contrast, under prospective assignment, the ACO is never responsible for seeing a patient prior to an ACO physician having seen them.

So I want to stress here that all of this data we've talked about is only through 2016, and assignment rules changed, benchmarking rules changed, and provider behavior will have changed since then also, and these regulatory changes we've talked about have implications.

The key changes are as follows. First, CMS is moving toward two-sided risk, and second, CMS is moving toward having 50 percent of the benchmark based on regional spending. This means ACOs that have historically been low spenders in their region will do better and ACOs that have historically been high spending in their region will do worse.

CMS is also allowing up to a 3 percent increase in HCC scores. ACOs we have talked about plan to put more effort into coding, so we expect ACOs to report increased HCC scores that will result in greater payments to the ACOs.

ACOs are also allowed to choose retrospective or prospective alignment, and you change that decision yearly. In our 2018 comment letter, we stated all ACOs should all use prospective attribution.

In 2019, ACOs can encourage specific beneficiaries to come in for wellness visits by paying them a $20 fee to come in for the visit. In 2016, about 18 percent of traditional fee-for-service patients received wellness visits compared to 33 percent of MSSP ACO patients. This difference, we expect it to grow in 2019, as ACOs try to improve their patient selection.

The net result is that the Medicare program's payments to ACOs could be influenced by changes in coding patterns and efforts by ACOs to improve their patient selection, and generating savings for the Medicare program may be more difficult.

Therefore, the current savings we see by looking

at this -- or the past savings we see looking at 2016 data, may not be indicative of what the savings will be like in 2019.

So this brings us to some potential discussion topics. First, you might want to talk about the ramifications of the relationships between assignment changes and changes in health status that we illustrated. You could also discuss issues regarding prospective and retrospective assignment, and you could talk about next steps. We plan to do further analysis after creating a more closely matched comparison group. We will look at wellness visits and the effect on spending, and examine the relationship between major health events and changes in attribution further.

And now we turn it over to Jon to start the discussion.

DR. CHRISTIANSON: [Presiding.] Well, I think all of this has been perfectly clear to all of us, but just in case it hasn't been, we could start with questions of clarification. Dana.

DR. SAFRAN: Thanks. You've done a great job, both in the chapter and in this presentation, in dealing

with a really complex topic, and I'll have some ideas to share in the comment round. But a couple of questions first.

So first question is, did you do any work -- when you looked at those who I'll call switchers, did you do any work to look at whether they were switching within or between markets?

DR. STENSLAND: No. We didn't do that, but we could look at that. They were just switching out of one ACO into another, or in or out of ACOS.

DR. SAFRAN: Yeah.

DR. STENSLAND: So we could look at -- I'm guessing we'll probably end up with more extreme results if we take out those who moved.

DR. SAFRAN: I think it's important, because in work that I led before my tenure at Blue Cross, where we had, among other things, an eight-year longitudinal study of Medicare beneficiaries and we were looking to understand performance differences between Medicare Advantage and fee-for-service Medicare, we had to confront -- and our outcomes were on functional status, not so much on cost. But nonetheless, I think that all the methods that we had

to grapple with are very relevant to what you're dealing with here. And we absolutely saw evidence that when people get sick, especially with something big and important, they often change system, not because they're dissatisfied, not because the, in this case, ACO is failing them, but because the care they need is somewhere else.

That's a different matter from a beneficiary who relocated. And so I think you'd want to tease those things out in what you're doing. So that was my first question.

Do you have evidence, or have you looked at what kind of health events seem to be triggering switching? I saw, both in the presentation and the chapter, this sort of hypothesis that there could be some health events going on here, and, you know, as I'm sharing from my own work in this area, I think you're right. So I'm just trying to understand whether you've explicitly looked to understand how health events seem to be triggering switch or whether it's just a hypothesis that you're putting out there.

MR. GLASS: We haven't looked in detail yet.

DR. SAFRAN: Okay.

MR. GLASS: Are we going to do that?

DR. SAFRAN: Okay.

DR. STENSLAND: We could look at new diagnoses, and certainly we can look at who was admitted and who wasn't admitted --

DR. SAFRAN: Yeah.

DR. STENSLAND: -- you know, that type of thing.

DR. SAFRAN: Yeah. And I think you're going to want to look at, you know, patients who had such a new diagnosis and stayed versus those who had a new diagnosis and switched, to really start to tease apart some of the hypotheses I think you have.

And then just one other question having to do with assignments, because I'll come back to it in the comment round, some of the important distinctions you're making between prospective and retrospective. This is just ignorance on my part with respect to how the program works when it's retrospective. I understand that with retrospective that the settlement on who your population was doesn't happen until the end of the year and claims reveal who that was. Is there any notification along the way, in the programs that use retrospective, which would make it more what I would call concurrent assignment?

MR. GLASS: Yeah. They -- I will try to get this

right. There is a special name for it. It's provisionally prospectively assigned with retrospective --

DR. SAFRAN: Yeah.

MR. GLASS: -- final attribution.

DR. SAFRAN: Yeah. Okay.

MR. GLASS: So, yes.

DR. SAFRAN: So it's not -- you know, because any layperson who think about this for a minute would say, "That's unfair. How can you manage a population if you don't know who you are?" But in retrospective assignment it's not that it's a black box. The participants are getting information along the way, but who, at the end of the day, they're accountable for gets settled up at the very end of the year, with who's still with you.

MR. GLASS: And they're told quarterly, I think, who is on the list.

DR. SAFRAN: Yeah, okay. Thanks for clarifying that.

DR. STENSLAND: They will know the ones who -- especially if they had them last year, they'll be on their prospective list for this year. But they probably won't know they're switchers until a couple of quarters after.

So the people that just started using them.

DR. SAFRAN: Yeah. Thank you.

DR. CHRISTIANSON: Bruce, I saw you --

MR. PYENSON: This is really wonderful work. I want to compliment the team on that. I noticed you excluded people who died during the time, and mortality is maybe 4 percent or something in the Medicare population. I wonder if you could explain what you think that meant or why you did that.

DR. STENSLAND: We did that purely for simplicity. We have another dataset sitting there with all the people who died, and we wanted to separate the people who died from the people who didn't die, and we'll be going through the people who died to see if we see anything different. Preliminary results indicate that the relatives don't seem that much different. Of course, you see a huge growth in spending for the people who died, you know, monthly spending in their last years of life. But in terms of the effective switchers, non-switchers, we haven't seen.

[Pause.]

DR. CROSSON: [Presiding.] Sue.

MS. THOMPSON: Thank you. What do we know about

their savings? Do we know anything about how they achieve savings?

DR. STENSLAND: I think we're going to come back to you in April with that, in a couple of ways. One is we're going to try to have a more closely matched comparison group, and then we'll break down things a little bit more to you in terms of, you know, how much of this is post-acute care, how much of this is acute, and that kind of thing.

MS. THOMPSON: And in our work in ACOs, have we done anything in terms of understanding the investment in infrastructure that's being made by the actual ACO?

MR. GLASS: We did delve into that some years ago, you know, in round numbers and million dollars a year, but, you know, that various, obviously, by ACO. We haven't tried to get into it in real detail.

MS. THOMPSON: Okay.

DR. STENSLAND: We talked in our last ACO chapter, we mentioned a percent, I think, something in the neighborhood of 1 percent, something like this, maybe 1 to 2, depending on what you do. And I think we don't have firm data on this, so what we have is we've gone out and

talked to people. And you guys were on these ACOs. You maybe have better firm data. But when we talked to people we tend to have more confidence in the little, small ACOs, where they have a separate group of people that you manage the ACO and you're in a little box and that's all you do with the ACO.

For some of the big systems we have, they have some people that are doing ACOs sometimes and they're doing other stuff, and it's hard for them sometimes to tease out what's the exact cost of this because they have people doing ACO and non-ACO.

MS. THOMPSON: One more question. In the breakdown of physician ACOs versus hospital-based ACOs, let's call them, do we know, by low, medium, and high use, how that breaks out?

DR. STENSLAND: We have a slide. We can -- yeah, if you click there's a -- I should go all the way down.

But, no, we don't have the numbers there. We have looked at that and the hospital ACOs, in general, tend to be more likely in the lower-spending markets, and the physician ACOs tend to be more in the higher-spending markets. And this would imply either that the physicians

are not as interested in setting up an ACO where they think they're not going to be able to make any money, or maybe if they're in a high-spending market, you know, if you're in Miami or someplace like this where you think you can save money as an ACO, you may be less interested in teaming with the hospital and maybe just want to do it on your own.

MS. THOMPSON: Thank you.

DR. CROSSON: Paul, David, okay, Pat, Jaewon, Brian, Jon.

DR. PAUL GINSBURG: Yeah. I would appreciate if you could go through in a little more detail which physician the patient, the beneficiary, is assigned to and which ACO they were in. You know, so think of a hypothetical beneficiary that just has primary care, and then they have a heart attack or cancer, and they start having a lot of visits with a cardiologist or an oncologist. Could you just take us through, you know, which ACO they get assigned to, based on their physician use?

MR. GLASS: So, actually, Kate Bloniarz has worked on this, and if I misspeak she will correct me, I'm sure.

The first thing that has to happen is the beneficiary has to have a primary care service from an ACO physician, and if they don't they are not eligible for assignment.

DR. PAUL GINSBURG: And do you find the primary care service as an office visit?

MR. GLASS: They have a list of them --

DR. PAUL GINSBURG: Okay.

MR. GLASS: -- and we have that list, if you want it. But it's mainly E&M visits. And then after that, if you have more primary care services from ACO primary care clinicians, and clinicians here includes physicians and nurse practitioners and PAs, so if you have more of those services from ACO clinicians, primary care clinicians, than any other ACO, or any other single taxpayer identifier number, then you're assigned to the ACO. Now if you don't meet that qualification but you do have a primary care service with a primary care clinician, then you're not assigned to the ACO. If none of those things happen, and you have more primary care services from ACO specialist than any other ACO or any other single TIN, then you're also assigned to the ACO.

So it's kind of complicated. What it means is if you're not assigned on your primary care services right away then you can be assigned on specialist service. They call it Step 2. And there are some weird things about, you know, I guess we discussed yesterday nurse practitioners, PAs, they're all counted as primary care people, even though they may be working in the office of an orthopedist, and that can lead to some odd things happening.

And also the other super-detail on this was that the visits, in SNFs, were counted in the years we're talking about. So if a beneficiary went to the hospital, was discharged to a SNF, then saw a SNF physician many times while they were there, they would probably get assigned to that physician, if that physician were in an ACO. So it gets very detailed.

DR. PAUL GINSBURG: Yeah, I appreciate you going through it because I think the implication is that ACO assignment is sensitive to whether the person is sick or not, and that's really, you know, a flaw and a weakness of the whole system, which your research is bringing out.

DR. GRABOWSKI: Great. I'm glad I get to ask this question right after Paul's because it very much

builds on Paul's question. I was trying to think through this myself and, David, you described this population as very complicated. Another way of describing them is that they're very selected. They're very different here. They've had a change in health status which has led to an interaction with a physician or a SNF, which ultimately changes their enrollment in the ACO.

I worry a little bit -- so I think, descriptively, I really like what you're doing in documenting this group. I worry a lot about trying to examine this group and look at the effect they might have on program spending, just because it's so hard to construct a counterfactual for them. You mentioned propensity score matching. I would love to learn more about what you're thinking there because I don't think -- this group is so selective that I just worry, are you actually going to be able to find a comparable group to actually do this in a credible way.

DR. STENSLAND: Yeah, I think -- you know, what we're thinking about doing, and you should send us a nice email later if you have any great ideas -- is --

DR. GRABOWSKI: I like that you used the word

"nice" there.

DR. STENSLAND: Yeah. I'm just trying to keep things polite. We're planning to do the propensity matching, but the propensity matching all has to do with stuff that happened before our time period. And then we have some of these unforeseen things that are happening that are moving you around. So we're thinking about, when we're going to looking at what the changes are for these propensity-matched groups, to look at it in different ways and then try to describe what we think the bias is in the different ways. I think, in some ways, you might overestimate savings and in some ways you might underestimate savings, and we can talk about that in the future. Maybe we'll have some more ideas on that.

DR. GRABOWSKI: As a follow-up, so why doesn't the intent-to-treat framework address this issue with the switchers. You're defining them at baseline. Isn't that just a simpler way to do this than to try to kind of take account of all the switchers over time?

DR. STENSLAND: We could look at like people that were initially in an ACO in 2013, and then just follow them all the way through, kind of more an intent-to-treat model.

And I think McWilliams' intent-to-treat model is fine too, and I think this kind of following them all through will be one of our assortment, our buffet of different outcomes that we'll have. And I think it will complement some of the intent-to-treat stuff that McWilliams did.

MS. WANG: Thank you. This was really interesting work.

This is just a question about, I guess, attribution to an ACO. Is an ACO permitted to change the physicians in the ACO throughout the course of the year, and if not, you know, throughout the course of the year, year by year? What are the rules around that?

MR. GLASS: Okay. I'm trying to recall this from memory. We can get back to you on it. But I think, in the MSSP program, they allow quarterly changes in your physician list, or your participant list.

MS. WANG: I'm sorry. I missed the --

MR. GLASS: Quarterly changes.

MS. WANG: Quarterly changes. That's really interesting.

MR. GLASS: Yeah. And then you raise another question of, oh, does that mean you have to change the

benchmark because now you have a different set of people?

MS. WANG: That actually wasn't -- but I think that is a good question. I was more wondering about, you know, susceptibility to managing your panel, to keep your healthier members --

MR. GLASS: Well, it's interesting you bring that up because there was a --

MS. WANG: -- on a managed care plan.

MR. GLASS: Yeah. There was a recent RAND-AMA study, and they did find that some organizations were realizing this and moving some of the physicians from one TIN to another, in and out of the ACO.

MS. WANG: Yeah. It's something to bear in mind, obviously.

The related question is whether or not, in your switchers, you have any information on differences in frequency or incident as between physician-led ACOs versus hospital ACOs. And I'm not suggesting any kind of pernicious behavior there. But one of the things that I think happens when somebody gets sick is they may have a primary care doc, you know, that they've been seeing for years and years. They develop a serious health condition.

They go a medical center and the medical center suggests "why don't you switch our PCP over here, because we can take care of you better." And I just wonder whether that's anything that you can pick up from the information you've looked at.

MR. GLASS: Well, anecdotally, we've been told by some ACOs that that is the case, and that they're losing beneficiary attribution over to a hospital-based ACO. So we've been told that. We don't have -- we haven't noticed it in the data but we haven't been, you know, searching.

DR. STENSLAND: We ran those numbers but we can put them in a footnote in your next chapter.

MS. WANG: I was just interested in the switchers, in particular, with the hypothesis that it might have been triggered by a health event, whether there's a closer look that can be made there. Again, it has implications for the evaluation of the performance of one type of ACO versus another type of ACO.

DR. CROSSON: I just want to clarify one thing myself now. So if the physician that the patient saw and as a consequence became part of that ACO retrospectively leaves the ACO, the ACO still has that patient. Correct?

DR. STENSLAND: Not if the patient moves with their physician. So if you were treating somebody and the ACO decided -- we would hope they wouldn't be doing this, but let's say they said, oh, this is Jay and he takes a long time with all his patients, people send him all their expensive patients and he's in our ACO, next year they could have you start billing under a different TIN, and then all your patients would leave the ACO.

DR. CROSSON: Next year, but not --

DR. STENSLAND: Next year.

DR. CROSSON: Not in the reference year.

DR. STENSLAND: Well, it depends. You know, it depends if you're the retrospective or prospective --

DR. CROSSON: We're talking about retrospective.

DR. STENSLAND: Yeah, so if it's retrospective and you are in the -- you sign up to be in the ACO for that year and they're seeing you that year, then they're responsible for the cost.

DR. CROSSON: Whether you leave or not.

DR. STENSLAND: Whether you leave or not during that year, unless you left in the middle of the year and started billing under a different TIN and they saw you more

often under that other TIN than they did under the prior TIN, then the patient would leave with you.

DR. CROSSON: Okay. Jonathan, you looked like you wanted to comment on that?

DR. JAFFERY: Well, that was -- the final point was the point I was going to make, because it's based on the plurality of --

DR. CROSSON: The plurality, so the -- okay. All right.

DR. JAFFERY: So if you left in September, you probably wouldn't --

DR. CROSSON: Got it, got it.

DR. JAFFERY: And then I guess one other point of clarification about this, and we were just -- I think we're recalling that for adding or subtracting MSSP physicians, you can only add annually, I think, not quarterly, and you can drop any time, which becomes, obviously, important because people leave organizations.

DR. CROSSON: Okay.

MS. THOMPSON: And when a provider drops, the beneficiaries attributed to that provider go out of the ACO?

DR. CROSSON: Go what, Sue?

MS. THOMPSON: Out of the ACO.

DR. CROSSON: Out of the ACO.

MS. THOMPSON: So if the ACO loses a provider, they lose the lives that were attributed to that TIN.

MR. GLASS: I'm sorry. If an individual provider leaves or if that TIN leaves?

MS. THOMPSON: I'm sorry. If an individual provider leaves with an individual TIN.

MR. GLASS: With an individual TIN, yeah. So in MSSP this is all done on the TIN level, which can range from one provider to an entire health care system. So that's another complication. It's not done at the TIN NPI level.

DR. CROSSON: Got it. Thanks very much. That helps. Jaewon.

DR. RYU: Yeah, on the shared savings payments, how does that get treated in terms of rebasing the benchmark and also in terms of how it impacts the MA benchmark? Is that treated as spending?

DR. STENSLAND: Yes. So there's a little bit of a multiplier effect here. Let's say the ACO is generating

savings and it's generating savings larger than the shared savings payment, so on net, the system is benefitting. That will lower MA benchmarks in the market, and the system will have a little bit of a secondary benefit by having lower MA benchmarks and lower MA spending. But it can go the other way, too. If, let's say, the ACOs actually just broke even but the shared savings payments were larger so on net the system was losing, well, then, on net that would increase the MA benchmarks.

DR. RYU: So if you add $100 of savings and then you had to pay back $75 of it as part of the shared savings payments, would the $75 of payment count towards the MA benchmark and towards the rebasing of the --

DR. STENSLAND: Yes.

DR. RYU: Okay.

DR. CROSSON: Brian.

DR. DeBUSK: First of all, thanks for a great chapter. I really enjoyed the analysis. I'm really looking forward to this matching that you're doing, too. I think there's some real novelty there.

What I was going to ask about, retrospective attribution has always been one of those serious flaws with

the ACO program, and it seems like prospective attribution solves a lot of those problems. Just sort of your initial impression -- and I know you're not done with the analysis. Are you left with the impression that prospective analysis -- or prospective attribution fixes or addresses this issue, at least in a reasonably complete way? Or is this just a way point or a stepping stone to maybe even a more sophisticated enrollment type mechanism?

MR. GLASS: Prospective assignment would not solve all of these issues.

DR. DeBUSK: So --

MR. GLASS: But it would be better and --

DR. DeBUSK: Okay, so we should look at this as clearly an improving direction. I think there is no doubt this is an improving direction. But this is a way point to maybe even something better in terms of attribution.

DR. STENSLAND: Yeah, like I said, I'm not sure if this is like this is an improvement and good enough or an improvement and we've got to make another step to make things even better. But I'm not sure what that other better step would be.

DR. DeBUSK: Okay. I was just trying to get a

feel for how complete prospective assignment is.

The other thing I was going to ask, have you guys looked at any ways to engage the beneficiary in attribution? Everything right now, I mean, some of these people have no idea they're even in ACOs.

MR. GLASS: I would say most of the people don't have any idea --

DR. DeBUSK: Yeah, I was going to be nice because Jeff likes nice.

MR. GLASS: Some of the physicians don't even know they're in ACOs. But, I mean, you know, this particular analysis, we didn't look at that at all. Recently, you know, they've introduced -- you can have voluntary assignment where if a beneficiary goes into Physician Compare, or wherever it is, and says this is my main doctor or primary physician, then they're assigned to that physician's ACO. So there is that. And under the new rules, they can also offer people money to show up, and that could increase attachment.

DR. DeBUSK: Well, thank you. I was just trying to get a feel for how close to settling this issue we are, and it sounds like this is sort of the second inning of a

long game.

DR. STENSLAND: And I think we should emphasize that we're talking about the MSSP, and we have a couple people here who are Next Gen, and they've already kind of moved into the second inning. You know, they have prospective assignment. They have assignment based not just on the TINs but also the NPIs. So it's not like we have to start from scratch here.

DR. CROSSON: Okay. I've got one of those people lined up. That's Jonathan, and then Warner and Pat.

DR. JAFFERY: Yeah. So thanks. First of all, I really appreciate this creative look. As we've acknowledged, this is now about -- we've got Medicare beneficiaries basically in three programs in about thirds: regular fee-for-service, MA, and now this. And I think you could argue that in terms of changing provider behavior, the ACOs is doing more than MA has in many ways. Clearly, there's lots of other changes that have happened, but providers are doing things, even if many of them aren't aware they're in ACOs, which I think is true.

A couple things. First of all, to follow up on some things others have said. So, Dana, you had asked

about the retrospective attribution and the number of people, and so the way that I think typically worked is you'd end up with your initial prospective assignment being very, very large and then every quarter it just gets smaller until you're left with a significantly smaller number.

I think the cost issue about ACO costs, I think that is tricky. Certainly in my organization, we do sort of try and assign some of the cost to the ACO, but it's not very self-contained.

A couple specific questions. Let me go to Slide 14. This is a pretty quick question. You've got the assigned to the same ACO, the bottom, and then left in 2016. Are those folks who are assigned to the same ACO for those three years and then left to another ACO, to not be in a new ACO, or a combination?

DR. STENSLAND: Combination.

DR. JAFFERY: Okay. And then I had one other question, but I forgot it, so sorry.

[Laughter.]

DR. CROSSON: Warner. You can always sneak it into Round 2. Warner.

MR. THOMAS: Has there been discussion or have you guys looked at just the whole concept just going primary care assignment for traditional Medicare? And what do you see as the -- it's obviously not being done. What has been the discussion on that? And where do you see the challenges with that?

MR. GLASS: Well, the history of this is that people didn't want to leave specialists out of ACOs. They wanted to get them involved. It was felt that there were a lot of beneficiaries who maybe they see their cardiologist as their primary doctor, and we don't want to leave them out. And I think so all of that kind of militated for some way to get the specialist into it, and they ended up with this second stage assignment sort of thing.

Now, why they shifted to the two-stage, I'm not sure, but they did have the two steps, and I think part of it is kind of the way the statute's written. It talks about primary care physicians.

MR. THOMAS: Do you think going to that model, even if you identified your cardiologist as your primary care doctor, do you think that would solve some of this problem? I mean, even just having the beneficiaries go

through the thought of like who is my direct caregiver and that they know that they're in this program, do you think that would help in any of these scenarios?

DR. STENSLAND: I think it would make a cleaner comparison between you and the other groups, and this is actually -- when McWilliams did his evaluation, he only -- he did his own assignment based only on primary care, because he thought that provided a better comparison between the ACO and the non-ACO. So I think for evaluation, that might make sense. The only -- the downside we have here is if we go to only primary care visits, you're going to end up with fewer people assigned to the ACO, because you've got about maybe 12 percent of the people that only end up seeing specialists in the year. So, you know, you have all these people in Medicare. About 10 or 12 percent don't see anybody. Another 12 percent only see primary care -- or only see specialists, so you're going to have a smaller group. And you're going to have to end up then trying to get bigger ACOs, because we already have a problem with some of these small ACOs which have 5,000 or 10,000 people having lots of random variation. Whenever it gets smaller, you have more random variation.

So I think to me this is a trade-off between better attribution versus smaller sample size in the random variation you have there.

MR. THOMAS: Has there been any studies done or have you guys talked to beneficiaries about how they would feel about the fact that they're in this organization, that the idea is to have better coordination? I mean, because I think there's always this view that, oh, well, we don't want to go to primary care assignment because it's limiting choice and beneficiaries are going to feel bad about it. And I just wonder if it was really explained to them as, you know, you're entering a system of care, we want to identify someone who's your go-to person, you know, that it probably would be much better accepted versus it being this kind of covert sort of thing. So has there been any dialogue or any studies around that?

MR. GLASS: When they started ACOs, there was a letter that went out to the beneficiaries saying, "Congratulations. You're now in an ACO. This means your data is going to get shared." And the reaction was incredibly negative. You know, "I don't want the government to know what doctor I'm going to." And beyond

that, it became -- it really caused a lot of trouble for the physicians' offices because they were getting all these calls, you know: "What does this mean? Why are you doing this to me?" And so they quit sending out the letters because it did not help.

MR. THOMAS: That kind of gets back to my point of, you know, perhaps there should be some study or some work done to understand from beneficiaries -- number one, to explain to them and have them understand like what are we really talking about. This isn't just like -- number one, the government can look at all your data anyway because they look at all the claims information. But, anyway --

DR. PAUL GINSBURG: They're paying the bills [off microphone].

MR. THOMAS: Exactly, they're paying the bills. But more importantly, you know, especially you want to have coordination and you want to have folks that are kind of focused on being preventative. I just wonder if we had a better way and approach to explain this, I think we'd get much, much better acceptance. I honestly think -- so I don't know -- I just know that there's been studies on

that, or maybe that's something we should think about doing.

DR. STENSLAND: We do focus groups every year, and we ask them things like, "Are you in an ACO?" And almost no one knows if they're in an ACO or not. And sometimes we try to explain what an ACO is, which I think for a lot of these people is extremely difficult. Like we have people that don't know if they're in an MA plan or in fee-for-service in these focus groups and what's the difference between a Medigap plan and an MA plan. A lot of them don't know that.

So if we tried to explain to them the difference between an ACO and an MA plan and traditional fee-for-service, I think the share that we would get that would really understand what's going on would be smaller than the share that would just be scared.

And then there's the -- but the thing that you touched on that might work that they can do is they can get on and say, "Who is your primary care doctor?" I think that's much more easy for them to understand, "This is my doctor," as opposed to "This is my ACO."

MR. GLASS: That route is open. Not many have

used it yet, but that's a matter of education, and I think people certainly in commercial plans are willing to say, "This is my primary care physician" and would certainly -- I mean, we could entertain the idea of asking that when people first join Medicare.

DR. CROSSON: Okay. I've got Pat and then Kathy, and we're still in Round 1, sort of.

[Laughter.]

DR. CROSSON: I think Round 2 is going to be kind of like what are the implications of these findings, and I think we're already doing that. But just for formality's purposes --

MS. WANG: These are actually questions. Do the changes in spending growth include Part D?

DR. STENSLAND: [Nodding affirmatively.]

MS. WANG: Okay. have you thought about looking at that?

DR. STENSLAND: Yes, and it's hard.

MS. BUTO: Jeff, Part D is not managed by the ACO, correct?

MS. WANG: It's true, but sometimes, you know, changes in spending in one area can -- decreases in one

area can result in increases in the other, and I think it's something that one would want to know about, the total package of care that's --

MR. GLASS: So you could conceivably look at it for the subset of ACO beneficiaries who are also in a Part D plan for which we have the data.

MS. WANG: Thanks. The second question is: Can you summarize the reasons in the comment letter on the new MSSP rule that you disagreed with the notion of both prospective and retrospective assignment?

MR. GLASS: Right. So in the comment letter, the Commission opined that allowing ACOs to switch between retrospective and prospective assignment was a bad idea, allowing them to switch annually between, because it opens up large possibilities of gaming, you know: I'm in retrospective this year. I noticed my -- I did really well. I think I'll switch to prospective. They'll give me the same set of beneficiaries I had last year. The simplest.

But it also introduces terrible administrative complexity for CMS because they have to compute a different benchmark. It's a different set of beneficiaries, and it's

a different lookback period, so they have to do a different benchmark if an ACO switches between one -- from prospective to retrospective or vice versa. And we didn't agree that it was necessary to do any of this. They implied that statute which was really changed to allow Track 1 and Track 2 to use prospective, therefore implied that going forward they should always be allowed to switch between the two. And since Track 1 and Track 2 no longer exist, we think that the problem went away.

DR. CROSSON: Jonathan, on this point?

DR. JAFFERY: Yeah.

DR. CROSSON: Okay. Go ahead.

DR. JAFFERY: Do you know in your focus groups if there are people who are interested in switching? Or most people I think are more interested in the prospective for some of the reasons we've said. So have you heard, gotten feedback from groups that like the retrospective?

MR. GLASS: I'm sorry, focus groups with ACOs?

DR. JAFFERY: Yeah, yeah.

MR. GLASS: Discussions with ACOs?

DR. JAFFERY: Yeah.

MR. GLASS: It seemed early on there were people

who did like the retrospective, but, yeah, I'm not sure. We haven't talked recently, being allowed to switch back and forth, whether people like that or not.

DR. CROSSON: Kathy

MS. BUTO: I'm going to hold off until Round 2.

DR. CROSSON: Okay. So Round 2 starts now, sort of, and we're going to engage in comments about the implications of the findings, and I think Paul has offered to begin the discussion.

DR. PAUL GINSBURG: Thanks.

Anyway, I think you've done a great job pursuing this research, and it has a lot of implications. The first implications were that Medicare's -- or CMS's decisions about rewarding ACOs or penalizing ACOs are subject to a lot of error because of the changes in the patient switching into or out of different ACOs. It also means that a lot of the research is subject to perhaps more error than we might have thought.

We probably wouldn't care so much with the latter if the ACOs were more successful than they've been, but since we're talking about 1 percent gains or losses, it suddenly becomes a big deal whether we think we're making

progress or not. If we had 5 percent gains, we probably would say all the different approaches, we don't even have to worry about those because the gains are clear, full steam ahead.

But the other implications, which came out a lot in our Round 1, is that the model can be improved, and I think someone asked a great question, is going in a perspective going to change it, and clearly that would be an improvement. But it's not getting at the underlying problem, which is the attribution, because I think the whole concept behind the ACO is that all beneficiaries would be assigned to their primary care physician, no matter what happens. We have these situations. some are clearly getting assigned to specialists, only when they get sick. To me, that's a really big problem for the ACOs as well as for the program, and I think it's really worth our time to perhaps come up with ideas to, in a sense, really turbocharge the process, pay the beneficiaries if they'll go in and identify their primary care physician, to really reduce this issue of people who don't have primary care physicians or have them, but wind up being assigned to a specialist when they get sick.

DR. CROSSON: Thank you, Paul.

Dana first, Bruce, Jonathan, Kathy, David, Brian.

DR. SAFRAN: So thanks for tackling this really important work.

Where I want to start is you made the distinction at the beginning that I think is a critical one for us to keep our eye on throughout this line of analysis of the evaluation against a benchmark evaluation, where we're trying to create the counterfactual.

I think you may not have said it exactly this way, but you did make the point that the benchmark matters to organizations because it drives whether or not they're succeeding in getting paid.

The counterfactual matters for all of us to figure out is the program succeeding.

So I think that the number one point I wanted to make is that the distinctions that you're making and the demonstration you did on one of the last slides of the difference that prospective versus retrospective assignment makes to the answer to both questions, whether the organization wins and whether we appear to have a program that's succeeding is a really important point.

I will make the point that I hear a lot of folks saying it's just so obvious, prospective is better. I will tell you that I don't share that point of view. That in the work that I led at Blue Cross, we used what we called "concurrent assignment," and that's why I asked the question I did about how it works for the programs for CMS because how that worked was you know all through the year who we think is attributed to you, but at the end of the year, we settle up on who actually manifests as your patient, because of all the switching that happens.

I'm not going to try to settle that here. I'm just flagging the fact that I think for the first purpose, how do we set the benchmarks, how do we settle the program, the policy questions -- or maybe we'll call them the "programmatic questions," I think this modeling of the difference that it makes, the prospective and retrospective, is it does a really important service, and so I would encourage you to continue that line.

The other comment I want to really underscore, I think I teed up a little bit with some of my questions, which is this issue that you're on to, which I think has been skipped over in both the academic evaluations and in

the CMS's own actuarial evaluations of switching is extremely, extremely important. You show the numbers are significant.

But it is -- I'll call it a closed course for professional drivers. I mean, like the modeling that you have to do in order to understand, just some of the basic questions I was asking you of like did this person have a health event that motivated the switch and how do you know that it was because of that, and what happened to the people that had the same health event that didn't switch, that sort of gets a little bit at the propensity matching you're wanting to do.

So I guess I just want to say I really encourage this line of analysis for the second category, which is establishing the right counterfactual so we can know more accurately how well this program is succeeding.

But I want to encourage you to engage a methodologist who has been driving on this course. I have at least one to recommend to you, so I'll do that after the meeting. But I think it's really important to address these issues of moving around.

Thank you.

DR. CROSSON: Thank you, Dana.

Bruce.

DR. PYENSON: Again, I continue to be just really impressed by the longitudinal study that you did as really adding a lot of knowledge.

Paul's comment that if ACOs were much more successful, we wouldn't be fussing over a lot of this and Dana's cautionary note that prospective is not necessarily the right way to go, I agree with.

But I did want to say, to me, this work identifies one of the prevailing myths of population health that I think many people have hoped would be realized with the ACO movement, and that is, that if somehow we simply engaged physicians and engaged patients better and got them into the system consistently, we would be able to bring the magic of better care to them, and they'd be healthier and less expensive.

It's not quite a perfect analogy to Jay's comment that "It's the price, dummy," but there's the issue of what spending is actually malleable.

There's often the attempt to blame the patient, "Oh, if the patients were only compliant" or only if they

were indentured servants and didn't move around, but the reality is it's not the patient that decides unnecessary surgery and admissions and excessive stays in SNF and things of that sort.

So, ultimately, I think what we're up against here is the failure to take the kinds of steps that are, in fact, short term and effective in the short term at saving money, and of course, the incentives are not aligned to make that happen. So, hence, we're in this awkward situation of a program that seems so promising but is disappointing.

The fluctuation in the churn of 30 percent or so that's been reported actually is not perhaps such a huge problem. That's existed for generations in the insurance industry. It's a little less now because there's so many fewer insurers, but it's risk. And there's certainly ways to manage it. Given that it's the reality of this population, I think that emphasizes the importance of short-term actions to make the care more efficient.

So this is my interpretation of the data that's coming out of this that it actually points in a different direction of what ACOs need to do to be effective than many

of the underlying assumptions that I hear very frequently because I think, certainly, within the context and the examples of MA plans, there's certainly potential effectiveness.

So potential things to change here, less concerned about attribution and that sort of issue, but the ability to direct care more strongly, I think would be a very important tool to get at some of the underlying potential savings in the short term.

DR. CROSSON: So, Bruce, just let me ask you to expand a little bit on that because I think the ability to direct care in this context would be -- correct me if I'm wrong -- the management of the ACO with respect to the, for example, individual physicians.

Now, to me, that brings into play, perhaps, a piece of this that we haven't spent much time on, which is how the individual physicians are paid, what the incentives are at the level of the individual physicians. Is that where you're going or somewhere else?

DR. PYENSON: More on a referral policy and ability to, if you will, some of the techniques that are routinely used in Medicare Advantage, for example,

utilization management.

DR. CROSSON: Okay.

DR. PYENSON: So the challenge with an ACO doing that is that it would be a loss for them to do that relative to the shared savings and especially given the churn. When you look at an organization, they're better off not decreasing admissions, not decreasing ER, and getting the revenue on that side rather than the relatively small shared savings.

DR. CROSSON: Because of the disproportionate shared savings. All right. Okay. Thanks very much.

Jonathan.

DR. JAFFERY: Yeah. Thanks, and thanks again for this. I do wish maybe we had had this conversation before I started at an ACO at a center. I'll have to think about that. Yeah. So I have, as you can imagine, a lot of thoughts, but I'll try and really limit it to implications of this report, things like that.

So I think the switcher idea is super interesting, and I would echo what others have said about thinking about additional -- digging deeper into the switches. I think the propensity-matching idea is

intriguing, important, and I want to acknowledge the potential issues that David and Paul brought up but think that that's important.

I'm trying to think about some other characteristics of the switches, some things that others have brought up about what does it mean around their health needs and changes in health needs, and then also maybe a little bit more about where they go. Are they going to ACOs with hospitals? Are they going to academic medical centers? Some things that intuitively might be driving some of the other differences we see, but I'd like to understand more about that.

And then a couple other things that I think the report reinforced that we've heard, that we've seen in to her reports, or people have observed that I think are really key to success of the program long term -- so one thing that you talked about in the report and today is the longer you're in an ACO, the more likely -- the longer the ACO exists, the more likely it is to achieve shared savings, at least relative to the benchmark. So I think that's something we need to think about that's important, especially in light of the 2019 rule, which is going to get

people -- moving people towards risk faster. If they have to be in risk in two years, but it takes on an average four years to get to the point where your processes are in place to make savings, it's just another hurdle for participation, which of course is voluntary at this point.

Then the last thing that keeps coming out -- and, again, you showed it today -- is that the best predictor of shared savings is to be in a high-use area, high cost of baseline, and none of these things really are getting at that. The long-term sustainability of the program that is asking organizations to make investments and then continually just beat their own success. So, hopefully, we can weave those things into further analysis too as we think about opportunities for recommendations about program design going forward.

MR. GLASS: Well, they are putting in regional spending into the benchmark, which will -- depending on whether you're high or low to begin with.

DR. JAFFERY: Right. I think I mentioned yesterday, depending on your market, that may make absolutely no difference.

DR. CROSSON: Okay. I've got Kathy, David,

Brian, Pat, Warner, Karen.

MS. BUTO: And Sue.

DR. CROSSON: Okay.

MS. BUTO: So I thought this work was really interesting, and I really want to commend you for doing it and actually taking a very innovative approach to looking at what is underneath the spending growth and particularly for switchers.

Like other people, I think it's important to really understand what's going on there. It raised for me two kind of issues that are not necessarily going in the same direction, if you will.

One of them was I think the point that Warner was getting at earlier, which is part of the ACO -- I guess our aspiration for ACOs was not just about moderating spending growth, but increasing management of care. So I think the bonding or the connection with primary care physician is something that if we understand better what's going on with switching, we might be able to tease apart in a way that we understand better how to increase the incentives or the elements of the program that would stabilize that relationship in a better way.

The ability to offer $20 to beneficiaries and have that make a difference in their showing up tells me that there are other opportunities there that for increasing connectivity and sort of engagement on the part of beneficiaries to the ACO, and I hope that at some point, we'll get more into that aspect of it.

On the other side, I guess the thing that I'm aware of is there may be really good reasons why people are switching, and yes, it leaves the spending growth, but would we want them not to switch, in a sense, in this construct? Yes, if they're in an MA plan, but this approach was designed to allow for greater flexibility. So that's why I think it's important to better understand why they're going out or why they're migrating outside the ACO, and it may be for very good reasons. Maybe they should be in a medical center if they're got a complex medical condition, and both the primary care and specialty care can be better managed together. So I think that's why it's important to go the next level.

MR. GLASS: I don't think we said switching leads to spending growth. I think people switch for a reason, as you just said.

MS. BUTO: Right.

MR. GLASS: And they get sick. They start seeing other doctors.

MS. BUTO: That growth won't occur.

MR. GLASS: I know from my own experience --

MS. BUTO: Wherever, yeah.

MR. GLASS: -- changes in health status are usually not good. It's going to cost you money, and it's going to be seeing a lot of doctors. And so the switching causes --

MS. BUTO: You're saying the spending growth would occur --

MR. GLASS: Exactly. Right.

MS. BUTO: -- wherever they are.

I'm just saying that the switching itself might be a very rational thing and driven by the right clinical consideration.

DR. CROSSON: Okay. So we are running out of our allotted time. I've got David, Brian, Pat, Warner, Karen, and Sue, and I think that will be the end of the discussion.

David.

DR. GRABOWSKI: Thanks again for this work.

On page 1, you write this paper examines the effect of the MSSP on Medicare program spending, and you have these three sections in the report, the first looking at performance relative to the benchmarks; the second, performance relative to counterfactuals, seeing some of the work from the literature, and then the third, this descriptive examination of switches.

I would argue based on that goal of wanting to look at the effect on Medicare program spending that only that second section is really meeting that overall objective, and Dana has already made this point, but I'll make it again. Benchmarks don't equal counterfactuals, and I don't know that that section belongs in here. I think it just confuses. The benchmarks are really important to the participating organizations, but they're not important to Medicare program spending.

I'll quickly note my colleague Michael McWilliams actually had bumper stickers printed up that said "Benchmarks do not equal counterfactuals." I'm going to get one for Jeff, and, Jeff, we're going to put in on your car at the next meeting. We'll go out and --

[Laughter.]

DR. STENSLAND: If that's not going to elevate my cool status, I don't know what will.

DR. GRABOWSKI: I don't know what will. That's right. That's right. I think it would look great on your car, though, Jeff.

DR. CROSSON: Let me just point out you've got a great football team over there. I think that makes much more sense.

DR. GRABOWSKI: That's right. Right, right.

DR. DeSALVO: It's going to be great until the Saints crush them.

[Laughter.]

DR. SAFRAN: I just want to mention that I have that bumper sticker.

DR. GRABOWSKI: There you go.

[Laughter.]

DR. GRABOWSKI: Is it on your car, though, Dana?

DR. CROSSON: All right.

DR. GRABOWSKI: The other point I wanted to make, quickly -- I'll come back -- I touched on this in Round 1, but the switchers are not random. They're a highly

selected group and I just worry that we have this change in health status which leads to this change in provider which ultimately leads to this change in assignment. There's something very different about these individuals. So I think Dana framed that nicely. It's a really challenging course and we want an expert driver. But I worry, even with an expert driver, that we're not going to be able to navigate it. It's really hard to kind of do this with propensity-matching and actually come up with a good counterfactual.

So I'll say I remain skeptical about whether we can actually do that. So thanks.

DR. CROSSON: Brian.

DR. DeBUSK: Thanks again on a really insightful chapter. I really enjoyed the analysis. And like so many others have said, I think studying and understanding the switchers is obviously a huge component of this.

I'll tell you the prospective assignment feels like progress. It does clearly seem like it's a step forward. But we're in a pretty awkward situation here because, you know, as we've talked about now, this clearly isn't an endpoint. This is a way point, at best.

And so I think we're going to be tasked with trying to push forward on even better ways to do this attribution in this assignment, and what I was going to encourage here is really two-fold. Number one, you know, from what we've learned from the switchers, I don't know that we can conveniently put someone in this box or in that box and say this is the person that's responsible. We may have to take more of a hybrid approach, where we do bring some retrospective ideas and some prospective ideas together, and maybe even do some cross-attribution or some mixed attribution. And, I mean, we can follow up with emails with that.

But I think having something that's more continuous, where someone doesn't have to leap from one ACO to the other may, at least, for analytic purposes, help us understand the nature of these transitions, because I could see someone being attributed to one ACO, getting sick, racking up claims in this new ACO, triggering their basically cross, or their reattribution, and then once they resolve going right back to their original ACO.

So let's think about, you know, are there more continuous ways to do, again, some type of cross-assignment or a more

continuous type of assignment, even that could be claims-based.

The other thing I was going to mention, too, is I think the analytics are only going to get us so far, and I think Kathy briefly alluded to the idea of beneficiary engagement, you know, if you were focusing on the $20 payment for a healthy visit. I still ultimately think we're going to have to do something to engage beneficiaries, and sort of, to me, the obvious mechanism would be some type, ultimately -- I'm probably going to get thrown out of here for this -- but ultimately some type of surcharge for people who insist on unmanaged care. If I don't want to identify a primary care physician, I don't want to participate in an ACO, and I don't want to enroll in MA, ultimately, we're going to have to capture that cost. Is it a $12, is it an $18 surcharge on your Part B premium? I don't know.

But at some point we need to recognize the fact that people who insist on not participating in any of the choices in front of them are costing the system extra money, and I think that may be the beneficiary engagement mechanism that we need to also address some of these

attribution issues with ACOs.

DR. CROSSON: Great. Pat.

MS. WANG: Thanks. Again, I commend you on the work and I think it's really important, and I think, just for the record, to state clearly, I think that the work is important to keep evolving the ACO program and to keep getting better and better and better at this.

The discussion around switchers is really important and people have raised all of the relevant points. Attribution models, even in managed care plans, are phenomenally difficult because we may think that somebody should recognize their PCP as, you know, the person in charge of coordinating everything, but human behavior often is not like that. And people will say, "You're my PCP but I go get my care someplace else," and you just have to recognize that as human behavior.

But the thing that is raises to me -- and I think the work is important and needs to keep going -- but what it raises to me is that ACOs are still such a partial and segmented solution, and that that is one of the reasons that we're spending a lot of time talking about why are people switching, you know, et cetera, et cetera. And it's

good, what are the characteristics of switchers; it's fine. But the goal, ultimately, is that those people who switch because they develop a serious health condition, or move to a different part of town, are still in an organized care delivery system that does the best job possible for them. Their health outcome may change because they might be gravely ill, so at that point they're really in an acute situation. You just want the care to be good.

And so, you know, I would just observe that over time, hopefully, this archipelago of ACOs will be connected into some sort of continent. Like ideally, you'd think about there's a regional ACO, because there are switchers. People are always going to switch for some reasons. You just want to make sure that they're moving from one organized delivery system into another organized delivery system. So we have a ways to go there.

One of the reasons that I asked about change or evaluation of Part D spending, and I understand that it's not part of the ACO's responsibility. I do think it's important to look at, because if you look at total program spending it's a big part of total program spending. And part of the reason to try to understand whether there are

any changes there is precisely because the ACO is not responsible for it. I think that we would want to know whether there are changes in care patterns that are producing, you know, changes in spending growth, up or down, that may be related to parts of the benefit package that are not the responsibility of the group that is charged with managing that population. Substitute medical care with increased prescribing would not be a good thing, but you kind of want to know that.

Over time -- and I don't know how to do this -- but it would be great for ACO members, who are, by definition, enrolled in freestanding PDPs, that don't really have quality metrics that are tied to health outcomes, to somehow align to what the ACOs are trying to do. Jonathan, you know, I think really vividly described yesterday the consequence of non-adherence to medications when somebody shows up in the hospital and it creates all kinds of problems for them. It would be great if, at some point, ACOs, who are managing those kinds of outcomes, could have aligned incentives and data-sharing with PDPs who right now have no -- there's no star measure for a PDP for med adherence, for example. You know, to somehow, over

time, examine how those linkages might be made so that at some point they're connected, because it's hard to imagine an ACO managing a Part D benefit but there might be something in between.

I'm not in favor of kind of pushing ACOs down the road of do your own utilization management. It's an incredibly costly enterprise. It has a lot involved in it. It's not just, you know, decide what you think should be approved, not approved. It will never go -- it's a different model than insurance and a capitated model, so it will never take that final step. But I think that, to me, the goal and the drive of ACOs is to create a more coordinated, connected delivery system that can fit into a better fee-for-service system, a better MA system, and, ultimately, those should be the two pathways for beneficiaries.

DR. CROSSON: So, pat, this question you raise about integration between ACOs and Part D is on our work plan.

Warner.

MR. THOMAS: I'll be brief, given the timing. First of all, I was actually pleased with the result, and I

think given the short time period that ACOs have been in existence, I think we are seeing results. So I hope that people feel like we're heading in the right direction here.

I'm also not surprised with the fact that for folks that stay with the same ACO or stay with the same physician that they see better results. And it's one of the reasons I really think we should look at primary care assignment or physician assignment. If we need to broaden it, I think that's fine, but I do think having people -- we're seeing this with our own employees. You know, once we went to primary care assignment they identify with that person, they create more of a system, they understand that they are part of a system. So I think the better we can explain that and help people understand that I think the better off we will be.

So I would just -- hopefully we can take away from this a positive view of what's happening here, and what's going to, I think, continue to push people down the road of more risk and more downside exposure so that there is more innovation around changing care, and I think we'll continue to see positive results. But I'd really like to see us take on the idea of educating beneficiaries, being

able to interact with beneficiaries in a much, much more direct way, and also this idea of primary care or physician assignment.

DR. CROSSON: Thank you, Warner.

Karen, a brief Drew Brees kind of factual would be allowed.

DR. DeSALVO: Like where he's best throwing passes -- short.

I want to just maybe underline some themes, that it seems that the program, as designed originally, or conceived, was to get people into better care management, and it's really, in some ways, maybe we're seeing some claims avoidance behavior. And so that care management piece, I feel like when the beneficiaries switch or for whatever reason are no longer part of the ACO, it's almost like they're being released into the fee-for-service wild, and that's the time when they may need the most care coordination, because they're having a lot of complexity. So the implication is along the lines of what Pat just shared, and Warner, that we really need to think about a world in which this is not a side business but there is accountability entity responsible for total health and

total cost of every Medicare beneficiary, so that they have a quarterback to help manage their care.

I want to just make two other points. One is that some of the physician results make me think about aligned incentives also, in that there's some writing from that world of physician ACOs that more proximate incentives, proximate understanding about quality and outcomes and also alignment really does change some of the practice behavior on the front lines, a little bit of what came up in this conversation with Bruce. So it's maybe not a comment but a question I'd love to tease out a little bit of. Is there something about that importance of aligning the incentives for the physicians? It's not just having an accountable entity.

And the final point is about selection, which is there are lots of ways. It seems that there's claims avoidance and selection happening. I just want to put on your radar the world in which big data is allowing plans to not just look back at who was in the hospital and was expensive but look forward and do that using retail data and social data. And it's turning into an entire industry that -- and most of its conception is about claims

avoidance, how to not allow people into your plan, but in its best format could be a real opportunity for care management to help identify people who are going to be in trouble, and wrap your arms around them and help them into the future.

Thank you.

DR. CROSSON: Thank you, Karen. And Sue.

MS. THOMPSON: I will also be brief. But thank you again for this chapter. And, David, I think it was you who said in the beginning of your remarks that this is data from 2015 and '16, and there are a lot of changes coming in '19, that I just think it's important for us to put in context here. What we are looking at here in '15 and '16 are primarily, predominantly ACOs that were upside only, and in '19 -- and I think it's important in terms of sort of the pace and the urgency, those of us who are in ACOs are feeling about the impact that the changes in '19 are going to make on continued enthusiasm for remaining in ACOs. I mean, basically the risk coding and the quality becomes just baseline expectation. We're rebasing. So there's going to be a lot of industry sort of, "Oh, my god, do I want to stay here or not?"

So I agree with Warner. This is probably the most enthusiastic I have felt the Commissioners about ACOs, despite the fact, you know, the results are still in question. But I would remind everyone, what we're looking at here is upside only ACOs. So just to keep that in perspective.

A couple of points I want to make. On page 5 you did reference the Pioneer ACO, predominantly urban. I am fairly familiar with one that was quite rural and quite small, so don't forget those organizations out there that are cost-based, that are rural, that probably have specialists providing primary care, that are probably messing up the whole specialist attribution model. Because I don't want to lose that portion of our country in staying engaged in this work, thinking that they're somehow going to be outside and exempted from. Just a call-out for the old rural Pioneer ACO. Thanks.

DR. CROSSON: Thank you, Sue, and thank you, Jeff, for this breakthrough research, and David and Luis for the presentation, and thanks to the Commissioners for this discussion, the pathway to value-based payment leading to better care and less expense for beneficiaries in the

program. Part of that lies through ACOs, and I think the work here, continuing work to get that improved, is something that we will dedicate ourselves to.

We have now finished the discussion and we have the opportunity for public comment. If there are any of our guests who would like to come up and make a comment, please come to the microphone so we can identify you.

[No response.]

DR. CROSSON: Seeing no one at the microphone we are adjourned until our meeting in March. Thanks very much. Safe travels, everyone.

[Whereupon, at 11:45 a.m., the meeting was adjourned.]