MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Thursday, January 16, 2020
9:04 a.m.

COMMISSIONERS PRESENT:

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AGENDA PAGE

P R O C E E D I N G S

[9:04 a.m.]

DR. CROSSON: Okay. Let's come back together again. We can begin. I'd like to welcome our guests to the January meeting of MedPAC.

We have two very important policy issues on the table for this morning's discussion. The first one is going to be a continuation of our work on restructuring Part D. We have Shinobu and Rachel and Eric here, and Rachel is going to start.

DR. SCHMIDT: Good morning. The Part D drug team is here to cover two things this morning.

First, we'll present an abbreviated version of our annual status report on Part D, and we're happy to take any questions you have from the draft March report chapter that was in your mailing materials.

Second, we'll spend most of our time continuing the conversation we've been having for about a year now about restructuring Part D. Today we hope the conversation turns to specific parameters related to the restructuring. If you come to a consensus, we'll be back in March and April for you to vote on a combined package of

recommendations.

In 2019, among more than 61 million Medicare beneficiaries, 74 percent were enrolled in Part D plans. Just over 2 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 23.6 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.

Medicare program spending for Part D was more than $83 billion in 2018, predominantly for payments to private plans, and $800 million for the RDS. Part D makes up about 13 percent of total Medicare spending.

In addition, Part D enrollees directly paid over $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 plans.

Since the start of Part D, enrollment has grown at about 5 percent per year overall, but with faster growth

in Medicare Advantage drug plans than stand-alone PDPs. In 2019, 44 percent of enrollees were in MA-PDs and 56 percent in PDPs. Twenty-eight percent of all Part D enrollees receive the low-income subsidy, which provides extra help with premiums and cost sharing, which is down from 39 percent in 2007. Since 2010, many employers have moved their retirees out of the RDS and into Part D plans set up for them. Today about 16 percent of all Part D enrollees are in employer group plans.

The average Part D premium across both PDPs and MA-PDs decreased slightly in 2019 to $29 per month. Average premiums have remained at around $30 per month since 2010 despite big growth in catastrophic benefits. However, there's wide variation in Part D premiums across individual plans.

Plan sponsors offered more options for 2020, with higher growth in MA-PDs relative to PDPs and in special needs plans with drug coverage. There are also 13 percent more PDPs that bid low enough to make them premium-free to low-income subsidy enrollees.

This table compares Part D spending at the first full year of the program, 2007, with 2017 and 2018.

The direct subsidy is a 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 cost of prescriptions filled in the catastrophic phase of the benefit. Those two subsidies combined are designed to cover about 75 percent of the cost of basic benefits for all enrollees. Medicare's low-income subsidy payments to plans cover the extra help that LIS enrollees receive for cost sharing and premiums. You can see that total Medicare program spending for Part D increased from $80 billion in 2017 to $83 billion in 2018.

What we've been concerned about is that Medicare's payments to plans based on cost have grown while those based on risk have declined. Reinsurance has grown by an annual average of 16 percent since 2007, totaling $40.9 billion in 2018. Reimbursement to plans for low-income cost sharing makes up the vast majority of the $28.6 billion of LIS spending, and LIS spending has increased by 5 percent annually. With low-income cost sharing, plans are paid their actual costs. Meanwhile, between 2007 and 2018, the direct subsidy, which is risk-based, decreased by

nearly 3 percent. Risk-based payments generally provide sponsors with stronger incentives to manage benefits.

Part D uses a market-oriented approach in the sense that private plans compete for enrollees based on the drugs they cover, cost sharing, pharmacy networks, and premiums. The original intent was to give plan sponsors strong financial incentives to manage benefits by having them bear insurance risk. For plans to come out ahead, their revenues from premiums and capitated payments need to be higher than benefit spending and administrative costs.

Under Part D, plan sponsors use PBM tools such as formularies with tiered cost sharing, rebates from manufacturers, and negotiated payment rates with pharmacies. To help ensure appropriate access, CMS places restrictions on some of these tools that are tighter than what plans can use for their commercial clients. Shinobu will review some of these in a minute.

Part D includes Medicare subsidies, risk-sharing, and a late enrollment penalty. At the start of the program, those features were intended to encourage market entry by plan sponsors and broad enrollment among beneficiaries. But since then, many things have changed.

Early on, plans were successful at switching enrollees to generics for many widely prevalent conditions like high cholesterol.

By 2010, manufacturers had shifted focus to specialty drugs that treat conditions with smaller patient populations, like rheumatoid arthritis and cancer. These newer therapies are often very expensive, and their list prices grew rapidly.

Part D's benefit design changed. The Affordable Care Act called for phasing out the coverage gap for beneficiaries who don't receive the low-income subsidy. To help finance the more generous benefit, manufacturers of brand-name drugs were required to discount their products in the coverage gap. However, the discount makes the relative price of brands artificially cheaper to plans and enrollees, and this is one of the key reasons Part D needs to be restructured.

There has been rapid growth in Medicare's cost-based payments to plans -- that is, reinsurance for 80 percent of catastrophic benefits and low-income cost sharing. Most enrollees who reach the catastrophic phase receive the low-income subsidy, so growth in low-income

cost sharing interacts with growth in reinsurance.

On the right, you can see growth in costs above the out-of-pocket threshold, shown in orange. In 2018, 41 percent of spending was in the catastrophic phase, paid mostly by Medicare. That's more than double the share in 2010. The pipeline shift, changes to Part D's benefit structure, and misaligned incentives have all contributed to this trend.

Over time, these factors have led to a situation in which plan sponsors are responsible for much less Part D benefit spending than they were at the start of the program. We borrowed the idea for this slide from a recent article by Erin Trish, Paul Ginsburg, and colleagues. On your left we compare our estimates of the distributions of Part D claims costs net of rebates for beneficiaries without the low-income subsidy in 2007 and 2017. On your right are similar distributions for LIS enrollees. We don't have detailed rebate data, so for this we assumed that plan and Medicare reinsurance spending was reduced by the average percentage rebates reported in the Medicare Trustees report. We applied the same percent rebates to non-LIS enrollees and LIS enrollees.

If you focus on the blue portions, we estimate that among beneficiaries without the low-income subsidy, plans' responsibility for net spending decreased from 53 percent in 2007 to 29 percent by 2017. Among LIS enrollees, plan liability fell from 30 percent of net spending to 19 percent. Notice that Medicare's cost-based payments in gray (reinsurance on the left-hand side and the combination of reinsurance plus low-income cost sharing on the right) have increased substantially.

In 2016, the Commission recommended a package of changes to address some of the same concerns we just talked about. The recommendation would phase in an increase in plans' liability for catastrophic benefits from the current 15 percent to 80 percent while simultaneously increasing capitated payments in order to return to an incentive structure more like what we had at the start of the program. The package would also give plan sponsors greater flexibility to use formulary tools and would modify LIS cost sharing to encourage use of lower-cost products.

Subsequently, however, benefit design changes, an increase in the brand coverage gap discount, and increased spending for specialty drugs have further reduced plans'

incentives to manage spending. In some cases, the changes encouraged preferential formulary treatment of high-priced, high-rebate drugs, which increases both program costs and premiums. The focus on rebates may also have affected how some manufacturers price their products.

To show you how incentives are misaligned, let's look at the benefit structures for enrollees without the low-income subsidy on the left and with the LIS on the right. These figures depict the benefit for brand-name drugs and biologics. The region between the initial coverage limit and the out-of-pocket threshold is called the "coverage gap."

As you can see, in the coverage gap, plans, shown in blue, are responsible for just 5 percent of brand spending on the left and, on the right, none of the spending for LIS enrollees. Plan liability is 15 percent in the catastrophic phase for both types of enrollees. Based on CMS data, rebates on brand-name drugs average nearly 30 percent. That means for some brand-name products, the value of rebates exceeds plan's benefit costs.

Another thing to note is that for beneficiaries

without the LIS on the left, the 70 percent manufacturer discount in the coverage gap applies only to brand-name drugs. For generic drugs, plans are liable for 75 percent of the costs in the coverage gap. This artificially lowers brand prices relative to generics, distorting price signals.

There's no manufacturer discount for LIS enrollees on the right. Medicare's low-income subsidy pays for the cost sharing throughout the entire coverage gap.

In addition, Medicare's reinsurance pays for 80 percent of the costs above the out-of-pocket threshold.

So, what this shows is that the current structure doesn't provide strong incentives to push back on high prices or to manage spending for high-cost beneficiaries.

One way to restructure the benefit would be to eliminate the coverage gap and make plans liable for a consistent 75 percent of the benefit up to the out-of-pocket threshold for all beneficiaries.

In the catastrophic phase, Medicare would provide lower reinsurance, and the remainder would be a mix of plan liability (which would be financed through a higher direct subsidy) and a new manufacturer discount.

MS. SUZUKI: Potential reforms consist of two major changes that build on the Commission's 2016 recommendations.

The first set of changes would revise the defined standard benefit for all enrollees and make plans responsible for a consistent 75 percent of spending between the deductible and the out-of-pocket threshold.

The second set of changes would restructure the catastrophic benefit to provide all enrollees with a complete insurance protection and shift insurance risk from Medicare to plan sponsors and manufacturers.

These changes would restore the risk-based approached envisioned for the program and eliminate structures that distort market incentives for plan sponsors and beneficiaries.

Both sets of changes are integral to ensuring that plan incentives are better aligned with Medicare and that they are consistent throughout all benefit phases.

Here is an example of the parameters of a restructured benefit compared with the current benefit. We are hoping this would help facilitate your discussion today.

In this example, we kept the annual out-of-pocket threshold to be roughly equal to the amount paid by beneficiaries under current law.

Focusing first on the top half, under the restructured benefit, the coverage gap discount that applies to non-LIS enrollees and the coverage gap for LIS enrollees would be eliminated. These changes would make plans responsible for a consistent 75 percent of spending between the deductible and the out-of-pocket threshold.

The restructured catastrophic benefit would eliminate enrollee cost sharing to provide complete insurance protection. Medicare's reinsurance is lowered from 80 percent to 20 percent as in our 2016 recommendations. A new manufacturer discount would apply to brand and other high-priced drugs.

The 20 percent discount applied to all enrollees' prescriptions would have roughly offset the loss of coverage gap discount and the cost of the hard out-of-pocket cap in 2018. The remainder would be plan liability -- 60 percent for brand and other high-priced drugs and 80 percent for lower-priced generics.

In thinking about the catastrophic benefit, I'd

like to draw your attention to two items.

First, the manufacturer discount, which is 20 percent in this example, applies at the point of sale, meaning that the relevant price here is the prices they see at the pharmacy before any post-sale rebates are applied.

Second, plan and Medicare's shares would be calculated after accounting for post-sale rebates. So that means the actual plan share is a smaller share of gross spending than what's shown on the slide.

In order to help ensure a successful transition to a restructured benefit, we would need other changes.

Changing from the status quo would have a lot of moving pieces, and policymakers may want to phase in changes over time to allow plan sponsors to adjust to the new benefit structure.

Under the restructured benefit, it would be especially important for CMS to recalibrate risk adjusters because more of Medicare's premium subsidies would be capitated. There may be other ways in which to improve Part D's risk adjusters.

In addition to reinsurance, Part D also has risk corridors to protect plans at an aggregate level from

unanticipated losses. We may want to consider changes to the risk corridors, at least during the transition to the new benefit structure.

To ensure plan sponsors can effectively manage spending, the reforms would be accompanied by more tools and formulary flexibility.

Under the proposed reforms, CMS would need to recalibrate the risk adjustment model to reflect the higher benefit liability.

CMS has experience recalibrating the RxHCC model. They do this as part of the annual change in benefit parameters. They also have successfully recalibrated the model in response to ACA's phase-out of the coverage gap and in response to the recent increase in the manufacturer discount.

To see if the risk adjustment could accommodate the expansion in the LIS benefit, we looked at the distribution of spending and found that LIS enrollees have higher average spending than non-LIS enrollees, but variation in spending relative to average spending is lower.

This suggests that CMS would face no more

difficulty recalibrating risk adjusters to reflect spending for LIS enrollees than for non-LIS enrollees.

At the same time, because the model uses Part D claims, there is a lag between when major new therapies enter the market and when they are reflected in the adjusters.

CMS could investigate ways to incorporate those new therapies more quickly to minimize the large and systematic under- or overpayments for conditions.

We've talked a lot about Medicare's reinsurance, which applies at the individual beneficiary level. Now we're going to talk about risk corridors, which provides a cushion at the aggregate plan level. The risk corridors limit plans' overall losses when actual costs are higher than expected.

Given the higher insurance risk associated with spending in the catastrophic phase, we may want to consider enhancing the risk corridor protection temporarily during the transition period.

One option is to narrow the corridors during the transition to the new benefit, giving plan sponsors more protection against the risk of overall losses.

Similarly, policymakers could consider a temporary change in the shares of unexpected losses and profits borne by plan sponsors and Medicare in the corridors so that Medicare bears more risk during transition.

While the enhanced protection would be available to all plans, larger plan sponsors will generally have the member size to absorb the effects of unexpected changes in the pharmaceutical market. As a result, in practice the enhanced protection would be most valuable to plan sponsors with smaller membership size.

Consistent with our standing recommendations, the reform package would be expected to give plans new tools and flexibility to manage spending.

Most Part D plans use tiered formularies with differential cost sharing to manage spending, but LIS co-pays do not distinguish between drugs on preferred, nonpreferred, or specialty tiers. In November, we discussed differentiating LIS cost sharing for preferred and nonpreferred drugs.

Another tool that could become increasingly important would target specialty drugs. Part D plans can

apply higher coinsurance for drugs placed on a specialty tier.

As pharmaceutical pipeline shifts more towards higher-priced products, there may be value to allowing preferred and nonpreferred specialty tiers to encourage competition. It could also promote the use of biosimilars when they become available.

Another area that would benefit from more flexibility is protected classes. Medicare requires plans to cover all drugs in the six protected classes. This makes it harder for plans to obtain rebates and manage spending.

The Commission has previously expressed support for giving plans greater flexibility with protected classes as part of our 2016 recommendations and subsequently when CMS proposed a policy change that would make it easier for plans to manage spending for protected class drugs.

At the November meeting, several Commissioners raised concerns that higher nonpreferred co-pays would increase cost sharing for LIS beneficiaries and may affect their ability to obtain medications. The evidence on the access is mixed at best. We'd be happy to discuss our

findings on question.

Here, we'd like to highlight the multiple layers of beneficiary protection that exists in Part D. One such protection relates to CMS's formulary requirement that ensures broad coverage of medications.

CMS also reviews plan formularies to ensure that there is at least one therapy on a preferred tier, except when the class includes only specialty tier drugs.

That means LIS beneficiaries, like the other non-LIS beneficiaries, would only face higher cost sharing if the individual and his or her prescriber selected a nonpreferred product over the preferred therapy.

Another protection is Part D's exceptions and appeals process. Tiering exception is one type of exceptions under which patients can request a lower preferred cost sharing for a nonpreferred drug when medically necessary.

So, under the proposal, LIS beneficiaries with such medical necessity could request an exception from the higher nonpreferred copay.

While there may be room to improve the exceptions process, based on the available data, the majority of

appealed cases are approved in favor of the beneficiary.

Our goal today is to get your feedback on this policy direction.

Here, we've summarized the key components of the reform package. The first piece creates a consistent benefit below the out-of-pocket threshold. The second piece changes the allocation of financial risk in the catastrophic phase. Combined, they would provide better incentives throughout all benefit phases.

The key questions we are hoping to get your guidance on relate to the distribution of insurance risk in the catastrophic phase, and, related to that, is whether an alternative discount rate or formula should be considered and whether some of the other issues we discussed should be an explicit part of the reform package.

If there is a consensus to move towards a recommendation, we plan to come back in the spring with more specific policy language that reflects your discussion today.

DR. CROSSON: Thank you, Shinobu, Rachel, Eric. It's clear that you've done a lot of excellent work between the last meeting and today, including over the holidays.

So we really appreciate that work.

We're now open for clarifying questions. I see Brian, Bruce, Marge, Dana. Brian, Bruce, Marge, Dana, Amol.

DR. DeBUSK: First of all, great work. I'm a huge fan. I enjoyed both chapters.

I'd like to start my questions, though, on Chart 6 of the presentation. I noticed we opened the chapter talking about with beneficiary cost sharing included, it's a $97.5 billion spend, Part D. But when we look at the gross spending, it's $168 billion in gross spending.

I'd always thought that the rebate was 27-ish percent nominally. I think the chapter even said 27 percent. This looks like 40 percent to me, or is there something I'm missing on Chart 6? It looks like there's about $68 billion that go away from gross spending to net spending, and where did that money come from?

DR. SCHMIDT: What 2018 -- sorry. My eyes are starting to --

DR. DeBUSK: Yeah. The two numbers add up to $168.1 billion in gross spending in both phases, but then program spending, including beneficiary spending, is $97.5

billion.

MS. SUZUKI: So these are gross spending, right?

DR. DeBUSK: Yes.

MS. SUZUKI: And the program spending does not include what's paid by beneficiaries in cost sharing and also does not reflect the rebates that plans get. So there are a couple of things that are not in the 80-ish billion.

DR. DeBUSK: Well, in the --

DR. SCHMIDT: And in addition --

DR. DeBUSK: The 97.5, though, I think that does include because enrollees paid $14.2 billion of that 97.5.

DR. SCHMIDT: There's also the --

DR. DeBUSK: I'm just trying to tie the numbers because I kept noticing that we would do net spending some and gross spending some.

MS. SUZUKI: Yeah.

DR. DeBUSK: And it looks like there's about 68-ish billion dollars.

MS. SUZUKI: So we can get back to you on the breakout of the difference, but it's a little bit complicated. This really shows the total gross spending, and we were just saying there's some enhanced benefit

spending amounts that are reflected in the gross total.

DR. SCHMIDT: So that's supplemental benefits.

DR. DeBUSK: Oh, okay. So the difference -- so the rebates could be 27 percent, and the delta could be the supplemental benefits.

DR. SCHMIDT: Right.

DR. DeBUSK: So there's probably another -- 27 -- 30-ish billion in --

DR. SCHMIDT: There's employer spending in there too for wraparound coverage and other kinds of --

DR. DeBUSK: Okay. I was just trying to make the numbers tie because it looked like -- I mean, the rebates are astronomical. It just looked like they were even bigger than I thought they would be.

I guess then we'll have to do -- this will turn into a follow-up question too because on Chart 4 of the presentation, I was going to ask you to take the 2018 column and sort of back me into what the gross spending would look like. But that's probably not a -- you could do it off the top of your head, but you're going to pretend like you couldn't. So we can do it in follow-up.

DR. SCHMIDT: It would be messy. So it's

probably best to come back to you.

DR. DeBUSK: Okay, okay.

Let me go through -- also, when we're talking about the coverage gap discount program and we're talking about the new program where we would charge manufacturers, is that based on price at the counter? That's the counter price, which is really close, Bruce was telling me, to the WAC, basically. For all intents and purposes, it is the WAC.

So final question, it looks like the coverage gap discount program, about $9 billion, you know, what we would raise at the 70 percent threshold. In the reinsurance phase, it looks like you're collecting about $20 billion, right? If you're about 20 percent? I mean, it looked like the rate went up. Where did that come from?

MS. SUZUKI: So 20 percent included covering the gap discount amount inflated for the 70 percent discount because the data was for 50 percent discount, and then there was the out-of-pocket cap cost, so converting the cost sharing amount or long-term cost sharing amount into the basic benefit cost.

DR. DeBUSK: It just looked like the amount of

money we were going to collect from manufacturers went up.

MS. SUZUKI: It did.

DR. DeBUSK: It looked like about 100 percent, a little more than 100 percent, or did I do the math wrong?

MS. SUZUKI: It's not quite 100 percent, but I think what we started out with was data on 50 percent manufacturer discount in 2018, which we inflated to reflect what would be under the 70 percent manufacturer discount.

DR. DeBUSK: And that got you to $9 billion, I think.

MS. SUZUKI: Right.

And we also added on the cost of converting the cost sharing amount, which I think were a couple billion dollars for --

DR. SCHMIDT: So that the added new part of the benefit of having out-of-pocket cap, we needed a higher discount rate to pay for those benefits as well. We were trying to look at what rate it might require in a cap discount in order to cover that.

DR. DeBUSK: Okay. So the payments from the manufacturers under this new -- under this particular proposed arrangement would about double?

MS. SUZUKI: Relative to the 50 percent discount?

DR. DeBUSK: Yeah. Relative to the $9 billion now.

MS. SUZUKI: Oh. Relative to 70 percent?

DR. DeBUSK: What would the new number be?

MS. SUZUKI: I can go back and check. I don't think it quite doubled the amount because it would apply only to the brand -- our calculation reflected just on average, just brand-name drugs in the catastrophic phase, which is not the entire gross spend. And we thought it added to about 9-plus, couple more billions to reflect the out-of-pocket cap, but we --

DR. DeBUSK: Oh. So it's pretty close to a wash, then. The money is pretty close to even?

DR. SCHMIDT: Right. So, again, it was designed -- we were trying to find what rate it would take --

DR. DeBUSK: Okay.

DR. SCHMIDT: -- to accommodate what's now coverage gap discount at the higher 70 percent rate plus the new benefit of adding an out-of-pocket cap.

DR. DeBUSK: My mistake. In the reading -- I'm glad I asked that question. In the reading, it appeared

that there was an increase in what we expected to collect from manufacturers, a pretty dramatic one, but I was mistaken.

Thank you.

DR. SCHMIDT: I think there was something in the reading saying that -- you know, we were trying to say we're not doing a cost estimate here. That's CBO's purview, and part of what they have to do is think about how the share of high-cost drugs will change into the future and what the distribution of spend will look like. So the exact -- there's some fuzziness around the exact discount rate one might need to cover this or that benefit.

DR. DeBUSK: Thank you.

DR. CROSSON: Thank you.

Bruce?

MR. PYENSON: Let me echo Brian's appreciation for all of this work. It's really, really amazing work.

I have a question on Slide 7, and I think, Rachel, you characterized this as after-rebate dollars. There's a 13 percent other in 2017 for non-LI population. What is that?

DR. SCHMIDT: So that's mostly the supplemental

coverage of employers and other small, like out-of-state assistance programs and that sort of thing.

MR. PYENSON: Ah, okay. Thank you.

To get to the post-rebate numbers, was that a uniform percentage by category or --

DR. SCHMIDT: Go ahead.

MS. SUZUKI: So we applied just a flat percentage rate across both populations, partly because I think depending on the drug classes, there could be higher or lower amounts. But we couldn't think of a consistently higher or lower reason for one population compared to the other.

So just to be conservative, we just said same rate, same rebate rate applies to both populations.

MR. PYENSON: How about within the verticals? The portion of rebate netting the federal portion, was that the federal portion of rebates netted against federal spending?

MS. SUZUKI: Exactly. So we used how CMS would calculate the DIR applied to reinsurance in order to come up with the figures.

MR. PYENSON: Okay. Thank you.

Another question. I think in 2017, the Commission looked at changes to the risk adjustment process where we recommended using two years of data, and I'm wondering if that's something you thought about for risk adjustment for Part D.

I think the focus of our earlier work was really Part C, but have you thought about that for Part D?

MS. SUZUKI: We have not, but we could certainly think about it in the future whether using two years' data improves the under- or over-estimate based on condition categories.

I think one thing we were highlighting is in the pipeline for the future year, which is not going to be in your data, there may be new drugs that are launched that would not be reflected and if there's other ways to account for that launch in the risk adjustment model as well.

MR. PYENSON: In particular, I think the disappearance of certain codes, like the apparent cure of diabetes in patients who just weren't coded, wouldn't be the issue so much of new drugs, but more relying on encounter data without coding optimization, I think, was

one of the dynamics we were looking at there.

Thank you.

DR. CROSSON: Thank you, Bruce.

Marge?

MS. MARJORIE GINSBURG: Thank you, and thanks also for such a fabulous report.

I have a very basic question on page 3. You mentioned that 44 percent are in MA plans, and 56 percent are in individual PDPs. I'm curious. Since only about a third of the population are in MA plans, how come 44 percent are in drug plans affiliated with that, unless people who are in original Medicare, many of them are not purchasing Part D plans at all, which would then change the statistics? So that's question one is those statistics.

And the other is, do we ever separate out the drug use of the pattern of drug use of those in MA plans versus those who are in independent PDPs?

DR. SCHMIDT: I'll take the first one.

So to start out, I noted that about 74 percent of all Medicare enrollees are in Part D, so not everybody is in. So I think that's getting to why the MA share is higher.

The ones who are not in tend to either have either employer coverage or no coverage, and yes, they're probably more likely to be fee-for-service.

MS. SUZUKI: On the PDP versus MA-PDs, we do annually track the trends in the two populations in our June data book. MA-PD enrollees tend to have lower spending than non-PDP enrollees, and that's partly reflecting the population. The MA-PD enrollees are less likely to have low-income population. So some of that is that.

But even when you compare the same non-LIS population, there may be some differences, and we've seen generic use rate be slightly higher among the MA-PD population.

DR. CROSSON: Okay. Thank you, Marge.

Dana?

DR. SAFRAN: Thank you. This is momentous work. So thank you for these chapters.

My first question relates to some information you had in the chapter and you summarized on page 6 about the what's changed since 2006, and included there was brand manufacturers developing more high-priced specialty drugs

for very narrow populations.

I didn't see anything about what role, if any, we think that Part D had in stimulating that change, because I know when I was closer to this area of work was before implementation. And one of the biggest concerns was the challenges of getting manufacturers to develop therapies for small populations, rare diseases, et cetera. Do we think Part D has played a role in that shift?

DR. SCHMIDT: I suspect so.

You know, when the program began, all of a sudden, this big bolus of people had coverage, and we saw increased utilization. And at first, it was for the big blockbuster drugs for chronic conditions, and we saw a lot of spending associated with that. And I'm sure the manufacturers were happy, but they already had those products on the market. And then generics entered in the 2010, especially 2012 time frame. There was a big cliff, all of a sudden, where a lot of patent exclusivity ended and people, the plans and pharmacists are just switching people over to using generics. And so there went a whole lot of revenue, right?

But now you still have people with a lot of

coverage, the Medicare population and D in particular. So I'm sure that probably motivated investment in things like oncology treatments and other smaller population drugs.

DR. SAFRAN: Yeah. Okay, thanks. I think that's an important piece.

DR. PAUL GINSBURG: Dana, not in too much depth, but the regulatory environment, FDA approval, as many people have said, has had a big impact on the shift towards drugs for small populations, rare diseases, because it's less expensive to get them approved. Exclusivity is longer. So it's really hard to sort, and I don't know when those changes happen.

DR. SAFRAN: Yeah. Thank you, Paul.

Okay. A second question I had relates to what you show on Slide 10 about the proposed restructuring. I'm curious what impact you've considered that this might have on plan premium, you know, as plans take on this greater liability. It's striking in the chapter -- and you had a visual of it -- that premiums -- despite what's been happening with spending, premiums have stayed at about that $30 mark, which is quite remarkable. I found myself wondering how has that been possible, and then you look at

what the plan liability has been over time. And you start to understand why it's possible.

So I then look at this, and I wonder what do we expect to happen and what have you thought about in your modeling around plan premium costs.

DR. SCHMIDT: So the answer to that partly depends on the parameters selected, right? The answer depends partly on the parameters you select for things like the manufacturer discount in the catastrophic phase, but I think you're probably alluding to that over time, we might see -- if more of the spending continues to be in the catastrophic phase of the benefit and now beneficiaries have no out-of-pocket spending in that region, that probably will lead to some premium increases.

DR. SAFRAN: I'm going to hold it there, but I have other things, I think, that are better for Round 2. Thank you.

DR. CROSSON: Okay. Thank you.

Amol?

DR. NAVATHE: So, on that point, on page 21 of the reading, it sounded like you had done some estimates that increases in premiums by $4.80 per month. At least

based on some parameters that we might pick, is that roughly what we would expect, which seems like it's about a 12 percent increase in premiums?

DR. SCHMIDT: I think that piece of it was just associated with filling in the coverage gap.

DR. NAVATHE: I see.

DR. SCHMIDT: So, you know, throughout the paper there are different descriptions of where you might set a manufacturer discount, and again, these were estimates based on 2018 data alone. We can't do cost estimates. So this is just to give you a sense of things. And we'll have to -- if you come up with a package or a recommendation we'll have to go to CBO and ask for an estimate.

But this is to give you a sense of things. So there was one estimate of 15 percent, was to replace the current coverage gap discount of manufacturers, and then 20 percent would accommodate both that and increased benefit spending associated with an out-of-pocket cap. And then there was a higher rate of -- I think it was 35 percent-ish, would cover the cost of filling in the coverage gap for all enrollees.

So that was to give you a sense of the range of

what a discount might need to be to cover all of those costs. If you had a lower discount on the order of 20 percent and did not increase to cover the coverage gap, then it would require a premium on the order of 5 dollars a month. That was that estimate.

DR. NAVATHE: Great. Thank you for explaining that. And so I guess taking a step back, I have a few different questions. I want to definitely commend you for unpacking something that's very complicated and making it digestible, although I have to admit I didn't follow everything still.

So a couple of questions. So one thing is in -- you did a sort of side box on the impact of cost-sharing on subsequent beneficiary behavior, patient behavior, in terms of acquisition. But because we're talking about premiums here, I'm curious if we've done any review also on the effect of premiums on participation, because that may end up being a pretty important piece of sort of a data point for us to also be considering.

MR. ROLLINS: So off the top of my head I can't remember studies that have been done on premiums, but I think one thing to keep in mind is, again, like Rachel

said, there's a lot of moving pieces here and so the net impact on the premium is unclear. But it's quite possible that the end result of this will be, even if premiums do go up, the increase may not be particularly large. So it's not clear that to the extent there is a feedback on participation, it may not be very substantial.

Also, there is evidence that people do periodically change plans in Part D, to some extent. It's not a huge number that change every year. But one factor that does seem to drive changes in plan behavior is if your premiums go up.

DR. MATTHEWS: And just one additional point if I could. There is an indirect example on the effect of premiums on people staying or leaving their Part D plan when an LIS beneficiary is in a zero-premium plan that experiences a premium increase, it is not uncommon for that beneficiary to stay in that plan and pay the additional premium.

DR. NAVATHE: Sort of a status quo bias, so to speak. Yeah. Okay. That's helpful. Thank you.

So a couple of truly clarifying questions. So one is, it looks like there's two different estimates for

plan liability when we look at 2007 to 2017, and I suspect I'm just missing what it is. So on Slide 7 here we saw 53 percent going to 29 percent, and then on Figure 6, on page 53 of the readings, there is a 75 percent to 40 percent plan liability estimate. And I suspect it's just I'm missing what the denominator is between them, but I was wondering if you could help clarify that. It was page 53, Figure 6 of the status report readings.

MS. SUZUKI: So one difference is we're separating the populations, so the one you're looking at is for non-LIS population. The figure you're talking about combines all of them. I think that is the primary, and this includes the premium.

DR. SCHMIDT: Right, and it's not just basic benefits on this one.

MS. SUZUKI: Right. So Figure 6 is limited to basic benefits, and we're trying to figure out what percent is paid on a capitated basis to plans. This figure, we did not separate out the supplement benefit component, so that also changes the denominator.

DR. NAVATHE: Okay. Thank you. Thank you for clarifying that.

One other question. So when we talked about risk corridors -- I forgot which slide you actually mentioned it, but you talked about it; I think it's Slide 15 -- the plans being fully at risk for less than 5 percent of the aggregated expected benefit cost, and I was curious if we have looked at -- I guess this would have to be some sort of modeling -- what that would translate to in terms of the plan risk. Effectively if we try to calibrate it to the 53 percent, 29 percent type number, what would we expect that risk corridor level to roughly look like to give us some sense of what that threshold actually means for a plan.

MS. SUZUKI: So one maybe clarification. So the 5 percent is the corridor percent, right, and when the program began, I believe the corridor was narrower, the 2.5 percent around their bid. And so we were thinking there could be something similar that you narrow the corridor so the protection starts earlier. And one other justification for that would be that what's in the corridors would increase, in dollar terms, relative to what's in the corridor currently. So even the 2.5 percent may be similar to what's protected under corridors but 5 percent.

DR. DeBUSK: On that, what percentage of plans

hit their upper risk corridor in 2018?

DR. SCHMIDT: We don't know that yet. We don't have the information. We haven't been able to get much detail about that information for the past several years. But --

DR. DeBUSK: Over 50 percent hit their upper corridor, though, don't they?

DR. SCHMIDT: Through 2015, we know that's definitely true.

DR. DeBUSK: So over half the plans blow out the top end of their risk corridor.

DR. SCHMIDT: Right.

DR. DeBUSK: Okay.

DR. NAVATHE: So --

DR. CROSSON: Let's see. Where are we?

DR. NAVATHE: Sorry.

DR. CROSSON: You're still up?

DR. NAVATHE: No, I wanted to just clarify on this point. So, okay. So I think I understand the concept of the risk corridor, but at the end of the day, so when you look at the aggregate spending, we should be able to back out what the overall plan liability would have been,

given that they're capped at 5 percent, or whatever they're capped at. And so that would be -- that may not be something that we have off the top of our heads but I think it may be helpful to interpret that estimate. Otherwise, the 5 percent sort of lives in its own sphere. So if we don't have that maybe that would be helpful.

I'm done. Thanks.

DR. CROSSON: Okay. So Warner, I saw your hand. On this point or are you just --

MR. THOMAS: I just have a couple of quick questions.

DR. CROSSON: Okay. All right. And then Kathy. And so we've got Pat, Jon, Larry, Warner, Kathy. We're now approaching an hour for the question phase here, so I'd ask you to be relatively brief so we can get on to the discussion. Thanks.

Pat?

MS. WANG: This is a question on the cap discount. On page 26 -- and you referred to it just now -- elimination -- so 20 percent is the number that has been kind of used for purposes of modeling or what have you, but there's a reference on the top of page 26 that if one were

to consider the elimination of the coverage gap for LIS, the cap discount would be 35 percent.

So I just wanted to ask you to explain a little. I'm not sure I fully understand. So the 35 percent would represent across LIS and non-LIS? Okay. What if it were just LIS? How big would it have to be to sort of capture the elimination of --

MS. SUZUKI: Are you talking about how -- what percent rate is needed to cover what's currently LICS?

MS. WANG: Yeah.

MS. SUZUKI: So what we estimated from the 2018 data is that roughly a 15 percentage point difference between doing everything but the LICS phase-out for the coverage gap. And so 35 was including everything. Twenty was the number that just offset the current coverage gap discount, and the cap on the out-of-pocket costs.

MS. WANG: Right. Okay. So thank you. So I guess what I'm trying to get at is, because this modeling is sort of averaging across LIS and non-LIS, and I'm trying to understand better what it would actually be like. Let's say that there's a plan that is exclusively serving LIS. So if the cap discount is 20 percent, if the cap discount

is 35 percent, what I'm trying to get at, is there a differential impact on -- let's, in my example of a plan that serves exclusively LIS -- is there a differential amount of risk shift that is going to the plans serving the LIS?

MS. SUZUKI: We can try to take a look. I think part of the thing we need to think about is how much of the spending for the LIS population is in the catastrophic phase versus the below the threshold, and to date, more people, more LIS population reaches the catastrophic phase and they do account for the majority of spending. So in that case, the more people you have in the catastrophic phase, the more you would get out of the 20 percent discount, because you have more spending in that phase.

So it's not clear whether it would be less for a plan with more LIS.

MS. WANG: I guess I'm trying to understand the relative situation that a non-LIS plan is facing in terms of proportionately. Would a plan with non-LIS be accepting less of a risk shift than a plan with LIS, if you were to maintain the same cap discount that is averaged across both types of plans.

DR. SCHMIDT: So remember, though, that -- so for non-LIS enrollees in the coverage gap that their plans are liable for 5 percent on brand-name drugs. So it's not much more than what the LIS-heavy plans have too. So I think it's fairly sizeable risk in both cases.

MS. WANG: Is there -- I guess where -- and I'm just really asking because I just really don't know -- is there -- the whole approach towards this has been LIS and non-LIS have different benefit structures, which is well illustrated in the different pictures. The thrust of this is to have one unified benefit structure that covers both LIS and non-LIS, and I'm trying to tease out whether there is a differential impact proportionately on plans predominantly serving LIS members, because maybe more risk is shifting to them.

I mean, there's risk in general because of the need for the population and the high level of spending and the vulnerability of the population, but is there something in the structure of the cap discount and the idea of homogenizing everything that will have different impacts, better or worse, for plans that are in this different benefit structure today?

MS. SUZUKI: And we can definitely think about the impact separately on the cap discount. So one statistic we have in the past is that two-thirds or more of the spending in the catastrophic phase is incurred by low-income population. So you're taking, let's say, 20 percent of that in manufacturer discount for the LIS population versus the one-third that's non-LIS times the 20 percent.

So there is going to be a differential impact depending on the usage of the drugs in the catastrophic phase and how much of that is brand or high-priced products. So we'll definitely think about that.

DR. CROSSON: Okay. We've got Jon, Larry, Warner, and Kathy. Jon?

DR. PERLIN: Thanks. Let me agree with Dana's framing. Momentous work.

Every proposal is predicated on intended effect. I did a search for both the Part D status report and the proposal on the terms unintended consequence, and I only found one reference, and that was Lieberman, Chowdhury et al. on the original Part D.

But what should we be thinking about as potential unintended consequences here, in this, as we contemplate

this?

DR. SCHMIDT: So I think Dana pointed to one thing, which was the potential for, over time, premiums to increase, and perhaps that's appropriate, though. If benefit spending is increasing and the government is subsidizing roughly 75 percent, then, you know, premiums might want to rise proportionately, because that's how the program is structured, unless you want to recommend something different.

We've also heard from Commissioners in the past the focus on if there's more risk borne by plans, smaller regional plans are fearful that they may not be able to bear that much risk and it might lead to consolidation. Those are sorts of things.

Another potential we've tried to address by looking at least at literature and thinking about is what might happen with respect to increased -- or differential cost-sharing for the low-income subsidy enrollees. You know, would they be less likely to remain adherent or not? And the literature on that, I think we showed you, was somewhat mixed, but the policy that we were suggesting to go hand-in-hand, which would be to have preferred and non-

preferred differential on the LIS cost-sharing would be applied in situations where there was a choice of therapies. So not necessarily leaving somebody with just higher prices. There would be another alternative, or they could seek an exception.

So those are the main unintended consequences. We didn't label things as such because we were trying to think through, as you prompted us at an earlier meeting, to think through what the unintended consequences might be.

DR. PERLIN: I appreciate that. As I think about it now I also wonder about the interplay not only within the dynamic of Part D itself but the dynamic with, say, Part B, as well, and even effect on drugs may, to the limited extent, is there -- I just get the sense of, you know, sort of push and pull. But thank you.

DR. CROSSON: Thank you, Jon. Larry.

DR. CASALINO: Thanks. Would it be possible to provide a bit more information, maybe with some simple modeling, on the likely annual out-of-pocket costs to LIS and non-LIS beneficiaries, kind of on average, and then maybe an example of someone who had a very low need for expensive medicines and someone who had very high, again,

LIS versus non-LIS. And so both their premium costs and then their -- which you'd have to kind of guess at what happened with those -- and their just out-of-pocket copays for drugs, what that might look like, on average, and then kind of high cost and low cost scenarios for LIS and non-LIS. I don't think you've already done that, at least that I've seen, or have I forgotten?

DR. SCHMIDT: No, we haven't done explicit modeling like that, at a beneficiary level, but yeah, I think the general outcome of this approach -- and again, depending on what parameters are selected for how the manufacturer discount is, how the distribution of risk looks in the catastrophic phase, it might tend to be that all enrollees pay a slightly higher premium to cover things like what's now a coverage gap, and higher benefit spending in the unified benefit. But those enrollees who have very high spending out-of-pocket today, because they're paying 5 percent indefinitely for high-priced drugs, would have a hard out-of-pocket cap. So they're going to see a really strong benefit there.

DR. CASALINO: Yeah. I mean, I think if I was a congressperson, I might be really interested in seeing what

these numbers would look like, just not meant just for the program but for my constituents. You know, what would be likely to happen. And I suspect some of them -- some of the numbers might look really good, for the reason that you just gave. But then for the LIS population, there's quite a bit of discussion in the report on even a very, very small increase in out-of-pocket costs might make quite a difference for people with chronic disease. And we had some debate about that at the last meeting. It might just be nice to see some numbers modeled as best you can model. I'm not talking about extension modeling. Almost more back of the envelope, based on your preferred structure for the restructuring of Part D.

And just a couple of very minor things. There is a sentence here -- I didn't mark the page number -- where beneficiaries can request an exemption. I think we discussed that a little bit last time. Generally speaking, it isn't the beneficiary who is going to request an exemption. It's the physician.

And this may seem like a small point, but we did discuss it last time. I think physicians feel that every day one more unpaid job gets given to them. And while it

may seem trivial to non-physicians, again, when you're talking to medical group leaders, when I asked them, can you just ask your people -- can you just have your people do one little thing, your physicians, and they say, "The physicians tell me, with gritted teeth, not one more thing." So just the language, I think, would be irritating to any physician.

And then two other -- one other language thing and then one other quick request.

Page 36 toward the bottom, I think -- I know you don't mean it this way, but I think to anyone who reads it, it might seem like an exceptionally cruel sentence, really. "Researchers found that for people with chronic conditions such as diabetes or schizophrenia, higher cost sharing for prescription drugs is associated with higher medical costs for services like inpatient care and emergency care." That's not cruel. This is the cruel one. "However, it is not clear if these added medical costs" -- in other words, these people are having to go into the hospital because they don't have their meds -- "are high enough to offset the lower spending in prescription drugs." I don't think you mean this, but it sounds like we're recommending, okay,

if Medicare can spend less on prescription drugs, it's okay if people wind up with unnecessary hospitalization. I know that's not what you mean, but it reads that way.

And just a last thing. In your appendix, you talk about the possibility of electronic prior authorization, and toward the end of that, the next to the last paragraph or so, you talk about how basically EHR systems, if I understand you properly, are set up deliberately to exclude competitors, so Optum won't allow electronic communication with CVS, Surescripts won't -- and so on. Is there any way that you can imagine that Medicare could -- we've had now many years of kind of EHR makers on their end and health plans on their end blocking access to competitors, and, again, it raises the effort for physicians considerably to request these prior authorizations or exemptions. Is there any way that you can imagine that Medicare could require that to participate you can't do that?

DR. SCHMIDT: I think Karen might be able to answer some of these issues better than I can.

DR. DeSALVO: About how the technology can support the front line?

DR. CASALINO: The technology can do it. It's a business decision, right?

DR. DeSALVO: Yeah, it is, and thank you all for the appendix, by the way, in the chapter talking about some of the strategies. Yeah, I mean, it's culture and business decisions, I think some of it is, absent understanding that sometimes the technology can be embedded in the work flow and improve what we want to do. Doctors have a knee-jerk reaction, probably appropriately, to saying not one more thing, which is what you're saying Larry. And I don't think the technology feels as seamless as it should. Even if it's technologically feasible, a lot of systems are choosing not to facilitate that for obvious reasons.

DR. CROSSON: Okay. Sorry. Warner.

MR. THOMAS: Jay, I'm going to hold until Round 2.

DR. CROSSON: Okay. Kathy, last question.

MS. BUTO: A quick question, really the flip side of what Pat was getting at, which is before beneficiaries hit the catastrophic cap, I'm wondering if you feel confident, having read the chapter -- it feels like you do, but that the risk adjuster plus potential narrowing of the

risk corridors and some additional cost sharing for LIS beneficiaries is sufficient to give plans the tools they need, especially those plans that have a lot of LIS beneficiaries, sufficient tools to absorb that 75 percent risk for those beneficiaries. I wonder if you have a comment on that.

MR. ROLLINS: I think that's right, and we talked about this some at the presentation we did in November. We interviewed a number of plan sponsors about sort of taking on more risk in different phases of sort of drug spending. When we asked specifically, you know, how do you feel about if you were responsible for spending in what is now the coverage gap for the LIS population, by and large they seemed to think that was going to be a fairly manageable reform for them in that, you know, constrained range of spending, so they had a fairly good handle on sort of what their spending profile would look like in that range, and the sort of judgment seems to be that that was something that sort of could be picked up in the risk adjustment system.

MS. BUTO: So I'm just wondering. The risk adjustment system would suggest that spending -- there's

little variation in the spending for the -- it's higher per LIS beneficiary, but not much variation. It also suggests there isn't much room for, I guess, managing or influencing LIS beneficiary prescriptions. So that's why I wondered if plans, particularly those that have a high concentration of LIS beneficiaries, would feel they could really manage that risk.

MR. ROLLINS: The sense we got was that they thought they could.

MS. BUTO: Good, and you talked with high-LIS concentrated plans.

MR. ROLLINS: We did talk -- yes.

DR. CROSSON: And so one implication of that -- and I'll use this as a transition statement for the next section -- is as we put together this package, because that's what it is, for March and April, to what degree do we want to -- and you'll see this on Slide 18. To what degree do we want to include in our, and I would say, bold-face recommendations some of these elements that we think need to be there in order for this to work for those plans?

So having said that, let's throw up Slide 18, which is, I think, the listing of some of the specific

questions that the staff would like to get responses to, in addition to the general issue of support for this direction. And I think Paul has volunteered to begin.

DR. PAUL GINSBURG: Thanks, Jay. Let me also give my praise to the team up there for the really terrific work they've done on this. And I was struck when I was reading it about how responsive it was to our discussion in November and the issues that came up there.

To me, this is the most important policy topic that we're taking up in this cycle, and it's perhaps ratified by the size of the audience at the moment. And, you know, I think what we're talking about is that when Congress passed legislation that set up Part D in 2003, they opted for a private plan approach, that they decided not to do a single payer approach for prescription drugs the way Medicare does for hospital and physician services but to go with private plans that would be at risk. And to me, three things that have happened, as you've sketched out in the paper, since the implementation have really compromised the essence of the structure that Congress set up with private plans, and the three are: the policies to reduce the impact of the doughnut hole through substantial

manufacturer discounts that, you know, reduce the risk that plans faced. Another one was the growth of rebates for certain drugs, which created the situation where plans sometimes have incentives now to actually push the highest-priced drugs because of the rebate structure. And then also the development of new, very expensive drugs, price increases for existing expensive drugs have pushed so much more of the spend into the catastrophic phase.

So I think there's really some urgency in doing something about this because the Part D approach has been undermined. I think the risk corridor approach that you sketched out will be very useful in transition, especially for the smaller community-based MA-PD plans. And the questions you pose on this slide about the parameters, my sense is that we should devote all our energy to the structure of the reform and not get hung up on exactly what percentage in the catastrophic phase the manufacturer discount should be. I think we're best off with examples, and if Congress takes this up, they'll decide how much savings they want to get, and, you know, the politics of the moment, and they will choose the parameter. But to me, the important thing is this change in structure that has

been laid out.

DR. CROSSON: Okay. Thank you, Paul.

We'll now start the discussion. I see Brian -- okay, let's see. We'll start over here. Brian, Dana, Pat, David, Jon, Warner, Jaewon, Kathy, Bruce, Amol. Everybody? And did you get that nameless person down at the end?

[Laughter.]

DR. CROSSON: Okay. Brian.

DR. DeBUSK: First of all, thank you again for fantastic work. I categorically support the recommendations and the direction that this is going, so I think it's wonderful work, and I was excited when I read the early parts of it in 2016, and I'm even more enthusiastic today.

I also want to echo Paul's comment. It is remarkable how responsive you guys have been to some of the issues that were raised in the previous meeting, so thank you.

I think your chart on page 12 really summarizes. I think it's an excellent template. You know, again, not to get into the specifics, I think the 20 percent fee, if you will, on manufacturers so that you can fund the out-of-

pocket gap as well -- I apologized earlier. I read your 15 and 20 in the reading and read 15 billion and 20 billion, and I thought, oh, I wonder how we're going to get that money. So got it, completely square, and I think that's an excellent template.

I do want to focus on one thing. I do think adding a new co-pay in the LIS benefit for drugs that have a generic available where someone's making a conscious effort, I think adding that third co-pay is very reasonable and maybe even reducing the co-pays for the existing two, the 525 and 825 co-pays, something in that range. But, anyway, if we could maybe even reduce that and bring in a new co-pay for generic available drugs.

I do like the risk corridor treatment. I think that's an excellent idea. I'm still skeptical over how much risk any of these plans take, if over half of them hit their upper risk corridor every year, so I don't know if we're really dealing with what we would think of as risk to begin with.

And then my final comment was -- and you know what it's going to be -- please, please, keep chasing the rebates. Please follow the money, because there's 60-ish

billion dollars floating around here that is being allocated through that sort of arcane DIR formula. Any model that we do, at some point I hope we can do a little thought experiment and say, well, what if rebates were 80 percent, not 27 percent, what would that do to our model?

I do think as long as the taxpayer -- and I'll circle back to why I like Chart 12 so much. I think with the taxpayer on the hook for only 20 percent, I think rebates are going to have to rise to such a high rate, and if you can tie that -- that's why I like the 20 percent manufacturer fee, because, you know, that's net -- that's not -- doesn't have the net rebate price in it. So, in theory, as they run up the rebate, not only does that create a drag on pricing just to run up the price, but if you don't tie it to the net rebated price, if it's the at-the-counter price, people who demonstrate this really bad rebate behavior are going to pay a larger and larger portion of -- you know, effectively their rate goes up from 20 percent as their rebates go up with their price. I know I'm butchering that, but I don't know -- I suspect you guys did that intentionally. If you did, it's genius. If you did it by accident, which I seriously doubt, you're very

fortunate. But I do think that there's a lot of cleverness in the way you've done that, and I support it categorically.

DR. CROSSON: Yeah, I defaulted to genius on their part, but that's okay.

DR. DeBUSK: I agree.

DR. CROSSON: Dana.

DR. SAFRAN: Yeah, thanks. I really appreciate how Paul teed this up, and I guess what I want to also recognize, sort of the overarching theme of my comments, and it will sound familiar from last meeting, is, you know, it is striking that this is the area of the Medicare program where Medicare really doesn't have control over price, and so they're relying on plans for that function. So I do fully support the direction that you're moving here in trying to increase the accountability of plans. And several of the dimensions by which you're trying to do that I think are really wise. My concern will continue to be about unintended consequences, so my comments are in that spirit.

You know, one of the things I wonder about, you know, just staying on rebates, which both Paul and Brian

have mentioned, is I just wonder whether as a condition for participation we could require, Medicare could require fully transparent pricing from plans that want to participate. You know, why can't we do that? Because I think we have to address rebates, and we're not -- I didn't see it here. So throwing out that idea.

Then other aspects about price. I like how you're giving the plans more tools like tiering to address the use side. I think one of the things that I was thinking about in my previous question was this issue that premium prices do seem very likely to rise, and I liked your point, Rachel, that, you know, is that really a bad thing? You know, should to some degree beneficiaries be experiencing the underlying increasing costs that are happening and that are coming at us like a tidal wave with specialty drug development that's coming down the pike?

We have to put some boundaries and safeguards around that, so I think that's something to think about. But I think we have to expect that premiums are going to rise and deal with that kind of explicitly in the chapter.

I'll raise again an idea I put forward last time, and I think Jim had indicated it was in the chapter

materials, but I'm afraid I didn't see it if it was. It's this idea of a standard formulary because, since Medicare has yielded to the plans the price, I think we have to find a way that puts the plans in the position of putting pressure on the manufacturers around price. And the best idea I can think of for how we do that is that, as we do in the Medigap market, Medicare stipulates what the product has to contain, what it looks like, in the way of a standard formulary, and then the plans have to figure out how they can deliver that product at a price that will be market competitive.

I know that's too much for us to build into this chapter in the time frame that we have, but I would love to see us signaling that as a direction to be explored because it will become more and more necessary.

And then the final comment I want to make is that -- and I say it with some mixed feelings, but I am concerned about the zero cost share in the catastrophic phase. And, you know, it probably goes without saying, but just to be clear, I think we have ample evidence going all the way back to the RAND health insurance experiment that when care goes on sale, patients use more of it. And I

think that given that -- I think we have to be concerned with that because, unless the plan and the manufacturer who are then accountable in that phase, in the new structure, really are concerned about the overall price of the product, which I don't think our current structure has them having that concern, then there's really no one interested in avoiding unnecessary utilization in that phase that can happen. And I don't -- and you made the point in the chapter that we now have hundreds of thousands -- I think it was close to 300,000 beneficiaries last year who with one drug fill hit the catastrophic phase, right? So I just think we have to be really thoughtful about where we set cost sharing to zero and what happens, and those who are accountable for cost on the other side really have the incentives that we need them to have to worry about overall utilization.

Thank you.

DR. CROSSON: Thank you, Dana.

Pat?

MS. WANG: Just to pick up where Dana left off, I think that it's a very good point about cost share in the catastrophic phase, and I agree with her on that.

I want to thank you also for the evolution of the work here and the incorporation of a lot of Commissioner feedback. I mean, it's very rich, and I also just want to say I love your attitude towards unintended consequences and it's a problem to be solved as opposed to just like noting it.

A couple of things. In the landscape chapter, this is more of a request, I guess, for clarification at the bottom of page 48. There was a comment that because LIS pays for most of enrollees, out-of-pocket cost plans don't bear -- they have little incentive. There are two things that I would say there. One is don't forget the incentive of not having to use -- for an MA-PD not having to use Part C rebate dollars to buy down the Part D premium. Trust me, that is a powerful incentive to lower your Part D spending. It's huge. That's number one.

And the second is the landscape chapter, in a way, is the foundation for the restructuring chapter. I think it's important to note that they have little incentive or ability to really address this, because if you look back on slide -- whatever it is in the slides -- I guess it's 9, misaligned incentives in Part D. If you look

at the way LIS is structured, this to me is the tradeoff for saying to plans serving LIS members there are no tiers. Forget they have differential copays. There's no -- you can't even display drugs in a different tier. Currently, the rules, it's one tier, preferred generics, nonpreferred generics, all brands, all specialty. It's one tier with a fixed-dollar or zero copay.

And we've talked about the protected drug classes, so forth and so on. LIS beneficiaries use a lot of drugs, and I think it's -- and there's no manufacturer discount in the coverage cap. So this, in a way, this design matches the way that the benefit runs today, and I think that what's great about the restructuring chapter is that you're saying if this is going to change, those fundamental underlying tools for plans must change with it. So, to me, that is the linchpin of the restructure for LIS.

You made a point on page 27 of the Part D, of the restructuring chapter, that reinsurance has been used to counter sponsors to avoid high-cost enrollees. So I would add to the list of unintended consequences that really need to be emphasized and require a solution is if you're going to change reinsurance in a way that it is now, especially

for more vulnerable beneficiaries, risk adjustment is the replacement now to avoid that kind of selection and avoidance of beneficiaries that have certain conditions and that rely on certain types of drugs, frankly. And so I think that it can't be emphasized enough.

I also -- you know, what I heard Eric say about the plan interviews was -- and I may have misunderstood, so forgive me -- is that in the interviews, plans said that risk adjustment in the -- up to the out-of-pocket threshold for what's now the catastrophic, the 75 percent could be addressed by risk adjustment. I think that's probably true, at least from my perspective. The real question is what happens beyond that in the reinsurance level where spending is very, very big for LIS beneficiaries. Is it possible -- and which is now cost-based through the reinsurance design, the importance of risk adjustment addressing that and the spikes and the unexpected levels of spending in that reinsurance level.

Thank you for following up on the question about the size of the cap discount, and by the way, I feel that in this entire package of proposed reforms, the cap discount is probably the most significant piece. And

moving from the manufacturer discount to a cap discount is, to me, anyway, structurally the most meaningful change and very, very important. So I think that it's very important to pursue that.

On page 35 of the restructuring part, again, there's some conflation, I think. I think it would be helpful to do this in two steps. Again, it goes back for LIS. There are no tiers. It's not a matter of -- the chapter sort of jumps to maybe there should be differential copays for the different tiers. There are no tiers for LIS beneficiaries. So step one has to be that plan sponsors have to be permitted to display preferred, nonpreferred, a five -- they have to at least be able to display it. And step two is differential cost sharing. I think that's critical because, candidly, if people decide that they don't want to go there with copays, just even being able to display different drugs also for prescribers -- because there is absolutely no ability for anybody to know what's more expensive and what's less expensive today for LIS.

Then, finally, I would just continue to encourage us, you, please, to think about whether the redesign really does need to be the same and homogenized for LIS versus

non-LIS. I continue to think that there are reasons the size of the cap discount, some of the concerns around risk adjustment, et cetera, to have a differential benefit design for LIS particularly in the share borne by the parties in the catastrophic phase. So I just ask that we continue to be open to that.

Thanks.

DR. CROSSON: Thank you, Pat.

David?

DR. GRABOWSKI: Great. Thanks.

So I find Part D to be maybe the most complicated area in Medicare that we focus on here. So I really appreciate that I think these efforts are sort of increasing accountability and transparency, and I think this is a huge step forward. So I would say, overall, I'm very supportive of these reforms.

I won't go through -- Pat just made a great set of comments. I just want to pick up on one part of her comment, just emphasize that, and that's around the tools that you list out. I'm very supportive of that. I like the way you frame that. That has to be done, because right now there just aren't the set of incentives in place.

The preferred/nonpreferred, specialty tiers, the copays, yes, yes, and yes. Let's move forward with that.

So I'll stop there, Jay.

DR. CROSSON: Thank you, David.

Jaewon?

DR. RYU: Thanks.

I wanted to also echo the complexity on this is just astounding, which is why I like the set of proposed approach -- or recommendations. Slide 10, I thought summarizes it really well, and I think the simplicity of that compared against the complexity of what we have right now, I think it resonates.

I also appreciate the commentary in response to some of the concerns from the last discussion. In particular, I like the risk corridor idea as a way to sort of soften the transition, especially as it might impact or disproportionately impact smaller plans. So I appreciate that.

You know, I want to go back to something that Larry said, and I don't know if this is easily doable. But there's some commentary in the materials around we're going to assume behavior static and here's what we think the

impact would be. As we think about some of these levers, though, it almost begs the question, well, we know behavior won't be static, and in what ways might we expect or anticipate behavior to change of the various actors?

So as we look at the different levers and the structural proposal elements, I think it would be helpful if there was some sort of -- I wouldn't even call it modeling because I think that overstates what we need, but some sense of if this lever goes this way, we might expect to see Player A act this way and Player B act that way. I think that would just help to flesh out what some of the anticipated effects of this could be.

Then, lastly, just on the LIS and the copay differentiation, I think that's absolutely got to be -- you know, I'm in favor of all of them, but that one really felt very compelling. In particular, I think Brian mentioned earlier in scenarios where there is a generic alternative and yet no copay differentiation, I just feel like that's a miss that we should make sure finds its way alongside all the others, so thanks.

DR. CROSSON: Thank you, Jaewon.

Paul had a comment.

DR. PAUL GINSBURG: Yeah. I'm glad Jaewon brought up the issue of projecting behavior, because it's something I neglected to mention when I spoke first, which is that we've been focused about how plans will behave differently with their incentives to use more tools to steer their enrollees into the most efficient drugs.

This, of course, is going to flow through to drug manufacturers in their pricing decisions in particular, and that, I think, is a key part of this approach. You incentivize the plans, and you indirectly incentivize the manufacturers to not price so high. I think this is a key market-oriented tool in seeking lower drug prices, particularly for new drugs.

DR. CROSSON: Jonathan, I'm sorry. I jumped over you because I can't read that well. Go ahead.

DR. PAUL GINSBURG: I can't write that --

DR. CROSSON: He actually -- you don't know this, but he actually has an M.D. degree, and I thought that he was going to be writing clearly, which is something I can't do, but apparently, he's got a surreptitious M.D. degree somewhere in his background.

DR. JAFFERY: Well, I can appreciate that as I'm

looking through the notes that I wrote myself about a minute ago. I'm not sure I can read them.

[Laughter.]

DR. JAFFERY: Well, I want to echo what others have said and just in the interest of time just try and emphasize maybe a few points.

I really appreciate how you're trying to get back to this notion of the goal was to provide about a 75 percent support for the Medicare program, yet at the same time try to create some stability and decrease some uncertainty for the plans.

I know talking to our own, some of the pharmacists in our own health plan, they comment about how over the last 5 to 10 years, they've gone from where year to year, they could really predict what costs would be. And now their ability to predict it is just less and less good each year and not necessarily in the same direction, and this is not a Part D thing, per se. This is -- they deal with a lot of commercial, probably more commercial than Medicare.

I also really appreciate Paul's point about maybe trying to get a way not too far in the weeds, the specific

numbers, but noting that Congress can and will and really must decide some of the specifics, and if we can get this sent to the general direction, the exact percentages may not be the most important relative to the overall structure.

Some of the things, the discussion questions and next steps that we haven't talked about as much, have been some of the alternative rates or formula indexed to different things. I think Bruce brought it up a couple months ago about how we might index the manufacturer's rebate, and there are different ways to do it. I mean, we could think about projecting that over even a particular drug cost or total costs to the beneficiary.

To me, that's one of the stickiest, trickiest things is thinking about the behavioral change that's going to come from manufacturers in response to the rebates, and if we may be driving prices up with some of these rebates, then how do we get some diminishing returns for them in that regard?

I really like the enhanced risk corridors for the plans for the reasons people have said, and I think this had come up in a previous discussion. I didn't quite see

it here as much, but there may be some thought given to how you would structure that, even on a longer-term basis, potentially for plans that have a higher percentage of LIS, depending on what we see with some of the ability to risk-project there.

Then, finally, Dana, I really liked what you were talking about in terms of getting to a standardized formula and also acknowledging that we can't probably do that right here, but thinking about projecting that. It comes back to some of the comments about giving plans tools. Maybe there's something at this point that can project in that direction that is a little bit more forceful about eliminating some of the protected classes or all of the protected classes, and it would start to -- this may be an interim step towards getting there.

And then, finally, my final comment will be about -- again, this goes back to Dana. You were talking about having no copays in the catastrophic phase. I do worry about out-of-pocket costs for beneficiaries overall. I'm open to thinking about ongoing, some type of copay, but I guess thinking about the fact that, as you said, there are over 300,000 people now who reach that phase in a single

month, that means that those folks are paying, as it's currently structured, 5 percent of what is a very, very expensive drug for another 11 months. And there are plenty of other people who get there in two or three or four months.

So I guess if we're going to have that, I would be less interested in a percent copay, which could still be very large, and maybe there's a monthly limit to a copay, even at a catastrophic phase for beneficiaries, so, again, they have some predictability and the potential for some prolonged affordability.

Thanks.

DR. CROSSON: Thank you, Jonathan.

Jim?

DR. MATHEWS: Yeah. Just to pick up on a couple of points of discussion that have occurred up to this point in time -- and I'm doing this because, after this meeting, we're going to have to go back and sort out the discussion and come back to you in March.

So I understand the intent and the potential benefit of developing a recommendation that lays out general direction with respect to the allocation of

financial responsibility in the catastrophic phase and not laying out specific percentages necessarily. I get that.

But a couple of Commissioners have raised the possibility or concerns about the hard out-of-pocket bene cap or the zero liability in the catastrophic phase.

Just a bit of history here, when we did our 2016 recommendation, this was something that a couple of Commissioners felt quite passionately about, and it was for the reasons that, Jonathan, you just alluded to, that if a beneficiary has a condition or is in such a state of health that they are incurring that kind of cost in the catastrophic phase and especially if they are using sole-source drugs for which there are no alternatives, no competitors, that imposing cost sharing in the catastrophic phase isn't really getting the beneficiary to think about the cost of what they are using and whether there are low-cost alternatives available but rather -- and, again, I'm characterizing prior Commissioners' discussion here. This is simply punitive, that the 5 percent copay serves no real purpose with respect to getting the beneficiary or their clinician to evaluate alternatives.

So that is why, as we've crafted the current

package that you've been discussion, we have retained the hard out-of-pocket cap or the zero copay as a component of this package.

Obviously, if the Commission decides to take a different direction, we can pursue that, but it does get implicated in the overall approach of not specifying percentages, because when we do come back, we are going to have to say either no copay in the catastrophic or some copay in the catastrophic.

So, as the discussion proceeds from here, it would be helpful for me, again, as I go back and sort this out, to get a sense of where you want to be with respect to that specific element.

DR. DeSALVO: Just a clarifying question, Jim. Is part of the rationale for not having copay in the catastrophic phase because of the percent copay in the non-catastrophic phase? So there may have been a lot of out-of-pocket because of the high cost of the drug, so people, theoretically, meet the cap more quickly? And if you shifted out of a percent in --

DR. MATHEWS: I think again -- and I'm trying to articulate the concerns of a couple of prior Commissioners

-- it was more what purpose does it serve to require a beneficiary who is, you know --

Do you want to --

DR. SAFRAN: Yeah. So this is such a delicate, difficult issue, right, because this program was designed to protect beneficiaries from the financial harm of high medication cost.

On the flip side of that, we have to deal with the reality of a lot of evidence that shows that when cost sharing goes to zero, people will just use a lot of care, sometimes more care than they need. So how do we balance those two difficult things?

I don't think that -- you know, this is just me. I don't think the purpose of cost sharing, at least in the catastrophic phase, is to cause people to think about like which drug should they be on. I think it's more about having people consider the whole volume of drugs that they are on.

So I think that Jonathan's point that continuing with a percentage basis for cost sharing in the catastrophic phase may be a really poor idea. Given the kinds of drugs that often are landing people there, that

would just be a very high -- you know, but I think -- so there's copayments as opposed to coinsurance as a mechanism. There's Jonathan's idea about once you're in the catastrophic phase, a per-month cap on out-of-pocket cost, something like that.

If others agree that we should be thinking about something that isn't a hard cap and it goes to zero for whatever the rest of the year looks like, then I think there are ways to mitigate the concern that we all have that that not impose really terrible financial exposure for the sickest Medicare beneficiaries.

MS. BUTO: Jim, since I was here for that discussion I want to also mention another factor which entered into our recommendation, which is we were still dealing with the coverage gap. We decided that we would eliminating counting the manufacturer rebate to get to the coverage gap. And so what that ended up doing was having many beneficiaries never reach the coverage gap. So the quid pro quo, if you will, was for those who did reach it, because it was now a lot harder to get there, the copay or coinsurance would be zero.

Now this structure eliminates the coverage gap,

so I think it's fair game to go back and look at that again. But that was, at least for me, one of the strong reasons for going to zero, was to compensate for the fact that those who reached it were really going to be super expensive and have potentially put out a lot of out-of-pocket payment.

DR. NAVATHE: I would also say, from a clinical perspective, if we look at what's transpired over the last four years, the types of medications that are priced such that people would reach this -- you know, up to this catastrophic phase, probably there's a lot more medications where there is some discretion than we had even five years ago, in terms of disease management types of medications as opposed to, you know, more chemotherapeutics and the acute phase kind of things.

So I think there is probably some reasonable clinical rationale also to reconsider this piece.

DR. CROSSON: Okay. So we have Warner, Amol, and Larry, and then I think -- I'm sorry, then we missed Kathy, we missed Bruce. We missed you?

DR. DeBUSK: Yes.

DR. CROSSON: Okay. Sorry. So I think that will

do it, though. Warner, Amol, Larry, Kathy, Bruce, and then we need to end.

Warner?

MR. THOMAS: Yeah. I'll be brief. So on Slide 12 I think you do a good job really outlining how this could work, and I would just -- you know, this is a really complicated topic. I would concur with Dana's points around having a standard formulary, because I think that's really important. The recommendation I would put out there is that we not necessarily cap the manufacturer discount at 20 percent. I'm not sure why that wouldn't, you know, increase over time or be considered to be larger, given the size and scale of this increase over the past couple of years.

You know, I know we've talked before about, you know, Medicare doesn't really buy drugs in a lot of the program and in this one it does. And so should we be proposing in here some sort of inflationary cap that sits on, you know, drugs, and then that may kind of help mitigate the escalation in some of these costs and it may also play into that manufacturer discount. But, I mean, this idea of capping increased costs I think is -- this is

a program that really, I think, is in a good position to be able to do that, and given that cost escalation is significant.

So those are a couple of comments. I do agree with Dana that, you know, having -- I think there should be a zero cost-sharing option for folks, but I do also think the idea of having some cost-sharing on items that are more expensive, just so folks can understand, would probably be helpful, versus it just being zero for everything.

So that's just a couple of thoughts.

DR. CROSSON: Thank you, Warner. Amol?

DR. NAVATHE: So I generally want to echo support for a lot of the ideas the Commissioners have raised up to this point. We already talked about the cost-sharing, the catastrophic phase, and Warner's point about thinking about an inflationary cap on the manufacturer discount. I think that's also worth doing.

I think it would help -- I have kind of three core areas that would be worth looking a little further into. I think one of the pieces is we have talked about how important risk adjustment becomes, and I think Pat highlighted that it becomes, for one of the key substitutes

in some sense, for reinsurance. It's also there's a potential, an intended effect on risk selection.

And the work that we've done thus far, I think, does provide a framework for LIS versus non-LIS, in particular in terms of adequacy. I think we could do -- it would help to do a little bit more work in there, I think, looking at sort of predictability of the model and predictive power of the models in terms of model performance, as well as looking at residuals.

I think we looked at variability, in some sense, but one of the pieces that I was concerned about is some of the lack of variability on the LIS side could be driven by the cost-share, or lack of cost-sharing differentials. And so that could actually potentially play into that, so we might want to take a little bit more look at the risk adjustment piece, just given how much more important I think it's going to end up being in this kind of structure.

The second piece that I was curious to focus a little bit more attention on is the premiums. If we take a step back and think about what insurance is really supposed to be about, it's supposed to be about protecting really large expenditures that usually are unanticipated. Part D

is not exactly purely insurance in that sense, economically speaking, but it should probably have some feature that around that.

And so the part that concerns me is around premiums and premium growth, and I think if we anticipate that plans are going to take on more liability, the natural expectation should be that premiums will probably grow. And I think, Rachel, your point that if overall the size of this pie is growing over time because drug prices are going up and drug volume is going up that the cost-sharing component in the aggregate sense should also grow for the beneficiary I think certainly resonates. But whether that gets allocated into premium versus into conditional on participation cost-sharing is a question I think we should actually have a point of view on.

And I will say that you've come up with quite an elegant design, because I've tried to think through other ways that we could try to protect premium growth and I haven't come up with anything better. But I think it's worth noting that we should think about how premiums grow and if we want to set, particularly in the context of a standard formulary for going in that direction, it may be

good to think about what kind of protections we want to put on the premium growth side of things.

And a related point is something that exists in other parts of the Medicare program, particularly in Part B premiums, is they are sort of income-rated or adjusted for income as well. It's an element that we haven't introduced here at all. It may have been considered in the past, but I was curious about the Commissioners' appetite to consider something like an out-of-pocket adjustment based on income level, and/or premium adjustment based on -- or some sort of subsidy that's --

MR. ROLLINS: At least in terms of the premiums the income adjustment that you describe in Part B is also part of Part D as well.

DR. NAVATHE: But not on the -- but we haven't considered that on the out-of-pocket side. So that's the thought here.

And then the last part was just, I won't actually get into the details of it, but just echoing this support for perhaps differentially generous risk corridors for plans that have a disproportionate amount of LIS benes.

DR. CROSSON: So just to bring those two ideas

together, are you thinking about, for example, you know, an income-related exception, if you want to call it that, for the beneficiary exposure in the coverage gap? For example, so you have --

DR. NAVATHE: In the catastrophic phase?

DR. CROSSON: -- you have a catastrophic absolute cap for some individuals but then other individuals could be required?

DR. NAVATHE: Or if we end up deciding -- I guess my thinking would be if we end up with some sort of cost-sharing element in the catastrophic phase then it may or may not be necessary. But if we don't, then we may want to think about the out-of-pocket maximum to be income-rated, effectively. That's the thought I had.

DR. CROSSON: Okay. Thanks.

DR. DeBUSK: The one question, this issue of cost-sharing in the catastrophic phase -- and help me because I may be off on this -- but in MAPDs you don't have that issue, right? I mean, they have the out-of-pocket limit. So one-third of the beneficiaries are off the table to start with. Of the fee-for-service beneficiaries that are left, are there med sup? Oh, that's right. It's not a

full -- I know. I know. My math is off.

DR. SCHMIDT: No, no. It's just that the hard cap for MA plans is with the A and B benefits, not the D benefits.

DR. DeBUSK: So D does still have the cost-sharing.

DR. SCHMIDT: Right.

DR. DeBUSK: Are there any med sup plans that have catastrophic cost-sharing relief?

DR. SCHMIDT: So you can't have D sups. I mean, you can't have Medigaps with really relationship to Part D.

DR. DeBUSK: Anymore. I think MACRA -- was it MACRA that wiped that out.

DR. SCHMIDT: Yeah. That was at the beginning of the program.

DR. DeBUSK: Okay. Okay. So we truly are, I mean, everyone is exposed to this 5 percent. Okay. Thank you. Thanks for clearing that up.

DR. CROSSON: Okay. We have Larry, Kathy, and Bruce.

DR. CASALINO: Yeah. One thing we haven't discussed very much is the consolidation of unintended

consequence, which came up towards the end of the last meeting, I think. I'm all for putting more risk on the plans, but the concern was -- and I think that staff had worked to address it -- that putting a lot more risk on the plans would make it more likely that smaller plans and possibly, especially small plans that serve a lot of LIS beneficiaries, would not be able to survive and would be absorbed by some of the big national plans that can more easily -- don't have to worry about reinsurance, really, costs. And we haven't discussed it much.

I think the staff tried to come up with risk corridors in a transition period as a way of helping with this problem, and this has been casually mentioned a couple of times as kind of the solution.

So I'm just curious if people who live in this world and/or know more about it than I do, is there a sense that having a -- I mean, after the transition period -- a transition period is a transition period -- the small plans are not going to be any bigger, probably, at the end of the transition period. So does a transition period merely delay what at least some of us think is an undesirable unintended consequence? And if that's all it does, we

should at least acknowledge that and not talk about a transition period and risk corridors during that transition period as an actual prevention of unintended consequences.

So I'm just curious. You know, Pat, Jaewon, others who really care and know about this, have we found the solution to the problem that we all want to put more risk on the plans but we don't necessarily want more consolidation?

DR. PAUL GINSBURG: Actually, Larry, before you go to them, I want to say that what makes a transition valuable rather than just postponing pain, is the fact that there's great uncertainty when you change the whole design for a plan, and it means that -- and they have to set a premium. So at least this means that by the time they have to set a premium with this new system they have a few years of experience under this regime and they can -- in a sense, there's much less uncertainty for them going forward.

DR. CASALINO: I can see how that would really help in the short run, but in the long run it might not alter the fundamental dynamic, I think. But that's what I'm curious to hear about from other people.

DR. CROSSON: Pat, would you like to comment, or

Jaewon?

MS. WANG: Just to start off, I think that we -- you know, the risk corridor proposal is very, very much appreciated. I'm not exactly sure how that looks when you actually get there. And don't forget that even at 2.5 percent, you know, you're still losing up to that amount of money, and I think it could put pressure. So it's just a concern. I don't know what the ultimate solution is.

But one of the reasons that I have continued to say let's consider potentially different benefit structure for LIS is that the exposure there is bigger. I mean, the chapter now sort of says there have to be additional tools given to the plans to manage this, and I think everything that was listed is critically important. But just even the size of the spend, even if you narrow the risk corridor to 2.5 percent, it's a lot more money that a plan faces to lose. And that's why given the characteristics of the population, there is still difficulty managing it, because you don't have full control over copays. A very good proportion of the population is zero. So, you know, and these are the dual eligibles who are nursing home eligible, who are in all the dual demos. I mean, there's not much

you're going to do to try to influence beneficiary behavior there.

I think that in the reinsurance layer there should be a higher share from both Medicare as well as manufacturers, in terms of absorbing the responsibility for the population. So, you know, to Warner's point about what's the magic about, you know, a certain percentage, I asked the questions about what's the 35 percent considering the elimination of the LICS in the coverage gap, what would that actually be for plans? Like a D-SNP sort of thing, LIS members.

So that's why I continued to suggest that it would be important to have more parties with skin in the game in the reinsurance layer, just to address the fear that the dollars are big, and at least for plans that are community plans, the exposure is great. I think that that's part of the solution, that Medicare should absorb more and manufacturers should absorb more, even a third, a third, a third, or whatever it is. Just bigger than the plan design that's being considered for non-LIS.

DR. CROSSON: Right. And I would add that, you know, as the staff has presented this revised package, it's

not the thesis that the risk corridor adjustments for a temporary period of time is the entire solution to this assumption of risk. But in addition, as Pat has maintained, and others, you know, creating more robust tools for the plans to manage the risk is an important part of this.

And I would say, as we go into March and April, we may want to hedge on putting some hard numbers down, as we've talked about. I would go in the opposite direction in terms of the specificity that we have in the recommendation for the improvement in plan capabilities, because I think that's an important part.

Okay. Kathy.

MS. BUTO: So, Larry, were you finished?

DR. CASALINO: Yeah.

DR. CROSSON: Oh, I'm sorry.

DR. CASALINO: You probably -- no, it was good intuition. No, just very briefly, I think -- so my six months on the Commission have made me feel a lot dumber, and two things in particular have made me feel dumber. One is talking to

Brian in detail about anything pretty much.

[Laughter.]

DR. CASALINO: I suspect I may not be the only one. But the other is Part D, and so it really is a magnificent achievement what you guys have done. I think the package is really excellent.

I just didn't want us to -- the transition and the risk corridors have been mentioned a couple of times as if they solve the problem, and I don't think they fully do. It may not be possible to resolve the problem and I appreciate that it may be more important to have this package than to fully resolve this problem. But I just didn't want us to assume that it had been solved.

DR. CROSSON: By the way, your experience coming on the Commission is universal. And for some of us it never goes away.

MS. BUTO: Okay. So my --

DR. CROSSON: I'm sorry. Kathy, go ahead.

MS. BUTO: So I have to say I think I have thought, since you first proposed this, this is a brilliant restructuring of Part D, and I just want to commend you on it. It's a joy to see the donut hole go away. It's really a joy to see a greater alignment in the benefit in a way

that I think had the money been there in the initial go-around they would have designed it something like this. They created the donut hole to make up for a funding shortfall.

I'm very concerned about the LIS population and plans that concentrate on that population. I think that, from what I can tell from reading the chapter, the combination of the risk adjustment, the risk corridors, and additional tiers and copays goes a long way to helping plans gain better traction on that population. But I don't feel as if that -- back to Larry's point -- that is something that is really going to approach their ability to manage the benefit for other beneficiaries.

So then I looked at the catastrophic phase, and I wondered whether -- and this is sort of along the lines that Pat was getting at -- whether there was -- we ought to consider having reduced plan liability for high-LIS-concentrated plans, having a lower percentage of risk in the catastrophic phase and then have the delta of that redistributed among manufacturers and Medicare.

Just something to think about. I recognize that for this go-around you may not want to do that, but I

thought, at a minimum, we ought to acknowledge that this is a potential area of concern, that there still aren't enough tools necessarily to help plans with high drug spend in the catastrophic phase, and sort of endless drug spend for that population.

I think we may want to consider -- again, I know it's not as neat -- but retaining, I think as Larry was getting at and Amol, the narrower risk corridors for the LIS-heavy plans, whether it's D-SNPs or some other category. But even if we transition out of that for other plans that we look at retaining it to give them more leverage or less risk in the pre-catastrophic phase.

So again, just for LIS plans, have a narrow risk corridor that continues. And wherever we can find tools that will help them, that would be helpful.

Back to Dana's point about the potential increases in plan premiums, if plans are not successful in managing spend for the LIS population and it continues to be disproportionate, that's going to raise premiums for everybody. So I think there is a spillover effect to all plans that we need to be concerned about.

So I think at least for this go-round, maybe an

acknowledgment that this is an area of concern and that there may be tools we need to consider going forward, whether it's separate plan risk percentage above the cap, whether it's sustained narrower risk corridors below the cap, other tools, just a way of saying we know this is not, you know, sort of the end of it, I think that would be helpful because I do worry that there are some unintended consequences here for those plans.

And, lastly on the issue of pricing by manufacturers, I think the discounts above the cap will make a big difference. It may influence behavior downstream. I think it will have the, unintended or otherwise, consequence of higher launch prices, because if you're going to demand discounts into infinity, I think that's what's going to happen, and particularly as we look at capping the increases in prices, I think that's going to lead to higher not lower launch prices.

DR. NAVATHE: Kathy, on that point that's where the idea of an inflationary cap may actually help, however.

MS. BUTO: But only after [off microphone].

DR. CROSSON: Okay, thank you. And we're -- Bruce is going to wrap it up for us.

MR. PYENSON: Thank you very much. Having done some modeling on similar proposals, I'm actually comfortable with the particulars that you've offered here, as well as the risk issues overall, though I'd like to characterize the risk issues as of different importance for MA-PD LIS versus freestanding small PDPs. In particular, the consolidation of the industry means there's only a few back offices throughout the entire industry, no matter what the name of the PDP is or MA-PD, but it's a different issue for MA-PDs and I think more important.

I've got a few thoughts on the tactical issues, a thought on DIR, which Brian mentioned, or the rebates, and an income-based cost-sharing concept, and, finally, a risk and behavioral comment.

On the tactical side, I think there's a lot of particular things that could be done to help manage -- that would help Part D plans manage risk and, in particular, the LIS plan. I'd like to point out a few of them. One is in the complaint tracking module and the appeals process. We've mentioned that in the past, but I think that's a very important issue for management of drugs. And if we're going to do utilization management, it can't all be trumped

through the risk of complaints in the way it might be today.

I think there's a need for mandatory generics, a federal preemption of DAW, and an openness to mail order. These are very, very common throughout commercial insurance and other forms of insurance, so easing the rules on that for Medicare could be really valuable.

And, finally, the risk adjustment, moving to using two years of encounter data, the value of that I see is in minimizing the value of risk score optimization and the differentials that large MA-PDs might have versus the regional and smaller ones. So I think that would be an important tactic to help make the whole package work.

On the DIR side, although the catastrophic share, fixing that will have a very beneficial effect, it doesn't take away the potential for blocking an anticompetitive behavior, but I think some other rules could. For example, the rules that would not allow blocking of generics or lower-cost biosimilars, I think those are things that are tactical and could be beneficial for the kinds of behavioral changes that we want, we all agree with.

I really do like Amol's income-based cost

sharing. I think the structure of that for catastrophic could be relatively simple if the data's available. That's done today kind of on premium, but there's a couple of grades of low-income subsidy on the premium side.

Finally, I think the behavioral issues that we hope for on the plan side would induce lower costs to the beneficiaries and lower costs to the federal government, and that's the goal, but I think it would be helpful to think about what -- and maybe to be explicit, what behaviors in Part D we actually would like to encourage on the part of the plans. So in particular, we would, I think, like plans to have behaviors that would lead to low premium rates, perhaps not the member premium increasing but stabilizing or even going down, or other costs going down. But I think we can -- obviously, the plans are going to try to make money, and there's probably other ways they can make money, for example, the vertical integration with pharmacies, and that's what a mail-order pharmacy is, could lead to other sources of revenue. So I think being a little explicit about what the behavior changes could be here would be a helpful addition to the chapter.

I know that's a long list. There's nothing

fundamental that I disagree with. I think the work is terrific, so thank you very much.

DR. CROSSON: Okay. Thank you, Bruce.

I just want to reiterate what a number of people have said, which is, first of all, this is outstanding work in its original conceptualization and in the flexibility that you've had to bring it to this point, taking into consideration points that have been made by the Commissioners in previous meetings.

I also think that equal to its importance and the quality of the work is the complexity of it, and to go back to Larry's point, you know, there was a period of time where just the conceptualization of the doughnut hole and trying to understand it gave me this mental image of falling into a pit because of the complexity of trying to understand not only how it worked and the ramifications of it, but potentially how to change it. And I think you've led us forward in an excellent manner there, and I think it's going to be in the benefit not only to the Medicare program but I think by and large to at least a number of beneficiaries who have now experienced really extraordinary financial risk. So thank you for this work, and we'll come

back again in March.

[Pause.]

DR. CROSSON: Okay. We had a somewhat prolonged first session, and so we've had a few Commissioners who had to take a short break here, but I don't want to get too far behind. And I apologize to our guests because the first presentation and discussion went longer than was scheduled.

Today we're going to take on once again the question of redesigning the Medicare Advantage quality bonus program, and we've got Ledia, Andy, and Carlos here to take us through this work.

MS. TABOR: Great. Good morning. We are here to continue the discussion of the redesigned value incentive program for MA, which was initially published in the past June report to the Congress and recently discussed at the November Commission meeting.

The redesigned MA value incentive program addresses the flaws in the current quality bonus program. Before moving on, we would like to acknowledge Sam Bickel-Barlow, who has been instrumental in the modeling work we present today.

Reforming the current quality bonus program is a

matter of urgency. One-third of Medicare beneficiaries are now enrolled in Medicare Advantage, and that number is growing. MA plans are also viewed as having the potential to be more efficient than fee-for-service while providing high-quality care. However, the Medicare program does not have the tools to judge the quality of care MA plans provide, and beneficiaries do not receive accurate information about their options.

In the QBP, 82 percent of enrollees are in MA plans currently classified as a high-quality plan, entitling them to Medicare Trust Fund and taxpayer-financed extra payments. Unlike the quality incentive programs for fee-for-service Medicare, which are budget neutral or produce savings, the QBP adds $6 billion per year in program costs or a potential $94 billion over 10-year savings as estimated by CBO.

In addition to the concerns over the QBP being a rewards-only program, the Commission has long discussed the flaws of the QBP, presented on the left-hand side of this slide. I will not go over them, but they are here for your reference.

The redesigned MA value incentive program will

meet five key elements of design presented on the right-hand side of the slide, which I'll walk through over the coming slides. Then Andy and Carlos will walk through modeling results of an illustrative MA value incentive program that incorporates these five design elements.

The MA-VIP scores a small set of population-based measures that focus on patient outcomes and experience. Using a small set of measures is simpler to administer for both the Medicare program and for MA plans than the current QBP with a set of 45 measures.

In November, the Commission discussed the importance of including a small number of prevention and chronic care management measures that are tied to clinical outcomes. This table displays an illustrative MA-VIP measure set that incorporates the Commission's discussion. This is not intended to be a definitive list of measures, and CMS should develop the MA-VIP measure set through a public review and input process. We anticipate that the MA-VIP measure set would continue to evolve as better data becomes available.

In our illustrative modeling of the MA-VIP, we scored the six measures that are noted with an asterisk.

Because plans currently collect and report quality results at the contract level and not at the market area level, we could only use measures where we had beneficiary level encounter or survey data that we could reassign to a plan within a market area to calculate a quality score. When the MA-VIP is implemented, CMS would be able to score a full set of measures based on plan level quality information collected at the market level.

The MA-VIP evaluates quality at the local market level, meaning it scores a plan's performance for the beneficiaries they cover in a local market area. The Commission has long discussed that the QBP's use of contract level results is too broad and inconsistent because contracts span noncontiguous geographic areas.

Using market level measure results gives a more accurate picture of quality for beneficiaries who are selecting a plan where they live and also for the Medicare program to understand plan performance. Under the illustrative MA-VIP modeling results that we'll present today, our reporting unit is a parent organization within a MedPAC market area that had sufficient enrollment to reliably calculate measure results.

The Commission's hospital value incentive program distributed rewards and penalties nationally, meaning a pool of dollars was distributed to hospitals based on their quality performance, regardless of the hospital's location. However, the MA-VIP uses a different approach, because the Commission has discussed that MA plans should be evaluated at the local area, which also leads to distributing rewards and penalties at the local area. This market level approach also makes sense because, unlike hospitals, plans change where they offer coverage each year, making it possible to enter more profitable market areas and leave less profitable market areas each year.

A national approach could have an unintended consequence of creating MA deserts because plans may move out of low-quality areas where they would not receive quality rewards. However, a trade-off with the market approach is that plans with low quality compared to the national average may receive rewards.

A benefit of the local market approach is that the best choices available to beneficiaries considering enrollment in MA in a given market will be the plans receiving rewards.

Medicare should take into account as necessary differences in enrollee populations, including social risk factors. One way to do this is to stratify plan enrollment into groups of beneficiaries with similar social risk factors to determine payment adjustment. Comparing groups with similar patient composition accounts for social risk factors without masking disparities and plan performance, as would be the case if measure results themselves were adjusted.

In our illustrative MA-VIP modeling, we stratified each parent organization's enrollment into two peer groups and then calculated measure results for each of the groups. We use eligibility for full Medicaid benefits as a proxy for social risk factors because it's a readily available data source and it captures a characteristic that may make a plan's enrollees more difficult to treat. Policymakers could continue to explore other factors that could be used in the peer grouping.

The MA-VIP uses a performance-to-points scale for each measure to convert a plan's result to a score, which determines the rewards and penalties the plan receives. There are two key features of this scoring mechanism.

First, plans know the performance scale before the performance year, which can drive quality improvement because plans will be able to see how they will be rewarded for improvements in performance on each measure. And the current QBP plans do not know the targets that will be used ahead of time.

Second, the MA-VIP scale is continuous, meaning that every change in performance will affect the number of points achieved and the size of any reward or penalty. There are no performance cliffs like the QBP.

Ideally, MA plans would also know the payment multiplier or percentage adjustment to payment per point that converts their quality score to a payment adjustment. Because the MA-VIP is rewarding quality within local market areas, it would be complex and potentially unreliable to prospectively estimate each market's payment multipliers since plan participation, performance, and payments are less predictable at the market level.

However, a couple of years after MA-VIP implementation, plans may have a general sense of how much of a reward they can receive for improved performance. In our illustrative modeling, we set each measure scale based

on a beta distribution of current national performance. Policymakers can consider other methods to set the performance scale.

I'll now turn it over to Andy to discuss modeling results.

DR. JOHNSON: Our modeling relied on claims and survey data for various measures. The scope of our modeling was limited by the availability of survey data, which are collected at the contract level, not at the market-area level.

We assigned available survey data to a parent organizations and a market area and limited our analysis to market areas with at least three parent organizations having sufficient data. Requiring a minimum of three parent organizations per market prevents the direct transfer of reward dollars from one parent organization to another if only two organizations are present.

We were able to include 78 unique parent organizations in 61 market areas for a combined total of 258 reporting units in our modeling. These reporting units represent 39 percent of MA enrollment.

When implementing the value incentive program,

survey collection requirements would change to eliminate the data limitation we faced, and the program would cover about 89 percent of MA enrollment.

Over the next few slides, I will review our modeling results, first by showing point distributions in a few example markets and then by showing the distribution of rewards and penalties which are applied as payment adjustments that increase or decrease overall plan payments.

In this example, we look at how the MA value incentive program would distribute rewards and penalties using a national distribution. This is the same method used in the hospital value incentive program.

This figure shows the results for parent organizations in three example markets for the non-full dual-eligible peer group.

In Market 2, the middle column, there were seven parent organizations represented by the seven circles. The size of each circle is proportional to the enrollment in that parent organization. The center point of each circle is aligned the number of points achieved, according to the scale on the left of the figure. The top parent

organization in Market 2 achieved about 7.3 points, and the bottom achieved about 4.5 points.

With national distribution, a single reward or penalty threshold is applied to all markets, shown by the line. Parent organizations in green above the line received a reward, and those in red below the line received a penalty. The size of any reward or penalty increases as the number of points achieved gets farther from the line.

One consequence of national distribution is that for some markets, all parent organizations will receive a penalty, as in Market 1, and all parent organizations will receive a reward, as in Market 3. About 30 percent of markets in our modeling offered only rewards or only penalties to all parent organizations in their market.

This figure shows market-level distribution of rewards and penalties for the same markets as the previous slide. The main difference is that the parent organizations performing above average in their market receive a reward, and those performing below average in their market receive a penalty. As you can see by the three lines, average performance varies across markets, and there is a different reward or penalty threshold in each

market.

Because the value incentive program uses a national points scale, shown on the left of the figure, beneficiaries can compare the quality of plan options in their market with MA plan options and MA plan quality across the country.

The two main reasons for using market-level distribution in the MA value incentive program modeling are, one, the ability of plans to leave and join markets in each year and, two, the fact that MA enrollees are limited to plan choices in their market.

Local distribution of rewards avoids persistently penalizing market areas with lower performance relative to the national average. The remainder of results we will present today as based on a local distribution of rewards and penalties.

This figure shows the range of payment adjustments for the 258 reporting units and the frequency of each size adjustment. The black bars show the results for fully dual eligible peer group, and the white bars show results for the peer group containing all other enrollees.

The results of our modeling show that payment

adjustments tend to be small for individual parent organizations in a single market. Our modeling used a reward pool funded with 2 percent of total MA payments, and we found a range of payment adjustments from 1.5 percent penalty to a 1.5 percent reward. However, nearly 80 percent of all payment adjustments were between a 0.5 percent penalty and a 0.5 percent reward.

If the size of these payment adjustments was deemed too small, policymakers could increase their magnitude in two ways. First, the performance to points scale could be modified so that points achieved were distributed more widely between zero and 10 points. And second, the size of the reward pool could be increased. For example, if the reward pool were increased from 2 percent of MA payments to 4 percent, the magnitude of each payment adjustment in this figure would double.

This figure shows the payment adjustments from the previous slide aggregated to each parent organization. Of the 78 parent organizations in our sample, 76 had an aggregate payment adjustment between a 0.6 percent penalty and a 0.6 percent reward. The red bars show parent organizations that operated in five or more markets, which

collectively account for the majority of observations in our modeling.

None of these larger parent organizations exclusively received rewards or penalties in all markets in which they operate. Instead, they received rewards in some markets, offset by penalties in others, and so their aggregate payment adjustments tended to be small.

Now I will turn it over to Carlos to discuss comparison with the QBP.

MR. ZARABOZO: This slide highlights the major findings of our comparison of the MA-VIP to the current QBP for the markets that we could analyze.

From the plan perspective, there are differences between which plans are in bonus status in the QBP versus those that have net positive payment adjustments in the MA-VIP. Plans enrolling large shares of duals fare better under the MA-VIP, and large organizations that had an advantage in the QBP system have less of an advantage in the MA-VIP.

From the beneficiary perspective, if plans have lower revenue from Medicare, there can be a reduction in extra benefits for MA enrollees, but in relation to the

current record-high level of extra benefits, the reduction is of limited magnitude.

The MA-VIP proposed design stratifies results for two populations, the full duals and all others, comparing results for each population at the market level. Our modeling found that this approach narrows the disparities in financial performance between dual populations and others.

In this slide, the first two sets of bars illustrate that in the QBP, a little over half of full duals were in bonus-level plans in 2017, the solid blue bar at 54 percent for full duals in the QBP results, as compared to the 82 percent in the solid blue bar for non-duals in the QBP. This large difference is narrowed in the MA-VIP. For full dual eligible beneficiaries, 53 percent are in plans with positive net payment adjustments in the MA-VIP, compared to a similar share, 57 percent, for non-duals.

The last two pairs of bars show that employer group- or union-sponsored MA plans continue to fare better than plans for other populations, while the under-65 beneficiaries, those entitled to Medicare on the basis of

disability, fare worse than other populations. This may argue for additional adjustments in payments or more stratification in a MA-VIP system.

Looking at results at the level of the parent organization for markets we could analyze, about half of organizations, 40 out of 78, have a positive net payment adjustment in the MA-VIP. Even though there was essentially a half-and-half split in the number of organizations with net positive results and net negative results, 40 and 38, the enrollment distribution was different.

As shown in the second column of numbers, a much larger share of the enrollment, 62 percent, was in organizations with a negative net payment adjustment.

Looking at the next column, you see that organizations with negative net payment adjustments have an average enrollment of 113,000 enrollees compared to 66,000 for organizations with a positive net payment adjustment.

These data show that the MA-VIP is less likely to favor larger organizations, which are the organizations that have benefitted from contract consolidations in the QBP and are also more likely to be the organizations with

high shares of employer-group enrollees.

In the 2020 star ratings, for example, there is a greater-than-10-percentage-point difference between the bonus status among enrollees of the 10 largest organizations, with 85 percent of enrollees in bonus status, and all other organizations, where 73 percent of enrollees are in bonus status.

There are some very clear differences in how organizations fare under the MA-VIP versus the QBP. In our data, there were 20 parent organizations not in bonus status under the QBP. In the MA-VIP, however, eight of these organizations have positive net payment adjustments. These organizations are all what are known as regional plans; that is, plans that operate in single markets or limited geographic areas.

Making the MA-VIP a budget-neutral system would achieve substantial program savings, $94 billion over 10 years as estimated by the Congressional Budget Office. The current QBP is financed by added program dollars of about $6 billion per year, or an average of about $24 per member per month for plans in bonus status.

Plans are not required to use such extra revenue

to finance extra benefits, but if they did, $24 would be the theoretical maximum amount by which extra benefits would decline in a budget-neutral system, and if plans chose not to reduce extra benefits at all and instead reduce profits, administrative costs, or health care costs, the theoretical minimum reduction in extra benefits would be zero.

However, our past analyses of bidding behavior included in the June 2019 report suggests that the reduction in extra benefits would be from about $6 to $17 per member per month. In the context of the record-high level of extra benefits, this would mean that extra benefits would decline from a year 2020 average of $121 per member per month to about $104 to $115 per member per month, close to the 2019 level of $107.

Turning now to policy options, the policy option we have been working toward would replace the current MA quality bonus program with a value incentive program based on the five design elements that we have discussed over the past two years.

It would score a set of outcomes-based measures, evaluate quality at the local level, account for social

risk factors using stratification into peer groups, and establish a system for predictably distributing rewards and penalties with no cliff effects on a budget-neutral basis.

The MA value incentive program could be phased in. For example, there could be a phase-in period with two transition years. The first transition year would bring the QBP rewards closer to budget neutrality by reducing the size of any bonuses by half. Benchmark increases of 5 and 10 percent would be reduced to 2.5 and 5 percent during this year.

In the second transition year, MA-VIP scoring would be used to determine any rewards and penalties, but the size of rewards and penalties would be half of their full size. For example, if in a fully phased in MA-VIP, the rewards and penalties are funded with 2 percent of plan payments, then in the MA-VIP transition year, the funding would be based on 1 percent of plan payments rather than 2 percent.

As Ledia discussed at the start of the presentation, we are unable to assess MA quality in a meaningful way, and beneficiaries lack good information about MA quality in their market area. Yet the quality

bonus program generates additional nonbudget-neutral spending that costs the Medicare program about $6 billion annually.

Our modeling demonstrates the feasibility of the MA-VIP design and shows how the five aspects described in the policy option offer an improvement of over the current QBP.

In March, we plan to return with a Chairman's draft recommendation to replace the QBP with the MA value incentive program. We would like your feedback on the aspects of the MA value incentive program that we presented today as well as considerations for describing the program in the chapter that we are working on to support the development of a recommendation.

Thank you, and we'll now turn it back to Jay. And in view of the time, I think we do not have time for questions or comments.

[Laughter.]

DR. CROSSON: Good luck with that.

So I just have a clarification myself, and I think you know what this is going to be, Carlos. Could you turn to Slide 12?

Right. So I just wanted to ask you to point out that this range of payment adjustments here across the distribution is in addition, as I understand it, to the return of the 2 percent withhold. So these are net numbers. Is that correct?

MR. ZARABOZO: That's correct. They're net.

DR. CASALINO: Say that again?

DR. CROSSON: So where you have this range at the bottom of minus 1.5 to plus 1.5, that's net of the return of the 2 percent withhold to all the plans?

MR. ZARABOZO: 2 percent back plus --

DR. CROSSON: Yes, yes.

MR. ZARABOZO: -- 1.5 percent.

DR. CROSSON: Yes.

MR. ZARABOZO: Okay. At least to me, I didn't think that was clear, actually.

DR. DeBUSK: If it's zero, then would it consider that you get your money back, or it's zero for your 2 percent?

MR. ZARABOZO: Zero is you get your money back.

DR. DeBUSK: Okay.

DR. CROSSON: Right, right, right. Okay. Got

that? Okay. All right. Thanks.

Clarifying questions? I'm going to take a break for a second.

DR. PAUL GINSBURG: Yeah. Okay. Marge and Dana. Pat and Jon.

MS. MARJORIE GINSBURG: This is a great report.

DR. PAUL GINSBURG: And Jaewon.

MS. MARJORIE GINSBURG: I jumped the gun. Am I jumping the gun, or am I on? Okay. I think I'm on.

Anyway, wonderful report. In my view, this is one of the most important topics that the Commission has to deal with in the coming year. So it's very exciting.

I have a number of questions. I'm going to try to keep them smaller.

On page 24 of the report -- let me find it -- in the middle section, it says the parent organization with the highest quality score in the market will receive the greatest reward. The organization with the lowest score will receive the greatest penalty.

What if the scores are really, really, really close? How do we -- I mean, that's a pretty dramatic difference between reward and penalty for something that

may be a very, very small score.

DR. JOHNSON: It still would be the case that what is written is true, that the highest scoring organization would have the highest reward, but if the points are very similar, the size of those rewards and penalties may be very small. So they would not be at the ends of that distribution. It may be only a few tenths of a percentage point reward and a few tenths of a percentage point penalty.

MS. MARJORIE GINSBURG: Okay. So it is relative to the size. The difference between the scoring determines the size of the reward or penalty.

DR. JOHNSON: Yes. That is part of it, and the other aspect that determines the size of any reward or penalty is the distribution of enrollment within those parent organizations.

MS. MARJORIE GINSBURG: Okay.

On page 17 of the report, Table 2, are some more important than others of the various measures here, and will they be weighted? Or do they all have equal value?

MS. TABOR: So we did in our modeling apply a weighting system for the six measures that we included in

the modeling, and we followed CMS's lead on the weighting that they apply for the quality bonus program, where the outcomes measures are weighted at 3 and the process measures are maybe about 1. So, in our modeling, the breast cancer screening have the lowest value, but the hospitalizations have the highest.

MS. MARJORIE GINSBURG: Okay. And I may be getting redundant here. I'm trying to get it right. Is the reward/penalty for this table then based on cumulative scores of all five categories, or is each one weighted separately?

MS. TABOR: So I think that would be something that policymakers could consider as to whether the weight the domains or whether to weight the individual measures.

In our modeling for the six measures that we used, we didn't kind of follow the domain, just because we only have six measures. So we weighted each measure individually and, again, kind of gave higher preference to the outcome measures.

MS. MARJORIE GINSBURG: Okay. I may have some more later, but that's it. Thank you.

DR. PAUL GINSBURG: Okay. As I keep looking this

way first, I'm going to do the people I have on the other side. Amol?

DR. NAVATHE: So a quick question, because we had debated in the past about this notion of the prospective element of the scoring versus tournament typical model. In some sense, is that here, the prospective piece? Is that sort of a distinction without a difference? Because we end up doing the assessments at the local market level and adjusting, as we just talked about, and although there is some predictability in terms of if my score goes up this much, I get this many points, at the end of the day, the dollar amount that I get is still dependent on what happens in my local market.

MS. TABOR: That's accurate, yes.

DR. NAVATHE: Okay.

MS. TABOR: There is still a relative nature to the system.

DR. NAVATHE: Okay. Thanks. I just wanted to make sure I understood.

DR. PAUL GINSBURG: Sue?

MS. THOMPSON: Thank you all.

Talk a little bit more about the 2 percent and

what sense we have that that's enough to motivate behavior.

DR. JOHNSON: I don't know that we have looked at any of the literature that suggests what percent is the right amount to motivate behavior. I think originally in the original conception of the Commission's view of what a quality incentive program would look like in the MA program, it was to be a small percent. So we started with a small number.

I think purely for modeling purposes, one of the things we wanted to see was what the distribution of rewards and penalties was and see whether or not they tended to fit the entire two or even smaller, since we found they're even smaller. So that certainly is a parameter that I think could be figured out when implemented.

MS. THOMPSON: So it was used for modeling purposes?

DR. JOHNSON: Yes.

MS. THOMPSON: Okay. So as the cliffs go away and the geographies get smaller, how do we think about -- or how do you think about what happens with scale impacting the results?

In other words, do we need to worry about that with the cliffs going away? As the cliffs go away, how do we think about the impact scale will have, because these -- as the geographies get smaller, the numbers will get smaller. How will scale affect the results?

DR. JOHNSON: Do you mean scale of the parent organization?

MS. THOMPSON: Mm-hmm.

DR. JOHNSON: So in our analysis, as we've done it, each parent organization with a market is treated separately for each market that they participate in. So there still might be some dynamic that larger parent organizations in a market, you know, might have different results. But the national aspect of the parent organizations that is driving a lot of the QBP results, I think a lot of those negative aspects are mitigated by looking just at the market level.

MS. THOMPSON: And my final question. In parts of the country where there's not a great prevalence of MA products, where they might be one plan offered, any thoughts about what might happen in those markets to the MA opportunities to the beneficiaries?

MS. TABOR: So we have thought about this, and I think a couple of different options could be is that those plans are still included in the value incentive program. Perhaps they join the next contiguous area. Perhaps the enrollees that are tied to that area are then also kind of tied into plans in the next contiguous area. So I think we'd want to kind of put in -- or CMS should kind of put in place opportunities to evaluate and hold as many enrollees as possible.

MS. THOMPSON: Thank you.

DR. PAUL GINSBURG: So Jaewon is next.

DR. CROSSON: Okay. Jaewon?

DR. RYU: Sure. I had two questions. One was around the peer grouping around the dual eligibility. It seems like that would introduce some state-by-state variability, given the Medicare eligibility component. Is that significant? Not? Have you all looked at that?

MS. TABOR: We have thought about it, yes, and that's kind of one of the reasons we chose full dual as opposed to partial dual, because the variability really comes into play more when you're looking at the partial duals.

DR. RYU: Okay. How much variability still exists, though, even with the full dual criteria?

MS. TABOR: We can come back and explain that more.

DR. RYU: And then the other question was -- and you cover some of this on Slide 17 -- between the MA-VIP and the current QBP, how do -- I'm wondering if there's a way to further stratify, because so many plans right now, 82 percent of beneficiaries are in a star bonus environment, right, under the QBP. But within that is it possible to sub-segment into plans that are, quote/unquote, "higher performers" versus those that may not be as high but still qualify for the bonus, and how would this change impact them? You know, currently they get the bonus, but then in the new MA-VIP, how do they land? Something like that would be a good picture to have.

MS. TABOR: We can look at that more, yeah.

DR. CROSSON: Jon.

DR. PERLIN: Yeah. Thanks for your work on this. It makes good sense to gain insight into performance at the market level. This is my own limited understanding of this but I want to make sure I've got this right.

So the performance is calibrated nationally, but with two different markets. Assume two different markets with equal risk populations. Could better performer in a worse market, or worse-performing market, actually do financially better on the return than a worse performer in a better-performing market?

DR. JOHNSON: Yes.

DR. PERLIN: Okay. So that's just -- okay. That's good on that one.

In moving budget neutral, which, you know, has a symmetry with the other programs, do we expect any added downstream pressure on providers given obviously net-negative margins that providers experience for Medicare beneficiaries in the first place?

MR. ZARABOZO: Well, potentially. I mean, we don't -- that is one possibility. As we mentioned, if, for example, a plan says we don't think we can reduce the extra benefits so we have less money and, therefore, we will have to cut costs somehow. So either cut administrative costs, reduce our profits, or pay less for the Medicare coverage.

DR. PERLIN: Thanks.

DR. CROSSON: Pat.

MS. WANG: Great work as it continues to evolve. Am I correct that the vast majority of Medicare Advantage plans also offer the prescription drug benefit?

DR. JOHNSON: Yes.

MS. WANG: So what happens to the PDP or the Part D quality metrics, which, you know, previously I think there were 14 of them. I mean, what is your thinking about an MAPD that would participate in this streamlined program for MA, but what happens on the Part D side?

MS. TABOR: I will say that we have been thinking exclusively just for the MA part of the program, and at this tie have not thought about the Part D. But if the Commission would like us to, we can kind of take that on also.

MS. WANG: I just would observe that if you leave the -- you know, 14 measures there and whatever it is, 5, on the MA side, it's something to think about. There are a lot of plan administration measures in the Part D side. It's hard, I know, because the majority of people are in freestanding PDPs, but it's far too common. I guess it would be good to think about that.

On the HOS, I think it was great that the paper

acknowledged the need, or encouraging CMS to make improvements in that. And maybe since there is an expert sitting at the table she can comment too. But other than small sample size -- because I remember in previous reports you guys were like pretty critical of the HOS and the value, because I think it was the small sample size and the differences were so small. Do you think that increasing sample size is the thing that needs to happen, or are there additional things to suggest to make the HOS more reliable, since it's going to now drive such a bigger part of the program?

MR. ZARABOZO: Well, in this modeling exercise we did see differences among plans, even at the small sample size level.

MS. WANG: Okay.

MR. ZARABOZO: So, I mean, our concern was previously the way it was reported of, you know, how do plans fare compared to the national average essentially, in terms of who did or didn't improve, and, you know, how far away from the national average were they. So it turns out few plans are far away from the national average. But there are distinctions, even in our modeling, on the two

measures, the mental health and physical health measures.

MS. WANG: Okay.

MR. ZARABOZO: And we also say, you know, we would like fee-for-service to also have an HOS --

MS. WANG: Would you recommend that caps and the HOS survey volume sort of be by local market area? So that's implicit in this. I got it. Okay. Okay.

Question about the dual versus non-dual and adjustment for SES. Did you consider -- so the current stars program has got an SES adjustment based on proportion of LIS members, which is a federal definition, and it gets to Jaewon's concern, I think. Did you have the ability, or do you have the ability to sort of compare your modeling of dual versus non-dual against that sort of adjustment they have, and whether the high-LIS plans fare the same? Because you wouldn't want to go backwards in terms of recognizing SES factors.

MR. ZARABOZO: Well, we can do that, and that was one of the points of the bar charts, various bar charts, that said, by the way, for example, the under-65, 40 percent of whom are dual, we still have an issue with you might need further stratification of that population. So

if there are differences -- and there are state-level differences. For example, in California everybody is a full dual pretty much. You don't have the frequency of partial duals that you see in other states.

So, I mean, we did this partly for simplicity, in terms of showing, yes, when you stratify in this manner and do it at the local level you get very different results from what we're seeing today. So you could do further stratification. But again, when you're dealing with small numbers, or it could be in a state situation, you could do partial and full. But in none of the states you say, well, it doesn't make any sense in this state to do that kind of stratification.

MS. WANG: Or even picking up a page from what CMS does currently, which looks -- sort of makes point additions based on the increasing proportion of LIS members to total members. I mean, they have that table. There are 10 deciles and then there a disability table.

MR. ZARABOZO: Right. But I think our proposal -- the MA-VIP is better in the sense of -- so you could have a plan in an area that has, let's say, 10 percent duals, and they don't do well at all for the duals. But because

they're 90 percent non-dual they are a bonus plan. They have a competing plan, and this is 100 percent dual, and is not doing well because they're all duals.

So this situation just compares how do you perform for duals versus how do your competitors in the area perform for duals. You are getting more money than the organization where we have isolated their dual performance compared to your dual performance.

MS. WANG: Right. Right.

MR. ZARABOZO: Different from what the PDP does.

MS. WANG: Okay. On the budget neutrality issue, which, you know, I think is a challenging issue, question -- the first time you presented this it was -- there was a separate presentation on benchmark reform. So is this recommendation on budget neutrality going to still be a completely separate conversation from benchmark reform? Because, you know, the benchmarks were created in tandem with the creation of the current, you know, quality program, the stars program. So how are you thinking about that?

DR. MATTHEWS: Right. So given the prior Commission discussion, I think back in November when we

presented the last iteration of the MA-VIP work in the same meeting as our benchmark discussion, there was some concern about the potential cumulative impact of discussing both of these policies at the same point in time. And given that our work on MA-VIP was further along, and given the fact that there is some urgency to being able to assess the quality of care provided under the auspices of MA, we've decided to move ahead with this policy first. We can continue to explore the benchmark work that we first raised in November, but that would probably be on a longer track, and we'd like to see if we could get some resolution here first before we proceed.

DR. CROSSON: Okay. And I think I'd extend that a little bit more. We have other -- without getting into the details right now, we have other MedPAC recommendations with respect to MA reimbursement that are already outstanding. So just as was done with this presentation, which is to look at the economic impact, potential economic impact on plans of this change, it's my thought that as we approach others, including the benchmark issue, at that time we look at, you know, in a transparent way, the potential cumulative impact of that change compared with

this change compared with the other changes that we already have on the docket, and make sure that, you know, we are going where we think we ought to be going with respect to MA reimbursement.

MS. WANG: Okay. Thank you.

Final question. I didn't see anything in here that translates these results into beneficiary information. Is the intent -- I mean, I know that there was a reference to focus groups, and people said that they didn't pay attention to the stars. I think there's different information on the ground that people do pay attention to the stars. So what's your thinking on that?

MS. TABOR: I think we wanted to focus the discussion on just the payment side, because I think that there is a lot to be done with also what's shown to beneficiaries. I think that there is general alignment, in particular, of this program using local market area reporting, because that will allow for better information. So I think we're kind of focusing the discussion again on the payment side, with the potential to look at the beneficiary side later.

MR. ZARABOZO: I would also add that the current

situation is, as you know, the stars reported to beneficiaries are the adjusted stars. So if you're getting a bump-up because you have a high proportion of duals, the stars that the beneficiaries see say that you are, for example, a four-star plan. Now this gets to Jonathan's point, Jon Perlin's point about, well, that may be or not. Maybe you're actually at three stars if you look at the performance based on a national scale, as we're doing. All of your measures taken together, you're at three stars, but you get a bump-up because of your proportion of duals.

So I think people need to be aware that if we're looking at the market level, it's possible -- what may happen is that what will be reported is this particular plan, for its duals, performs here. Here's where it is in relation to the plans in this market, and here's where it is in relation to the national standard that's established. They're number 2 in this market but they're number 52 in the nation if you're looking at this particular categorization of people.

So I think this could be an improvement, just in terms of the public reporting issue, I guess, compared to the PDP.

MS. WANG: It sounds like that is a rich area for conversation that is going to be taken up another time. So you're not intending to cover that here. Okay.

MS. TABOR: No. I'm creating job security for myself.

[Laughter.]

DR. CROSSON: Okay now. I've got Dana and then Larry. So Dana?

DR. SAFRAN: Thank you. Just three questions from me. One is, near the end of the presentation, Carlos, you were talking about the transition year in the middle, and in the first year of the new program that the bonus potential would be 1 percent before it gets to 2 percent. What was the rationale for starting there, given that we're already -- plans are already taking a hit?

DR. JOHNSON: I think just to make sure that plans had at least a year under their belt with feedback of how their performance is under the new VIP program, and that the impacts of those, of that performance, those results, wouldn't be quite as big, but --

DR. SAFRAN: On the penalty side, in other words.

DR. JOHNSON: Yeah, on both sides, but yes, more

out of concern of the penalty side.

DR. SAFRAN: Got it. Okay. Second question relates to something somebody asked, I think Marge, that somebody over there asked, about the 2 percent. Maybe it was you, Sue. Have you looked at that as relative to margin? Because Larry and I had been having that conversation over here, and, you know, I only know one plan that I work for. But I think, you know, 2 percent bonus would be quite motivating, because it's pretty close to the margins that plans have. But what do we know about that?

MS. TABOR: I think we, again, just kind of picked 2 percent as something to model, and would think there needs to be more discussion about what the proper withhold is. And part of that decision should take into account the margins. And, you know, there's also kind of other options of perhaps transitioning into further withholds over time, which a lot of programs do.

DR. SAFRAN: Yep. Okay. Last question, which may be the most complex one. But help us understand how, with the new approach to target setting, as well as the new approach to scoring being local, how is it that a plan knows the performance targets? Because you said they're

prospectively set. So how do they know the performance targets for them, for the coming measurement period?

MS. TABOR: So what they'll know is, if I have a readmission rate of 16, and they'll be able to see that if I improve that rate to 15, I'm going to get 2 more MA-VIP points. And they won't know exactly what are the dollar amounts tied to those points, but know kind of the magnitude of how much of a change in their performance means a change on the scale.

DR. SAFRAN: Got it. Thank you.

DR. CROSSON: Okay. Thank you. Larry.

DR. CASALINO: Yeah. Great work. As far as I'm concerned, the sooner this would get in I think the better. I guess this is supposed to be a question. Do you think that the sooner this --

[Laughter.]

DR. CASALINO: But, really, it's great work, and, of course, the simplicity of it is very welcome after the Part D discussion.

So just one comment -- question. So back to this net and withhold thing. And Jay asked if someone were to get a 1.5 percent bonus, they get their 2 percent back and

they get the 1.5 percent. Correct? And it goes the other way -- does it go the other way as well? If you were to get a 1.5 percent penalty, you don't get your 2 percent withhold back and you also get -- no. You just -- so I give 2 percent -- I get a 2 percent withhold, and then I'm projected to -- I'm a little bit worse than average on quality in my market so I would get what you guys call in the report a half a percent penalty, say. How does that relate to the withhold?

DR. JOHNSON: So the first step, and our first conceptualization of this, would be a 2 percent withhold, and then there is a give-back amount, and based on our results that give-back amount would be between half a percent and 3.5 percent. So the net is a negative 1.5 to a positive 1.5 percent adjustment.

I think what we may have confused you, a few of you, a little bit by is one concern might be that if the payment adjustments are relatively small, withholding a large amount of money from the plans and then giving most of that money right back to the plans, with some differences here and there, might not be a necessary use of all of that money.

And so an alternative would be instead of applying a withhold and giving most of that money back, just in slightly different configuration, an alternative would be to come up with a payment adjustment, and this is how the hospital value incentive program works as well, in which, in a practical sense, no money is actually withheld but a payment adjustment is calculated based on the numbers on the slide that's up right now. And then those adjustments would be applied in a future, or the next plan payment year, as an adjustment.

DR. CASALINO: So it may just be me, but I think I'm more confused now than I was. I think the concept is simple, but I still don't quite get it. The fact that Jay and I, and maybe other people, couldn't just -- this has to be understood at kind of a first sight, I think, because it's really important.

So if I do -- when you talk about a 1.5 plus or minus range, as your example, how does that relate to the 2 percent?

DR. JOHNSON: That is assuming, in the original conceptualization, that if you get a -- a plan has withheld 2 percent, if they got back only a half a percent of their

payments, they would effectively have a penalty of negative 1.5 percent. However, if they got back an equivalent of 3.5 percent of their total payments, they would then have an effective reward of 1.5 percent.

DR. CASALINO: Okay. I think it's just real important that this be clear, probably in multiple places in the write-up, because if anybody gets confused by it, it's not good.

And then my only other question is --

DR. NAVATHE: On that point.

DR. CASALINO: Yeah.

DR. NAVATHE: So what will help is to sort of simplify what is the "financing mechanism" for the budget neutrality, which is the 2 percent, and separate that from what is the actual bonus or penalty that's paid, which is what you have up here, which in essence can be conceptually separated from the financing mechanism. That should hopefully clear it up.

DR. CASALINO: Yeah.

MS. TABOR: That's a good point.

DR. CASALINO: So the national versus local competition, let's just call it, or geographic area for

rewards and penalties, you give some discussion of why not to do it on a national level, and one reason is that plans can move, right? So if they're done on a national level, you might have small areas where there wasn't any plan at all. But you don't really -- so there's really three alternatives. You could do it all local, all national, or some mix, and within the "some mix" there could be any -- you know, it could be 80-20, 90-10.

Do you think it would be helpful to have some discussion of the pros and cons of some mix, you know, mostly local but some national, in terms of measuring performers and how it should be rewarded? So I'm not really taking a position on that, but just discussing the pros and cons of that.

I will say -- and this is probably the last thing I'll say -- on the top of page 23, you have a little discussion of local versus national, but you mix in with it the whole contract problem -- "Oh, we want to do local because of the contract problem." And I think that's relevant in the sense that you only want to measure in one little area so there can't be the shenanigans with the local, the contracts. But it isn't really relevant -- once

you just pick and you say, okay, I don't care how many contracts this plan has, we're only going to measure them one at a time in this local area, that can be done. But that's a separate issue from whether we would just reward based on local performance or we would reward based on national -- compared nationally or compared to local mostly and a little bit compared to nationally. It's a separate issue, and I don't think they should be mixed together like they are at the top of page 23. But, in any case, more discussion of the pros and cons of that third alternative mix I think would be useful.

DR. JOHNSON: That's a good point.

DR. CASALINO: That comes up a lot in the ACO area.

DR. JOHNSON: So we've talked about the difference between evaluating quality at the local level versus distributing any rewards and penalties at the local level, so we can separate those out more.

MS. TABOR: And I would also like to add this point of having kind of a mix, national versus market level approach, is something that we haven't considered. And I would actually ask the Commissioners to comment on that

because the immediate con that comes to mind is that it's complex and it still could create kind of incentives to go to some markets over others. So, again, I would just kind of ask that we talk about this idea more if others are interested in it.

DR. CASALINO: I don't think it would be that complex, but depending on the amount of national weighting in it, if you gave a lot of weight to the national, then it would still be a big incentive for plans to move. But even 10 percent might be an incentive for plans to move. That's what I think could bear more discussion.

DR. CROSSON: Okay. We're going to move on to the discussion phase now. Let's put up Slide 19. I think that's the best one for this purpose. We're looking for comments in terms of general support of moving in this direction. We've already had a few ideas about how to tweak or improve the policy option, but we'd also be looking for others. And Dana is going to begin.

DR. SAFRAN: Thank you. You know, I'm in full support. I think this is really exciting work. As you've pointed out here, overall we're trying to move to more value-based payment, and we have here a program that's got

about a third of our enrollees, and our approach to rewarding payment has been costing about $6 billion and not delivering a whole lot of value to beneficiaries. So I fully support what you've outlined here, and, in particular, I'd call out a few features of this that are really, I think, differentiated from the program, the QBP program, that you propose to move away from.

One is parsimony with an outcomes-oriented measure set is, I know, a philosophy you're trying to take as you go through each program area for quality across Medicare. But it really is, I think, quite well done here. I do really like that you've kept in some of the important preventive measures, as I think Commissioners urged last time we discussed this, but also really kept an outcomes-oriented focus and added in -- or, you know, depending on how we look at it from the program we'd be moving away from, retain the functional health outcome measures that are collected through a health outcome survey.

There's been some discussion and Pat pointed out some of the Commission's previous reports that were somewhat critical about the HOS survey measures and the fact that they didn't really appear to be differentiating

very much across plans. I think I'd say a couple things about that since it's an area that I've done quite a bit of work in.

One is, you know, before any area of performance is incentivized or incentivized strongly -- and I think this would be more strongly incentivized in this program where there are fewer measures than it is in the current program -- it shouldn't surprise us that we don't see those who are being measured differentiating themselves, right? I know in the commercial world -- I don't know if it was the same in Medicare -- we saw the same thing for readmissions before readmissions mattered, right? And yet we are for sure seeing that that doesn't mean that it's not possible to differentiate performance on readmissions. You simply have to make it something that matters.

So I do think that it is possible for plans to differentiate themselves on performance relative to functional status and well-being. And, quite honestly, if we're not trying to do that very core aspect of health that, you know, is really at the heart of what health care should be trying to accomplish, then, you know, really what are we doing? So I love that you have that in there.

I think we should contemplate the idea of how we might have the use of that survey or of other patient-reported outcome measures, start to look specifically at subpopulation groups for whom the condition that they have and the treatments available really should lead to differentiated improved functional status or well-being, right? Patients with depression, patients with musculoskeletal conditions, because I think that would even help strengthen this area of measurement.

A couple final things. I really love the way that you have moved to the local measurement. I was thinking about the same point that Larry raised about, you know, should we consider a blend, and, you know, something that you all said in responding to that I think was a good point, which is that we could consider having the blend for the rewards component but not for the reporting component, because part of what is great about the local measurement, in addition to the points that you've raised of, you know, not causing plans to hop around market to market but, rather, really compete for performance in the market that they're in, which is great, is the information for the beneficiary, right? It's that, you know, the performance

data should be very close to the experience they will have in that plan, should they choose it, and that's always what we're looking for when we're reporting performance data.

So I wonder if we could begin to blend in national so that the -- not for the public reporting part, but for the reward part. And the reason for that -- and I understand your points, and I agree with them -- that we have to do that carefully so we don't undo the goodness of measuring at the local from the perspective of plans choosing markets to be in, but a good reason to do that is we don't want to kind of allow there to perpetually be markets that are just where performance is low. So we somehow have to start to bring in that national benchmark.

I think my last point that I was going to make about what I loved about it is, of course, the way that you're setting the targets, getting rid of the cliff, so that performance is continuously motivating improvement and having the performance targets known prospectively. I know from my own work how motivating that is to those who are on the receiving end of the measurement, and we saw really dramatic and sustained improvements over 10 years of studying this when we moved to a methodology like that, so

I really applaud that move. And that was my summary.

DR. CROSSON: Dana, let me just ask you one question. How would you -- what do you feel about the notion that was described, which is with respect to reporting, that potential MA members would see the performance locally and they would see the national performance?

PARTICIPANT: You mean national benchmark.

DR. CROSSON: Yeah, right, the point being for beneficiaries, they might want to know, in addition to what they actually have available to them and how those compare, whether or not to go into MA at all based upon a relatively low performance compared with MA plans in other parts of the country.

DR. SAFRAN: Yeah, I guess where I'd worry about that is without showing -- you know, the way you just framed that choice is, well, if MA plans in my market don't look so hot, I guess I'll stay with traditional Medicare. But without having the corresponding data, you don't know that that's necessarily the right conclusion to come to.

DR. CROSSON: Okay. I agree. That's --

DR. SAFRAN: Yeah.

DR. CASALINO: But you still think it could be a good idea to show them both, but just to frame it exactly the way Jay framed it.

[Laughter.]

DR. SAFRAN: I suppose I'd want to think about it a little more. Why do we want to show them both? I might want to show them the plans in their market and then show them, by the way, you live in a market that's very low performing relative to the rest of the country, just to get some activation about like don't we deserve better here. I wonder if that would be a good way to split the difference.

DR. CROSSON: Jon.

DR. PERLIN: Yeah, this is why I asked the question, could a better performer in a lower-performing market do better than a worse performer in a better-performing market? Because I think the distinction is just to Dana's point. It's absolutely what I agree with. So I think it is useful the beneficiary potentially see the juxtaposition of the two, and you don't know, obviously, the other piece of that.

I think the other sort of insidious piece is that we want to relieve plans and providers of -- or recognize

the challenge of caring for a more socio-demographically challenging population. On the other hand, you don't want to desensitize and say, okay, from the patient perspective it's okay to get services that aren't. I mean, I think the incentive has to be how do you figure out the way to give patients who have the greatest burden the best possible outcome. And that's really tough because that operates with pressures in both directions.

So, you know, at one level, I think providing the information of what is relative performance is a way to solve that. Second, separating that from payment I think has utility. And the third is I wouldn't underestimate the power of public accountability or public signal of the Health Services Research, particularly where the incentives -- and Dana brings the information to what the margins area, clearly an area she knows better than I do. But when incentives are modest, I think the Health Services Research, particularly as you look at other countries, would indicate that the public disclosure and accountability is a pretty powerful signal in terms of motivation for improvement. Thanks.

DR. CROSSON: Okay. On this point, and then

we'll start -- David, on this point?

DR. GRABOWSKI: Not on this point.

DR. CROSSON: Okay. So on this point?

DR. NAVATHE: So I wanted to echo something that Jon just mentioned, which is, you know, we look at duals as a way to try to normalize a little bit; we do some peer grouping. But at the end of the day, it actually may be very challenging to truly adjust for all these unobservable in-claim factors. And so I think if nothing else, in our rationale around the recommendation, I think we could describe more explicitly that there is a trade-off, there is a situation that Jon described, which is a lower-performing plan in a market is actually high-performing overall, the national could be penalized, whereas you get this situation; but because we can't fully adjust for these socio-demographic or social factors that may influence, we're sort of accepting that possibility because the local market adjustment reflects beneficiary choice and doing so may actually more fully account for these unobserved factors. So I think it's worth articulating that rationale. I think that is a reasonable rationale for this, number one.

Secondly, I think Larry brought up the idea of, sure, we can definitely do the reporting, but we could even -- this would take us away from simplicity a little bit, but incorporate some sort of national benchmark performance also into the incentive computation, which, as I think about this, at the individual clinician level or individual practice level, I think we want to really espouse simplicity as an important value. When it comes to MA plans, which are sophisticated beasts, I think perhaps a little bit of complication is not the worst thing in the world. So I think it may be something to reconsider potentially.

DR. CROSSON: Okay. So now let's have the general discussion. I saw David, I see Marge. All right. Let me see. David, Marge, Bruce, Amol, Pat, Jonathan, Brian. Got everybody?

DR. GRABOWSKI: Great. I'm first. So let me start by saying I'm really supportive of this work, so thanks. This is great stuff. I just want to make one point, and that's really to pick up on the comment Jaewon and Pat were pushing you on in the first round, with does full dual status really capture or account for social risk

factors. And I've always had a funny feeling about this measure, and there was a paper this past month in Health Services Research that really confirmed my kind of queasiness. They used the Medicare current beneficiary survey and looked across state, how big is the variation among duals in socioeconomic risk and health risk, and it turns out, Jaewon, to your question, it's actually pretty big, about 25 percent state to state.

I know this is illustrative right now, but going forward -- and you have a nice footnote in the text here about, you know, over the coming cycle staff plan to research potential of peer groupings using additional social risk factors. I'm really excited about that work, and I hope you'll continue down that path, because I don't know that we're all the way there with dual status, and I think we can do better there.

Thanks. And further job security for Ledia here, so this is good.

DR. CROSSON: Marge.

MS. MARJORIE GINSBURG: Actually, my comment should have been attached to the last piece before we got into this, but that's okay. It's about reporting locally

and reporting nationally, and I'm now sort of wearing my Medicare counselor hat. Most people, if they're coming into Medicare, at least my experience only, which is this big [indicating], and they're debating between an MA plan or original Medicare, they want to know the pros and cons of both. Why would this be better for me versus this?

I guess I'm making an argument for not making this any more confusing than it already is, so I have reservations about reporting out nationally. I think people care what is this for me here now in my community, and I guess I'm a little concerned that they see better scores nationally, they're going to think, why are my folks so bad? And maybe I don't want this plan after all.

So I worry -- I think this would make a great focus group topic, if anybody wanted to take that on, Ledia. But, anyway, having said that --

DR. NAVATHE: But, Marge, wouldn't that potentially be a consideration we do want them to have? If they're picking to enroll in MA and if the plans that they have available to them are --

MS. MARJORIE GINSBURG: Well, maybe that's why it would be a good discussion group, because I don't know if

they would say yes, I would love to know how this particular group is nationally. But people look at their experience, and they think in terms of what they know here and now, what they can get their mind around, what are their options here, and what's happening in New York I think has very little meaning to them, or even nationally for this particular health plan. It's their doctors and the hospitals and the care they get here is important to them. But I think a focus group on this whole topic would be really worthwhile.

MS. TABOR: I will say that in a previous life I have done focus groups on this topic, and there's also some literature on this, and it generally does say that people do get more confused when you throw in the national numbers, and they really want to know how to make the best choice for them. But, again, there's trade-offs to that, especially when you think about the public accountability piece.

MS. MARJORIE GINSBURG: And just one other thing about this and the distinction between scores for the dual eligibles versus not. Maybe I'm still not exactly sure about whether one shows a combined score. So let's say

you've got an MA plan that has a really high level of duals, so their scores may be lower. But we're differentiating between the two when we issue them penalties or rewards. Well, does a member coming in looking at making a decision know that the reason their score is lower is because they have a very much higher level of those who are dual eligible? Well, that may not be particularly appealing to those who are not dual eligibles and don't want to be saddled with a plan who's only focused on taking care of low-income folks.

So, anyway, I just wanted to raise that. Aside from that, this is great work, and I --

DR. CASALINO: On this point --

MS. MARJORIE GINSBURG: -- am very excited about moving forward.

DR. CASALINO: So I think -- I appreciate Marge's comment. I think it's important. I think we've had a distinction already made -- I just want to bring it up again -- that one purpose of public reporting would be to help individuals in their choice, and that's probably the most important part. But there is a potential second reason to publicly report which would be in favor of giving

national results as well, which is possibly to generate some local impetus for change, because otherwise how is the local community -- looked at as a community, not individuals making their choice -- to know that they actually are getting inferior care as a group? So it's a trade-off between the complication at the individual level counseling. And I just realized actually it's even a little more complicated, the counseling, because we wouldn't, I don't think, report necessarily scores for the whole plan; it would be the dual-eligible part and the non-dual-eligible part. So that was one point.

And the other point I wanted to make I think is obvious, which is that the reporting and the bonuses can be separated. So whether or not we report national locally, it would be possible to still do some kind of national-local mix for payment. Patients don't care about that, right? The beneficiaries. But the plans do. So they don't have to be totally synchronized.

DR. CROSSON: Bruce?

MR. PYENSON: Yeah. I don't want to miss an opportunity to put in a requirement for encounter data provision here. So I'd encourage staff to think about a

way to do that with a contribution to the pool but no upside if encounter data doesn't flow.

That, by the way, isn't only pressure on the plans. I think it's pressure on the CMS to fix some of the current issues.

I don't see any need for a transition. The bids are done annually. There's big changes that happen year to year, and I think that can be -- I just don't see the need for that. It could be wrong, but I think we could just do this. Otherwise, I support the recommendations.

DR. CROSSON: Thank you, Bruce.

Amol?

DR. NAVATHE: So thank you for leading this work. I'm very, very supportive, in general, of it.

I agree with Bruce. I think faster ramp-up should be totally feasible here. I think they could have a reporting year where they could see how they do an MA-VIP while they're still in the current program and then transition. I think that would seem reasonable.

Two other points. One thing was it would be nice. I think we articulated. We did sort of sample work around the breast cancer process measure, and I think then

cited some limitations around data, which obviously matters. I think it would be good if we could lay out some principles or framework around how those process measures would get picked. I think we would want to look for process measures where there is variability, for example, and they're not maxed out, so there's opportunity. I think a couple of different principles would be nice to articulate since we can't do all the analysis effectively.

The other question I had was, if I remember correctly, when we looked at the analysis in November, it looked like the ER measure and the acute hospital measure seemed to not be very highly correlated, and so I think at the time, I had proposed the idea of maybe combining them into an acute hospital use measure. And you could just double-weight it, for example, if we wanted. I was wondering if we had given any further consideration to that or if there was an explicit decision to not do that.

DR. CROSSON: Pat?

MS. TABOR: I'm working on it. So I think there were also other suggestions on how to improve the measure that I plan to work on in the summer.

DR. NAVATHE: Great. Thanks.

DR. CROSSON: Pat?

MS. WANG: So I think that a lot of this is fantastic, you know, smaller set of measures.

I do like the local market level. I think the discussion has been interesting, and I'm really very moved by Marge's comments.

To some of the other comments about wouldn't you want to know that your plan is not good compared to the national, but maybe the fee-for-service system is even worse compared to the national. So you are only getting a piece of the picture. So I worry a little bit about the kind of incomplete messages there.

I think the local market-level measurement is more appropriate for a lot of reasons, just because health care is local, and beneficiary information, it's like what's in front of you, what are your choices, and so I would just stick with that.

Endorse the sort of suggestion to maybe look a little bit more deeply at some of the peer grouping and how to adjust for SES, and all I was trying to suggest before was if there were a way in the modeling to compare these results with just dual/non-dual as opposed to carrying over

some of the current star stratification based on LIS percentage and disabled percentage to see if there's a correlation, even, about how plans perform, it might be valuable.

Elimination of the cliff is fantastic. I do think it would be important to figure out which two with the Part D quality measures, because otherwise you're going to have a really lopsided program with plans, MA-PDs, continuing to work on 14 Part D measures. It's just very lopsided. So there has to be some way to bring those together.

I have the greatest difficulty with the budget neutrality aspect of this because I think implicit -- and perhaps it should just be directly stated -- is that this is a proposal to cut $6 billion out of the Medicare Advantage program, and maybe $6 billion is the wrong number because of the contract consolidations.

But one of the things that I found, just reading through the chapter a little bit, confusing and potentially -- you know, the contract consolidation, which is correctly pointed to, was the source of a lot of the reason to need to change the program. It's kind of over because of the

work that you guys have already done. Like the game is kind of over, and so I wonder whether some of the ill effects, the 85 percent who are on bonus status, the $6 billion is working through the hangover, because there's such a lag between performance year and payment year in stars three years. So even in 2020, we're still dealing with like currently the effects of contract consolidation.

I think it's a very big deal to say there should be no -- that the total structure of the program should be changed because of bad behavior or whatever people -- however people want to characterize it because I think that when the program was created, it was in tandem with Congress sort of saying these are the benchmarks, a quarter of which are below the fee-for-service equivalent, and so actual payment is well below the fee-for-service equivalent.

So there was the benchmark structure plus you can earn extra money through stars. So I would say that at a minimum, this has to acknowledge that this is a fundamental change in the structure of the program from the way that it was originally designed, which contemplated an add-on.

So I wonder, for example, what was the level of

extra payments through the stars program before the contract consolidation thing started happening. I find that a difficult thing.

I understand that this report can't also address the benchmark issue, but at a minimum, I think there needs to be something stated that this is done as a proposal to restructure the financing or the shape of the MA quality program, understanding that in a budget-neutral scenario, it begs the question of what happens with the benchmarks, what happens with the original -- with $6 billion disappearing from the system, because at a minimum, I think it needs to be mentioned.

And that's all.

DR. CROSSON: Larry, do you want to comment on that?

DR. CASALINO: I'll wait.

DR. CROSSON: Wait your turn? Okay.

Jonathan?

DR. JAFFERY: Thanks.

First of all, overall very supportive. I like the direction and trying to bring the principles that we've had in other areas and also would echo this idea of don't

see the need for the longer transition period.

I'll focus my comments on the national versus local point, and also, in that regard, I think it is crucial that we be able to, again, compare things with fee-for-service. And so I think taking Bruce's suggestion of trying to take this opportunity to again emphasize the need to get encounter data is important.

I guess I am supportive of the national reporting, and I understand the issues that folks have brought up and would want to think through that a little bit more.

To the extent that I think these -- the points about people understanding that maybe they do live in an area where the health care delivery is not as high quality as others and using that as motivation for people to actually try and make some local change, I think that's an important thing to consider.

And I would say that there's another group of individuals that tend to care pretty deeply about how their area performs relative to others, and that's Members of Congress. So this could be a powerful tool if people start to see we're putting a lot of money into MA plans. We've

supported this, and now why is my district or my state so low-performing compared to others?

The final thing I would say, putting aside kind of that issue and thinking about the complexity or not, concern over complexity or not concern over that, I think about the work that's been done in benchmarking in ACOs. I think somebody brought that up before. We could look at that a little bit more.

ACOs have been dealing with that, and there's some good and bad to that. There have been difficulties with dealing with that, but maybe there's some lessons that are learned.

And I will say that having been part of an ACO for a while now, thinking about Jon's comments about what is it like when you're in a high-performing area and you feel like you're penalized when you're doing better than people who are getting rewarded who do worse than you but are in a low-performing area, that's a real consideration. And it leads to people not trusting the program as much.

DR. CROSSON: Okay. Thank you.

So what I've got left is Brian, Paul, and Larry. Then I think we're going to finish.

Okay. Brian?

DR. DeBUSK: First of all, thanks again for some really great work. I mean, obviously, this is a big step in the right direction because it's very consistent with what you've been doing with HVIB and some of the other things.

I love the no-tournament models, no cliffs. I mean, all that's been said before.

I do want to mention -- and a number of people have talked about this -- there may be a method for payment, say a blended local-national method. There may be a method for comparing MA plans, say replacing the stars, but I think -- and you saw this with Dana and Larry who started this, and it keeps coming back up again. Ultimately, you're going to have to be able to compare MA and fee-for-service.

And I think of it as like a Venn diagram. I mean, there may be things that just don't exist in fee-for-service that MA has and vice versa, but as you guys are designing these programs, I think we could be too idealistic and say, "Oh, they all have to be intrinsically comparable." I think you guys have shown that just doesn't

work.

For example, I think your treatment of the low SES people, the duals, the way you've peer-grouped them differently, I think it's very novel. I mean, I think it was necessary and good, and I think it's sound.

But I do hope that as you guys are designing these programs -- and I suspect you are -- at least by the water cooler, you're thinking of what common characteristics do these programs have. How could we pull all this back, even if it's just a tiny set of core matures? Maybe it's just mortality and readmissions and ED use rates. I mean, it could be something that simple.

But you're back to -- and I think Marge raised this issue. I mean, when someone says, "Do I choose MA? Do I choose fee-for-service?" I think our answer is going to have to be "It depends," because it depends on where you are.

And I do hope -- and, again, I know this is so easy to proselytize at a public meeting, which you guys have to go back and actually figure this out. If you could figure out what that small overlapping set of measures are and just work with that in mind.

The second thing I want to mention is back to the idea of making it budget-neutral. I think that there is an opportunity here to generate some program savings and to pay MA plans less. I would love to see, though, when we do the recommendations -- and HVIP, the technical treatment of the quality program, and then a discussion or recommendation around the budget neutrality or the cut, if we could tease those two apart and just have a thoughtful discussion. Since I've been on the Commission, we've talked about doing a further adjustment for coding intensity in the 2 to 3 percent range. I think we may even have an outstanding recommendation. So that's about $6 billion. I'm just, you know, swagging here.

I saw the presentation on removing the cliffs from the benchmarks, which is about another $6 billion. This is about another $6 billion, again, round numbers, but you could be looking at $18 billion worth of standing recommendations. And it would be nice. Maybe the number is $18 billion; maybe the number is 6. I truly don't know what the adjustment needs to be, but it would be nice to see almost an independent discussion, because consider this. Let's say the number is 6. Would you rather take

the number out of the benchmark and leave the 6 in quality, or would you rather take it out of quality and leave it in the benchmark? I mean, which one is a step toward value-based care?

I'm just thinking even if we decide that $6 billion is the right number, this might not be the compartment that we want to take it out of. Again, I don't know. I'm going to count on you guys and presentations to answer that.

DR. JOHNSON: I just want to say I don't think the outstanding recommendations stack up quite that way to suggest that it would be an $18 billion cut, but I think the biggest aspect of the $6 billion we're talking about related to the quality program is that it's before any changes in bidding behavior. So if bids did not change at all and the benchmarks came down 5 or 10 percent where they currently get that 5 or 10 percent bonus, that would be a$6 billion. But it does not mean that $6 billion would be cut from the program automatically.

DR. DeBUSK: I knew that and was hoping I wouldn't get called out on it, but thank you.

DR. CROSSON: Okay. Paul?

DR. PAUL GINSBURG: Thanks.

I'm really glad that Andy made that comment because this is a very complex process with bids, and it just may be that if the quality bonuses go away in the aggregate, the plans bid higher. And it just means extra benefits are lower. It's not that we're going to drive the plans out of business.

Just a couple of comments. I'm very supportive of the whole approach. You've done a great job.

I think on the issue of peer groups, based on socioeconomic factors, I think the right thing to say might be that we really support that principle. We've modeled doing it with full duals, and we think that works. There probably are better ways of doing it and look forward to the evolution over time in getting better precision in making the socioeconomic peer grouping.

I really like the idea of blending for payments, the national benchmark with the local benchmark, because if we have an area where all of the MA plans are weak, I don't think we want to be as generous as areas where they're all very strong. And I think this kind of a blend of a national benchmark achieves that.

I'm still up in the air about whether I want to broadcast that or not. We can talk about that in the future.

DR. CROSSON: Thank you, Paul.

Larry?

DR. CASALINO: Two things. One is I just want to reinforce Jonathan's point about the kind of morale effects of being in a high-performing area and performing higher than a plan in a lower-performing area, but one plan gets a bonus and another doesn't. This does not have good effects on clinicians or, for that matter, administrators.

To the extent this is happening in other programs, I think it generates a real kind of cynicism. I think it really can literally reduce physician professionalism.

Since probably 95 percent or more of what physicians say do that's important to patients doesn't get measured. We depend on their professionalism for them to do a good job, and that we don't really want to reduce that. So I think Jonathan's point is an argument for some national blend.

On the $6 billion or whatever it is and the

budget neutrality, personally, I just don't see a reason to subsidize MA plans through a penalties and rewards program. I don't see it at all.

Just as a thought experiment, how would people feel if we said, "Okay. Let's take $6 billion from taxpayers and put it into the accountable care organization program, and we'll just give $6 billion more to distribute to ACOs"? I don't think that would go over very well. So I honestly don't see why we should consider doing any of that for MA plans.

DR. JAFFERY: We could put that and vote.

[Laughter.]

DR. CROSSON: We have had that proposal at the table, but that's for another time. All right. But now that you've quantitated it, that will move it along.

Kathy?

MS. BUTO: Just one other fairly simplistic option would be to go ahead and add some of the $6 billion back into the base payment under budget neutrality. In other words, if Pat is right and part of the concept originally was that that was part of the payment to be distributed in a nonbudget-neutral way, you could fold that

in budget neutrally -- it could be less than $6 billion -- and sort of be done with it, without going cold turkey.

DR. CROSSON: Okay. Last comment, Jon?

DR. PERLIN: It gets to the question I raised about what we thought the downstream effects would be as well, and I recall, Carlos, your answer was that if dollars come out of these programs, that it can be taken out of margins, administrative overhead, the distribution of benefits the plan offers or payments to providers, and so it offers both to plans and providers a smoothing function in terms of implementation. I think that makes some degree of sense.

DR. CROSSON: Okay. Good discussion. A very intense morning.

Thank you for the presentation, Andy, Carlos, Ledia. You've been here a long time, and this is very good work. So we'll hear from you again in March.

We now have the opportunity for public comment. If there are any members of the audience who would like to comment, please come to the microphone. I'll give you an instruction in one minute.

Okay. So we would ask you to identify yourself

and any organization that you represent. Please comment on issues that have been before the Commission this morning, and we'd ask you to limit your comments to two minutes. And when this light come back on, the two minutes will have expired.

MS. UPCHURCH: Great. Thank you.

My name is Gina Upchurch. I'm with an organization in Durham, North Carolina, called Senior PharmAssist, which I started 25 years ago to help low-income older adults pay for medicines, manage their medicine. We're secondary to Part D. We help them get resources, stay in their home, and we're the SHIP coordinating site for Durham County.

I'm also on the American Geriatric Society Public Policy Committee, but I'm not here representing them.

First of all, thank you for simplifying the Part D drug benefit, and particularly, what we find that people have confusion is the initial coverage phase being a copay, and then when you get into the donut hole, it's a coinsurance. It's ridiculous. So having it a coinsurance all the way through makes it much more transparent for people to understand.

You talked about Medicare Advantage plans being something that people with more money tend to go to. We see in our area in Durham where Medicare Advantage plans are growing. Especially the D-SNPS are growing, with all the added benefits that are coming, especially oral health, dental health.

But please stop people from calling them "supplemental benefits" because that's super confusing trying to explain how supplements are different from Medicare Advantage plans. They should be called "perks" or "extra benefits" or something.

Just to point out a couple things that I hope are helpful to you, there are a lot of people that have catastrophic needs that turn to copay foundations that are often set up by pharma, companies to help people that can't afford the catastrophic. So maybe pharma will be sending a lot of money, not having to support that with this new benefit, and could use the money in other ways. That's one thing to look at.

The other thing I would just -- there is cost-sharing difference with people with LIS, partial LIS, up to 150 percent. They pay 15 percent of the cost. People

between 100 and 135 percent right now are paying anywhere $360 to $895. They have distinction in those copays, and people below 100 percent of the federal poverty with full LIS pay $130 or $390. So there are distinctions already in the LIS benefit with cost sharing, just to point that out.

The main reason we see people that don't qualify for LIS is because the assets test is so very strict, so something to look at.

The late enrollment penalty is keeping a lot of people out of the benefit that should join, especially people in community health centers that have been sitting here since June 2006, because they're getting a discount, FQHCs, at the pharmacies. So now that's a barrier to entry for them.

DR. CROSSON: Please conclude your comments, please.

MS. UPCHURCH: Okay.

So my last comment would be please -- and this may be out of your purview, but the plan finder is -- the updates to the plan find have created incredible challenges trying to help people sort through all of this.

Thanks.

DR. CROSSON: Thank you.

So we will reconvene for the afternoon session at 1:45.

[Whereupon, at 12:55 p.m., the meeting was recessed, to reconvene at 1:45 p.m. this same day.]

AFTERNOON SESSION

[1:50 p.m.]

DR. CROSSON: Okay. We welcome our guests to the afternoon session of the January MedPAC meeting on Thursday, and this is a portion of the meeting, a portion of the work of the year, actually, where we spend some time making recommendations to Congress on updates to the various parts of the industry that the Medicare program pays for. And we're going to start off with the hospital industry, inpatient and outpatient, and Stephanie and Jeff are here. And Jeff, it looks like you're going to start off.

DR. STENSLAND: Yep. All right. So good afternoon. This session continues the discussion on the update recommendation for hospitals, and we presented a full discussion of payment adequacy indicators in December, and so today we're just going to give you an abbreviated recap of that data.

You will also note that on the first page of your mailing we discussed additions to the chapter where we addressed the technical issued you raised at the last meeting, and I will not go through all technical details

here. And finally, before I start, I want to thank Alison, Dan, Ledia, and Carolyn, who all contributed to the hospital paper that you have.

To recap our data from December, most payment adequacy indicators are positive. Access to care to care is strong. While there has been an increase in closures, often due to low occupancy, most hospitals have the capacity and the incentive to serve Medicare patients.

Quality of care is stable with slight improvements in risk-adjusted mortality and readmissions. Access to capital is strong due to strong all-payer margins. The all-payer margin was 6.8 percent in 2018, close to an all-time high. However, Medicare margins were a negative 9.3 percent in 2018. Due to a relatively favorable update in 2020, we expect them to improve under current law to about -8 percent. The relatively efficient hospitals had a slightly Medicare margin of -2 percent in 2018.

Now let's review the current law updates for outpatient and inpatient operating payments.

As you can see in the shaded row, the update was 1.35 percent in 2019. However, due to the expiration of

some statutory adjustments, it increased to 2.6 percent in 2020, and is expected to be 2.8 percent in 2021. Given current CMS market basket projections, this would be the highest update in a decade.

As you recall, last month the chairman proposed a draft update recommendation that would differ from current law, and we'll go into that next.

There were several motivations behind the draft recommendation. The recommendation attempts to, first, increase payments by enough to maintain access to care, but also not increase them so much so that we can maintain pressure on providers to constrain costs to improve the long-term program sustainability. There is also a desire to minimize the difference in payment rates across sites of care consistent with our site-neutral work. Recall that the current law update for physicians have a zero percent update for them, so any increase to hospital outpatient rates will increase the differential in payment rates between physician offices and outpatient departments. Next, there is a desire to reward high-performing hospitals, and finally a desire to move Medicare payment rates toward the cost of efficiently providing high-quality

care. And clearly there is some tension between these objectives.

Next, we present the draft recommendation. This is essentially the same recommendation you saw in December, with some clarification to make it match the wording from last year's recommendation.

The draft recommendation reads: The Congress should, for 2021, update the 2020 Medicare base payment rates for acute care hospitals by 2 percent, and provide hospitals with an amount equal to the difference between the update recommendation and the amount specified in current law through the Commission's recommended hospital value incentive program, the HVIP.

This slide is the grand summary slide that summarizes the difference between current law and the draft recommendation. It can serve as a guide for your discussion. There are three broad implications of the draft recommendation relative to current law, and those are in the last column.

First, it would reduce the difference between physician office payments and hospital payments. Second, it would increase payments associated with delivering

greater value to the program due an increase in quality incentive payments. And on net, it is expected to increase payments by 3.3 percent given current inflationary updated projections, and this is due to the additional quality incentive program payments that we would have under the draft recommendation.

The recommendation is equivalent to the recommendation from last year and has the same score from the CBO. Relative to current law, the CBO estimates the recommendation would increase spending by between $750 million and $2 billion in 2020, and by between $5 and $10 billion over five years.

We do not expect these changes to affect beneficiaries' access to care or providers' willingness to treat Medicare beneficiaries. However, beneficiaries may benefit from hospitals' enhanced incentives to improve quality of care.

I now turn it back to Jay for your discussion.

DR. CROSSON: Thanks very much, Jeff. We will now take clarifying questions.

Seeing none, we will move ahead the recommendation as on page 5. The discussion will be on the

draft recommendation support or not, and we'll have a discussion.

Warner.

MR. THOMAS: You had to think I was going to make a comment, right?

[Laughter.]

DR. CROSSON: I was looking at you.

MR. THOMAS: You're looking at me. I was like--

So I guess a couple of comments. One, you know, I appreciate the proposal and certainly it's heading in the right direction. I guess, I mean, this isn't necessarily a clarifying question, but--

DR. CROSSON: No, we're past that. This is discussion.

MR. THOMAS: I know. I know, but it is a question.

DR. CROSSON: Oh.

MR. THOMAS: It's not a clarifying question.

[Laughter.]

MR. THOMAS: I just wanted to clarify that.

DR. CROSSON: Thank you for the clarification.

MR. THOMAS: Yeah, exactly. So I guess the

question I have, just generally, to the Commission and to the staff, is, you know, at what level do we think it's okay to have inpatient Medicare margins? I mean, is it -8? Is it -9? Is it -10? Is it -5? I mean, I guess, you know, we now have efficient hospitals negative, so should the target be that they be positive? I mean, I guess that's part of the question I've got. I'm trying to figure out like where are we trying to evolved this.

Understanding that, you know, there's not more than likely going to be an access issue for Medicare recipients, because I think it's virtually impossible for an acute care hospital to not be a participating provider in Medicare and be financially stable. Specialty hospitals can do that, because they, you know, essentially target commercial patients. But generally an acute care hospital, you know, is going to be a participating provider in Medicare because they have to be, so -- just to be financially stable.

So any thoughts about that, just in general?

DR. MATTHEWS: Yeah. I can take a stab at that one.

MR. THOMAS: Sure.

DR. MATTHEWS: You know, from my perspective, when we conduct payment adequacy analyses, we do not have a target margin in mind. We look at indicators of access, access to capital, quality of care, and, you know, we present that information along with what might be an appropriate draft recommendation for the Commission to consider. And it is up to the Commission's judgment to make a determination whether or not the recommendation is appropriate, whether it needs to change.

But with respect to the specific point you asked about the efficient provider or the efficient hospital in this sector, that is what has driven this formulation of an update recommendation, last year and this year, in the current construct of the recommendation. And we don't model, you know, the future projections at this level of detail but we have every expectation that the changes that we've identified in the draft recommendation would push the efficient hospital margin closer to zero, and then it could be a determination of whether or to, in a subsequent year, there needs to be additional movement in that regard.

So speaking only for myself, I think the efficient provider is sort of a bellwether, and we've tried

to contemplate what's going on with the efficient provider in a fiscally responsible way, and also in a way that's consistent with the Commission's motivation to reward value rather than general inflation.

MR. THOMAS: And I guess I wonder, with this chart right here, whether we ought to think about -- and maybe this is nomenclature -- whether we ought to think about that we support the total 2.8 percent increase. We just want to configure it differently and tie more of that to value-based payments. I mean, because, essentially, that's what you're doing. You're supporting the 2.8, even though you're essentially bifurcating the increase between two different areas. And I'm not sure we exactly say that in the chapter.

I think the other comment I would make, because I think this draft recommendation, you know, is certainly solid, there's a lot of comments in the chapter around consolidation and those types of things, and I just -- I'm not sure -- that's new information that's kind of in this chapter and it wasn't in the last chapter. I'm not exactly sure why that is new information that's there.

But I think the other thing I would challenge the

team, the MedPAC team, to look at is that hospitals are just generally better run today than they were 5 or 10 years ago. They had to get more efficient. And you talk to any hospital operator and you've got a few of them around here. Jonathan works for the largest, you know, hospital operator in the country. It had to get significantly better in the last, you know, 5 to 10 years because as we're seeing more people age into Medicare it has been absolutely imperative. And as we've seen escalation in labor and drug costs it's been absolutely imperative.

So I think that is another component that maybe should be highlighted, of what have the improvements that have been made in how hospitals operate, how they're efficient. I think they've gotten more efficient from a staffing perspective. They've done better from a quality perspective. They've used technology differently. I'm not sure those things are highlighted, which also lead to the fact that the overall economic performance is better. I don't think it's just driven by consolidation.

So I would just put that out there for consideration and for potential inclusion in the chapter in

addition to what information is there.

DR. CROSSON: Thank you, Warner. I had Larry next.

DR. CASALINO: I think I'll save it until the next section.

DR. CROSSON: The next section? The next section is on physician. Oh, okay.

[Laughter.]

DR. CASALINO: [Off microphone.]

DR. CROSSON: Okay. Wait a minute.

DR. PAUL GINSBURG: Warner, yeah. Just from what you said I don't want it to get lost that this recommendation is actually supporting an increase above the -- you know, the current law, rather than equal to the current law.

MR. THOMAS: Well, I think part of the question -- yes, I see the 0.5 percent.

DR. PAUL GINSBURG: It's 3.3.

MR. THOMAS: Right. It's a 0.5 percent elimination. But I also look at, you know, I'm not sure, you know, when or how that modification of that, you know, quality program is going to be put in place. I understand

it's a recommendation, but it may or may not be put in place, and usually what's looked at is kind of the base annual update.

So I think it's just important to understand that. I agree with you, Paul, that it is a total increase that's over the current law. I think it's warranted, given the economic performance that we see in inpatient Medicare rates. I'm just not sure that 0.8 and the 0.5, how those come to fruition, whether they happen given their tie to a major change in the quality program that we're not sure what's going to happen with that.

DR. CROSSON: Okay.

DR. CASALINO: I think I'll ask it now and then maybe in the next session too.

DR. CROSSON: Ask it again.

DR. CASALINO: It may not be a fair question, but I'll sleep better, I think, if I ask it. If I were one of the like 600,000 or so physicians in the United States who don't understand like how MedPAC develops recommendations, and just looked naively at this session and the next one, I might ask, why are we giving a pretty generous, under the circumstances, update to hospitals, recommending a pretty

generation update to hospitals, and recommending nothing at all for physicians? What would the answer to that be? I have to say, if a physician asked me that, I don't know what I would say, honestly, and I'd like to know what other people would say.

DR. STENSLAND: I'll take a stab at that. So at least when we're looking at the hospital, there is these balances of various indicators of payment adequacy, and one of them is how do your payments compare to your costs as a hospital. And that, as Jim said, is a negative efficient provider margin. And for some of you, you might be okay with that; others might not be.

But what this does is it moves it up so that the payments to the hospital are going to be closer to the cost of efficiently delivering the care.

DR. CASALINO: We don't have a comparable analysis for physicians?

DR. STENSLAND: And that's in the physician, we don't have a comparable analysis, and part of that is for a lot of physician practices the biggest cost is actually their own personal income. You know, this might be half of cost might be the money going to the physician. So it

makes it more difficult. And there's a greater reliance on the access to care and what our surveys say in terms of you still being able to access physicians and the other metrics.

DR. CROSSON: Yeah. I think, you know, the other aspect of it, sort of historically, Larry, is once the SGR was repealed and Congress came in with its own new recommendations about how physicians should be paid and rewarded and the like, I think it was our sense here at the Commission that, rightly or wrongly -- and I don't know that this needs to be maintained for all time -- but I think it was our sense that we ought to give these new initiatives from Congress a time to play out before we came in and made additional recommendations. Now that was -- I don't know how many years ago was that. Three years ago? So more than that. Right.

So, no, I think it's a fair question to say, at least here within the deliberations of the Commission, does that default stay in place forever or not, or does it need to be reconsidered?

DR. MATTHEWS: Just to add two more points. One, as Jeff alluded to, we do pay a lot of attention to the

efficient provider in each sector where the data permit us to identify such a creature, and this is because our authorizing statute does require us to look at the adequacy of Medicare payments relative to the efficient delivery of care. And so that's why we kind of, you know, put a lot of weight on that particular measure.

As Jeff said, we do not have cost information on the physician sector or ASC, and so we aren't able to define an efficient provider as relatively low-cost, relative high-quality. And we default to our other set of indicators, and in the physician sector we actually one that's fairly strong, which is a direct measure of access, the beneficiary survey that we conduct every year. And it has been remarkably stable over time, and so that's the one that rises to give weight to our physician recommendation.

The last thing I would say is going to this notion of not increasing the differentials between settings with respect to the payment updates. Here we're at a 2 percent across-the-board update for hospitals. A statutory update for physicians is zero, but for those physicians who are eligible for a MIPS payment adjustment, I want to say it's, in the aggregate, 1.88 percent, if I've got that

number right, this year.

So there is a certain parity that is maintained in the way we have set these things up.

DR. CASALINO: This is helpful. I just would say to the Commissioners I think we should, not just about physicians but for everybody, we should all be prepared to answer a question like, "Why are you giving maybe 3.3 percent to hospitals and nothing to physicians?" We should all be able to answer that question.

DR. CROSSON: Yeah, thank you. Karen, on this point?

DR. SAFRAN: I share Larry's concern not only about answering the question but just generally about the strategy, and I would endorse that going into next year, that we revisit whether there is payment adequacy, taking into account, with all due respect to the hospitals, they have other sources of revenues that some physician groups wouldn't have, 340B programs, GME programs, disproportionate share dollars, upper payment limit dollars. So there are other ways that they're stringing together their margin, and you can see that reflected in the document, that the total margins aren't negative;

whereas, physicians probably have fewer levers at their disposal.

I would just call out, in addition to asking that next year we give some consideration to understanding better what data we would need to know, what it feels like to run a practice on the front lines given new expectations and technology and whatnot, but that in addition to the MIPS, there's some rebalancing of the fee schedule that the Medicare program is proposing, which also helps in a more nuanced way to drive the payments to a portion of the physician workforce and clinician workforce where we really want to make sure that they're receiving appropriate reimbursement for the services, primary care in particular.

So there are some changes, I think, that are underway in the next couple of years, but I would endorse the idea that, going forward, we should reopen that concept of flat update and see if it's time to reconsider it.

DR. CROSSON: Okay. Jaewon, on this point or a separate point?

DR. RYU: Sort of.

DR. CROSSON: Sort of on this point, okay.

DR. RYU: So at the risk of dragging us into

Round 1, I did have a couple clarifying questions in light of Warner's comments, so that's why it's "sort of." What would happen -- if the HVIP didn't go forward, what would happen to that 0.8? What do we contemplate?

DR. CROSSON: Current law.

DR. STENSLAND: So if the HVIP doesn't go into place, there's no like backup recommendation. If our recommendation is not accepted, then it would be current law, and you would have -- current law would govern, and there would be a 2.8 percent increase.

DR. RYU: And sort of related to that, the 0.8 that we're proposing would go into the HVIP, would that just go -- it would be an incremental amount that would enter into the HVIP pool? Is that how we're envisioning it?

DR. STENSLAND: Right. So you would have this -- you have a budget-neutral HVIP to start with. Then you have an extra 0.8 percent on top of it. So in the end, there would be a little bit more paid out in HVIP bonuses than the hospitals put in.

DR. RYU: So what was the -- I forget what the withhold amount was that we were envisioning within HVIP.

Was it 5 percent or 2 percent?

DR. STENSLAND: We had talked starting at 2.

DR. RYU: It was 2. So now it would be -- now we should think of it as 2 plus an extra 0.8?

DR. STENSLAND: Ledia?

MS. TABOR: Yes, we started with 2 going up to 5 so it would be 2.8 [off microphone].

DR. RYU: Okay.

DR. STENSLAND: And then don't forget the other aspect of this is the current quality programs are a net penalty, so those net penalties would go away, which in essence you start -- you're going from a negative 0.5 to a positive 0.8 on average.

DR. CROSSON: Jon.

DR. PERLIN: Thanks for this discussion. Let me start by saying that I generally support the recommendation. But I do think that I want to associate with Warner's comments here. I think how we articulate what we articulate is very important. I think there are a number of threads that have come up along this.

You may recall last time I asked exactly the clarifying question Jaewon just asked about HVIP that's

statutory, and given that it's statutory, the likelihood, at least if I had to handicap this, of this being enacted to change before the next fiscal year I think is slim.

With that in mind, I'd ask for just clearer language. I know it's the default, I know it's the law, but just that there be clearer language about the update. When you talk about a 2 percent withhold and then 0.8, you're talking about flat, and that's where I begin to get a little bit worried.

So if you go to page 40 in the reading materials, it says, "Hospitals under financial pressure tend to have lower costs." I'd just ask us to consider, what do we think that means? If I were to say outside of that context restaurants under financial pressure tend to have lower costs, what would you think? You'd probably say, "I'm worried. What's going on there?"

When you kind of put that right next to the part on consolidation, you know, we run into very few hospitals under fiscal pressure that really want to merge. What they want is to maintain their identity. What they want is to be able to serve their clientele. Hospitals under fiscal pressure don't stop seeing Medicare patients. They close.

And the closure rate doubled in this past year, and so I think we have to examine what the implications are of hospitals under fiscal pressure tend to have lower costs. I think it would be -- it's concerning. I think they tend to have lower costs, in fact, because certain things aren't happening, and they don't have the capital to invest in the things that would actually give them greater efficiency because those technologies are expensive. So as a large hospital operator, when distressed hospitals tend to seek us out, what are they desperate for? They're desperate for the sorts of investment, capital and operating, that can help them implement the technologies and the personnel and the systems to actually develop efficiencies to be competitive in the world. Otherwise, it's really a death spiral.

So I just come back to the notion as I said at the outset, I generally support this. I think it's a more rational process. I think we need to take stock of the realities of the political process which is superimposed. But I think we also need to sort of step back and understand the context of pressures this creates. Thanks.

DR. CROSSON: Dana, Sue, Amol.

DR. SAFRAN: So I appreciate this conversation, and I generally support the recommendation, but it does strike me that we have to find a way as a Commission to move forward so that hospitals are part of the accountability for total cost of care that we've begun to create in the physician community. And I think that we are, through this recommendation and through our policy in general, continuing to enable the foot in two canoes and for hospitals in particular to really continue to thrive largely on fee-for-service revenue, not on accountability for helping to manage the total cost of care. And so, you know, obviously at this hour we can't accomplish that. We need to make a decision for a policy recommendation, and so I do support moving ahead in the way that we've outlined here. But it just does strike me from this conversation that this is something that we can't ignore going forward.

DR. CROSSON: Dana, this is a comment you've made before and I fully agree with, and we've taken it to heart. And as we get into the spring and we're talking about the larger strategic view of the Commission and how we get to where you're deciding to go, the issue of how hospitals should be paid in the future is centerpiece to that. So

thank you for that.

Now I'm lost. Sue.

MS. THOMPSON: I'll be brief because I know time is of the essence. I agree, Dana, totally agree with what you just said, and Jay's comments. But I am also in support of these recommendations, so my comments are really around commentary in the document that relates to hospital closures. All good, but all very, very important and all very real to the beneficiaries.

To illustrate that, where I choose to live, I am 12 miles from the closest critical access hospital. It's under a lot of financial stress. The second closest is 34 miles. If I would need an angioplasty, I'm 54 miles, so I depend upon one of these two critical access hospitals to survive. So I can either get on a helicopter or be transported quickly to get into Des Moines, because I'm an hour away. That's very real in terms of what we're facing in terms of hospital closures in this country, and I anticipate we're going to see more. It has accelerated, as your paper supports, in the last two years, and keeping an eye on that is critical. So just a comment again about that set-up material. So thank you for that.

DR. CROSSON: Okay. Thank you, Sue. Amol.

DR. NAVATHE: So I also just wanted to voice support in general for the recommendations. First, I think certainly there's a lot of changes going on. I think I also echo Dana's comments. You know, we also know in general that there's a shift. We talked about this in the context of implications for IME and other things from the inpatient to the outpatient, how care itself is evolving. Care for how probably the way that beneficiaries want to be cared for is also evolving, so I think we should keep that in mind as well.

And I think Jon's point is a good one, however, which is that we should be mindful around the language that's used, and I think if we look across all the different stakeholders that we end up having to touch through the Commission's payment updates and other programs, we should create a consistency in terms of, you know, holding all sectors, all stakeholders to the same standard in some sense. And I think there is, I think, accountability and fiscal discipline. I think we generally understand that those are very important and they do spur cost efficiencies, and that's good in the long run for the

solvency of the Medicare program. It's good for the taxpayer; it's good for the beneficiary. But I do think that if we can institute some sort of consistency around how we present that as we go from sector to sector, that probably would be a good thing for us to do just to sort of espouse a very common way of viewing each group.

DR. CROSSON: Pat and then Bruce.

MS. WANG: So just on this theme, I agree with the importance of thinking through as we try to move to a more value-based system how to help hospitals feel that that is a system in which they can succeed. And so part of it is to stop doing certain things, and, you know, Dana's point she made clearly. But I think that we -- just a reminder that we should also be aware of, as Karen put it, there are a lot of programs in Medicare that hospitals use to stitch together a margin, and some of that keeps them rooted in the current system. So DSH is tied to inpatient statistics. You've heard me say this a million times. GME is paid to inpatient statistics. And I think that while we, you know, hold hospitals' feet to the fire to kind of get with what's happening in the country and in the world, we need to also take the responsibility to remember that

there's just a lot of stuff in the current Medicare system that has built up over time and it's just all still there that we need to think about changing to relieve some of the -- I mean, in some ways the way that Medicare is designed today anchors a hospital's foot in that other canoe. And so in addition to telling them you have to get with the program, you have to get into the Ferrari, I think we have to be mindful of the things that need to be loosened up so that people can change more easily when they have the will, because I think many places do really have the will.

DR. CROSSON: So, I mean, I agree. I think taking on the question of how hospitals are paid and what's included, the things you mentioned and others, is central, I think, to the mission that we're on here. I think it's going to be one of the heaviest lifts that this Commission has ever attempted, but I think it's something -- as I've said before on several occasions, it's something we have to do.

I had Bruce and then Warner.

MR. PYENSON: I just want to pile on to -- I guess Larry started the chain and then Karen and Dana. But I hope to feel better about this a year from now for the

reason -- and, you know, Pat has added to that. I can think of a number of accounting kinds of issues -- and Pat alluded to them -- that would help get us there. And I know it's a heavy lift. It's probably easier than Part D.

[Laughter.]

DR. CROSSON: Okay. I'm not sure if that's a low bar or a high bar. Warner.

MR. THOMAS: Yeah, just a couple of comments. So, generally, I can support the recommendation as well. I think Jonathan's point about indicating that if this new quality program is not put in place, then the 2.8 ought to be the recommendation.

I think also, you know, perhaps instead of putting these dollars towards quality programs or maybe they go that direction but they're only eligible for organizations that are in alternative payment mechanisms, like the ACO models or that evolved into risk or that sort of thing, because I think -- I agree with you, Pat. I think we do need to get organizations kind of moving down that path, and it's going to take financial incentives to get that done.

I'd also say the same thing on physicians. I

mean, essentially every time we've got to make any sort of physician change, it's still in kind of the fee-for-service mode. And we should probably put more dollars in that model, pushing them towards alternative payment mechanisms, and into, you know, partial risk or risk type arrangements. So I think putting more dollars in those areas would be smart for the Commission and for the program long term.

I would just say on the comment about why hospitals, not physicians, I think if we were sitting here having a discussion about physicians losing 10 percent on Medicare patients, we'd probably be doing a pretty big increase for them as well, if not more, because, frankly, physicians probably would stop, especially independent physicians would stop seeing Medicare patients if they had that type of loss, you know, from seeing that patient.

Now, luckily, today that's not necessarily the case, but I think the recommendation is good, I think with those couple of modifications that Jonathan talked about. I think that would be helpful. And I do think we ought to have verbiage in the chapter indicating that maybe there should be more dollars that are put towards organizations that are willing to go down the road of ACO models or other

alternative mechanisms, especially if we don't think some of the quality programs are going to be adopted. Maybe we should kind of, you know, target it in a different way. So just another idea.

DR. CROSSON: Okay. So just to be clear, if this entire recommendation is not picked up by the Congress, it will then default to the 2.8 percent.

MR. THOMAS: I understand, but I also think being clear that -- I understand it's the default, but I think being clear that we understand that if this part of the recommendation that's being put forward is not adopted, then we certainly would support the 2.8. We think it's adequate; we think it makes sense. I think maybe I'm -- I know you're reading between the lines, but I think being clear about it would be helpful to the reader of the chapter.

DR. CROSSON: And we can put that in the text.

MR. THOMAS: Yeah, exactly.

DR. CROSSON: To be frank, if it defaulted to 2.8 percent, that's less than what we've recommended, but we can say it's -- however you'd like to couch that.

MR. THOMAS: Yeah. I would also just echo

Jonathan's point around, you know, hospitals do not want to merge with other large organizations. They do not want to do that. They do it out of absolute financial need. So I do think that would be a component that should be compelling, and it's why you see organizations hold on as long as possible so that if they do do a merge -- and many of them are in very difficult economic situations because they do not want to do this. So if you read this chapter and you think about, well, that's what everybody's doing, and they're just doing it for economic reasons. They're doing it out of survival reasons. I'm not saying that's every single transaction out there, but many of them are out of absolute financial necessity.

DR. CROSSON: Okay. Thank you, Warner.

Seeing no further comments, the draft recommendation is before you. All Commissioners who wish to approve the draft recommendation, please raise your hand.

[A show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: Seeing none, it passes unanimously.

Thank you, Jeff, Stephanie. We'll move on to the next presentation.

[Pause.]

DR. CROSSON: Okay. Discussion and recommendation is on the adequacy of payments to physician and other health professionals. Rachel, Ariel, and Brian are here, and, Rachel, it looks like you're going to start off.

MS. BURTON: Good afternoon. In this session, we'll summarize our assessment of the adequacy of payments for physician and other health professional services.

We'd like to thank Ledia Tabor, Kevin Hayes, and Carlos Zarabozo for their contributions to this analysis.

We'd also like to note that the version of our physician update chapter that Commissioners were sent in advance of today's meeting reflects revisions made in response to Commissioner comments at our December meeting.

Fee-for-service Medicare pays for services provided by physicians and other health professionals using a fee schedule. In 2018, total spending for clinician

services was about $70.5 billion, or 17 percent of Medicare fee-for-service spending. About 1.2 million clinicians billed Medicare's fee schedule in 2018.

In 2021, current law calls for no update to clinicians' base payment rates, but clinicians can receive an adjustment ranging from minus 7 percent to plus 7 percent if they are subject to the Merit-based Incentive Payment System, or MIPS. Clinicians covered by MIPS can also receive an extra payment increase for exceptional performance, if they meet certain thresholds.

Alternatively, clinicians substantially participating in an advanced alternative payment model, or A-APM, can receive an annual lump sum incentive payment worth 5 percent of their total professional service billings. So far, about a million clinicians received additional payments in 2019 and in 2020 through positive MIPS adjustments or A-APM bonuses.

According to multiple indicators, Medicare beneficiaries have good access to care. In our 2019 phone survey, most beneficiaries reported no trouble getting appointments and described access that is similar to, or better than, privately-insured individuals near

retirement. We saw similarly positive access-to-care indicators in the 2017 Medicare Current Beneficiary Survey.

Using claims, we found that from 2013 to 2018, the number of clinicians billing the Medicare fee schedule has grown faster than the number of beneficiaries in the Medicare program.

We also found that the number of clinician encounters per beneficiary grew by 1.5 percent from 2017 to 2018.

And, finally, we found that 99.6 percent of clinicians' Medicare fee schedule claims were paid on assignment, which means clinicians accepted Medicare payment rates as payment in full and did not balance-bill beneficiaries.

Our findings on quality are more mixed. According to CAHPS data, beneficiaries rated their care quality an 8.5 out of 10 in 2018 and rated the Medicare fee-for-service program an 8.3 out of 10, consistent with prior years' ratings.

But there was wide geographic variation in the rates of ambulatory care-sensitive hospitalizations and ED visits, with rates twice as high in some hospital service

areas as others. This signals opportunities for clinicians to improve the ambulatory care they deliver so they can prevent beneficiaries from needing to use the hospital.

Next, we found that providers' payments and costs are both rising somewhat. Physicians all-payer compensation continues to rise.

Medicare payments per beneficiary have increased over time by about 1 percent per year on average from 2013 to 2017 and by 2.3 percent from 2017 to 2018.

Private insurers continue to pay clinicians higher rates than Medicare, which may be due to increased provider consolidation.

In 2018, private PPO rates were roughly stable at 135 percent of Medicare's rates, up only slightly from 2017.

Clinicians' input costs, as measured by the MEI, are increasing and are expected to grow by 2.6 percent in 2021.

In addition to these puts and takes, about a million clinicians also received additional payments through positive MIPS payment adjustments or A-APM bonuses in 2019 and 2020. Most of these clinicians received

positive MIPS adjustments, which means their payment rates were increased by up to 1.9 percent in 2019 and by up to 1.7 percent in 2020.

In contrast, only about 50,000 clinicians received negative MIPS adjustments in 2019, and that number fell to 18,000 in 2020.

Many clinicians have already figured out how to do well on MIPS measures, since their median score in 2020 was 99.6 points out of 100, up from 89 points in 2019.

The number of clinicians qualifying for 5 percent incentive payments because they participate in an A-APM is smaller but is growing. So although current law specifies that clinicians receive no update to their base payment rates, they do receive additional payments through MIPS adjustments or A-APM bonuses.

Based on the preponderance of our indicators, which include very strong access-to-care indicators, we are concluding that a current law update is warranted. In particular, despite Medicare paying lower rates than commercial plans, Medicare beneficiaries enjoy access to care that is similar to, or better than, commercially insured individuals near retirement.

Our draft update recommendation therefore reads, "For calendar year 2021, the Congress should update the 2020 Medicare payment rates for physician and other health professional services by the amount determined under current law."

In terms of implications, there would be no change in spending compared with current law, and this update should not affect beneficiaries' access to care or providers' willingness or ability to furnish care.

This concludes our presentation. We're happy to take questions.

DR. CROSSON: Thank you, Rachel.

We'll now have clarifying questions. Larry?

DR. CASALINO: You all made quite a bit about the MIPS payments to physicians in the presentation. This is a budget-neutral, basically. So if very few physicians, as you mentioned, are getting penalties and almost everyone is getting bonuses, it must mean that bonuses are quite small?

MS. BURTON: Yes.

DR. CASALINO: That could be clearer, I think, because the way the presentation sounded, at least to me, was, okay, physicians won't get any update, but don't

worry, they're getting MIPS payments. The MIPS payments are pretty small, I think.

MS. BURTON: It is up to 1.7 percent in --

MR. WINTER: And I just want to point out they are getting -- for six years, they will be getting $500 million per year. That's in exceptional performance bonuses that are not budget-neutral. That's over and above, and that's why the highest, the maximum increase is 1.7 percent in 2020. Whereas, the maximum penalty is much less than that.

Also, the 5 percent bonuses for advanced APM participants is also not budget-neutral. That's over and above the money that's in the base.

DR. CASALINO: The exceptional performance is included in the 1.7 percent, you were saying?

MS. BURTON: Yes.

DR. CASALINO: Okay. Oh, yeah, I didn't understand this. That would be great to make that clear. Otherwise, the straight MIPS without the exceptional performance would be right now less than the 1 percent.

MS. BURTON: It would be like 0.2 percent. It would be very low.

DR. CASALINO: Okay. Yeah, that probably would be good to have in there.

DR. CROSSON: Yeah. I just want to make one point. Just to be clear, it was the projection of this Commission based on staff work that what is currently playing out was, in fact, going to play out, and it's one of the reasons that we suggested relatively early on that the MIPS program needed to be replaced with something else.

Amol?

DR. NAVATHE: So it's my understanding, at least in the earlier years of MIPS, that the predominant metric was essentially based on reporting measures as opposed to performance in measures. So when you're citing the 2020 numbers here, how much of that is reflecting reporting purely versus actual, quote, "performance"?

MS. BURTON: I don't have a specific answer for you, but in general, you're correct that in the early years, it's more just reporting as opposed to performance. And I can get back to you with something more specific.

DR. CROSSON: Clarifying questions?

Yeah, Marge.

MS. MARJORIE GINSBURG: I just wanted a better

sense of what we're talking about when we're talking about 1-point-something percent increase in physician compensation.

So I realize physician compensation varies, depending on region and depending on what type of physician they are. We're talking about all levels and all -- but your typical, can you give us an example of a typical PCP in a typical Midwestern city? What are we talking about here, and what is the range?

I mean, 1-point, whatever it was, percent doesn't sound very high to me, and I just wanted to get a better sense of what it means.

MR. WINTER: I'm just trying to understand the 1 percent. What are you referring to?

MS. MARJORIE GINSBURG: Okay. So we are talking about the increase in physician fee schedules.

MR. WINTER: Okay.

MS. MARJORIE GINSBURG: And I thought I heard reference that what we're now looking at is the possibility -- I mean, I'm sorry. I'm blanking on the number, but the percent increase that is --

DR. CROSSON: 1.7 percent.

MS. MARJORIE GINSBURG: Thank you.

1.7 percent.

MR. WINTER: Oh, under MIPS, the maximum increase under MIPS.

MS. MARJORIE GINSBURG: Yes.

MR. WINTER: Okay.

MS. MARJORIE GINSBURG: Okay. So I just want to get a sense of what that actually represents in real dollars --

MR. WINTER: I see.

MS. MARJORIE GINSBURG: -- for an individual physician.

MR. WINTER: Right. So to do that, we would need to look at kind of median -- or mean physician, Medicare physician revenue -- Medicare physician fee schedule revenue for a physician. I don't have that handy. We'd have to do probably some calculations to get that for you.

It sounds like you're also asking about kind of typical all-payer compensation. We have that information in the chapter, and I can give you some of that, some of those numbers, if you would like now.

MS. MARJORIE GINSBURG: I guess part of my

interest, we know hospitals are running a deficit if they're relying only on Medicare patients, and they stay alive because they have commercial patients. Is that true? Is the same thing true for the average physician? How many commercial patients do they have to have to balance out their Medicare income to give them what one might consider a reasonable income?

DR. CROSSON: Let me just point out, Marge, that that last few words was kind of central to the conundrum that we have, which is at least we think we understand that with respect to institutional payments or most of the other areas of reimbursement we're going to be dealing with today, we have some data that can indicate what the costs are. Now, whether the cost is the right level of cost is another question, but we can look at cost. And we can look at revenue or income, and we can say is it too much or too little.

As Jeff pointed out in the previous session, that with respect to individual physicians -- let's look at it that way -- a significant portion, 50 percent or more of practice costs for the physician is the personal income for the physician. And so just as you said what's a reasonable

income, that's an issue -- an absolute reasonable income is an issue that we've not engaged in, and we don't exactly -- I don't know how we could do that.

To the extent that we've engaged in this issue at all, it has been on the issue of relative income, and the problem that has been created by the relative payment rates and the impact that that is having on the -- at potential adequacy of primary care services for Medicare beneficiaries.

But to kind of answer the question of what is a reasonable income for a particular specialty is not something I think we can do.

Yeah. Jim?

DR. MATHEWS: Yeah. Just to add two points that might help how you think about this, Jay is, well --

DR. CROSSON: You can say I'm right. Go ahead.

DR. MATHEWS: That's exactly what I was going to say, so since you said it --

[Laughter.]

DR. MATHEWS: A couple of things. Each year, we look at the relationship between Medicare payments to clinicians under the fee schedule relative to commercial

payment rates, and it has been relatively stable over time. And I think our most current metric is that commercial rates are about 135 percent of Medicare, and that ticked up a point from last year.

There's been a little bit of an erosion over time but reasonably steady. So that's one metric that we do year after year that might help you think about physician compensation.

The second is something that we have done in the past, and I don't think we have done this routinely year after year, but several years ago, we went through an exercise where we modeled what physician total compensation would be if they were paid for all of their business under the Medicare fee schedule. We did do this, correct?

MR. WINTER: Yeah. And most recently, like 2014 or '15. So it's been several years.

DR. MATHEWS: Right. And so I cannot recall specifically what the numbers were, but they were portrayed in one of our report chapters. And you can see what kind of income would pertain to a physician if they were paid entirely at Medicare rates, and in terms of whether or not that represents a reasonable income, I won't opine. That's

up for you to decide, but we've done those kinds of analyses in the past that at least indirectly bear on your question.

MS. MARJORIE GINSBURG: Just drawing a comparison to disproportionate share hospitals, has it ever been broached that we look at disproportionate share physicians who take more than their fair share of patients with lower compensation?

DR. CROSSON: Well, to a large degree -- I'm talking off the top of my head now, which is all right, I guess. Well, I'm going to hold that comment because I have to think more about how to answer that. Sorry.

DR. DeSALVO: You know, the system may think that it has a solution to that, Marge, in the federally qualified health center program, where there's an opportunity for off-site compensate.

DR. CROSSON: Yeah.

Jon? Jonathan?

DR. JAFFERY: Yeah. Just one or two quick points with respect to this. So one is that the 134 or 135 percent of Medicare rates is a national average, right? So there's just quite a little bit of variability --

MR. WINTER: Yes, definitely.

DR. JAFFERY: -- across the country.

MR. WINTER: And by service.

DR. JAFFERY: Yeah. And I think most of the studies that I've seen that try to get at some of the variability have been a little bit challenged by not having tons of complete data limited to maybe a couple of the big payers. It may still be helpful if you try to see the scope of variability but may not help with a particular region.

Then just in a separate thought, I'm thinking about we've had conversations not that long over the past few months where -- or at least a conversation about geriatricians, and there's a population that certainly is predominantly get paid, sees Medicare patients, so something to think about.

DR. CROSSON: And are disappearing.

Jon?

DR. PERLIN: Yeah. This is on Marge's point. I've honestly forgotten whether we are in Round 1 or Round 2.

DR. CROSSON: Well, we are in Round 1.5. We'll

give you some latitude here.

DR. PERLIN: Thanks.

That's about perfect for this. We examine hospitals and physicians as if they are completely independent, but in the real world, they're really not. Because of payment rates, the physicians, if anyone here has in any way been involved in running a hospital, show me a hospital service and emergency service where there are really hospital-based physicians that aren't subsidized in a way that kind of bolsters what would not be tenable to have those physicians seeing patients at the facility based on Medicare rates alone. So I'd just note that there's an interplay there that I think we have to be sensitive to.

It probably gets back to the larger point that we need to think more broadly and in the aggregate about how these things operate together and how they're compensated together.

DR. CROSSON: Okay. So we've sort of drifted out of 1 into 2, so go ahead, Larry.

DR. CASALINO: This is actually a clarifying question. Help me out with the cost a little bit. In the last session, it was pointed out that we probably know more

about hospital costs, and we know little or nothing about physician costs, which was pretty much what I thought. But you do have a slide here that showed, if I added it correctly, about a 5.8 percent increase in MEI, the input cost for physician practices over the last three years. So that's some knowledge about costs, right? Or one could say 5.8 percent input cost but no update over that same -- no payment update for physicians who aren't in an A-APM over those three years. Is that a correct statement?

MR. WINTER: Yeah. This is a price index developed by CMS, and as we talked about last time, the cost rates at least are based on fairly old data, from 2007, 2008, but the price data are updated annually. But if you think the cost rates are out of date, then you might have some questions about whether this is still accurate or not. But it is the best data source we have, and so given all these qualifiers, that is the best estimate of cost, of increases in cost inputs for physician services.

DR. CASALINO: Are physician salaries included in that or just rent and staff and things like that?

MR. WINTER: It includes physician compensation --

DR. CASALINO: It does.

MR. WINTER: -- as well as nonphysician staff compensation, and those two components are the bulk of the cost, about two-thirds.

DR. CROSSON: So the only point I'd make in addition is we're going to get to this, I think, in a minute or two, but in terms of how MACRA was constructed, there was an intentionality on the part of Congress to create a gradient in payment updates or rewards towards A-APMs, you know, which carries with it, for successful ones, based on our policy, a 5 percent bonus.

So I think it's -- we're going to get to this towards the end, but I think I agree with Karen that maybe enough time has elapsed now since we first said let's wait and see how this is working out, with respect to the adequacy of payments for us to come back and say, okay, maybe now is the time to take a harder look at that. But I don't want us to lose the fact that Congress, in their wisdom when they created this, purposely created a gradient token to try to get physicians, for the reasons we've talked about, try to get physicians involved in payments systems that are more based on managing the costs

and quality of the population.

DR. CASALINO: And can I build on that in relation to part two?

DR. CROSSON: I'd be pleased if you did that.

DR. CASALINO: So, no, I understand what you just said, Jay, and it's a good point. Building on what Warner said in the last session, I think, so basically Congress said to physicians, and I agreed with this, was if you want to keep on as you are, you can, but you're not going to get a payment increase for five years or so. You might from MIPS but you won't get a regular rate increase. But if you want to get into one of the new advance payment models, we'll give you an automatic 5 percent each year. So, you know, I think that was a reasonable policy.

But I think Warner -- and he didn't say it in these words -- but in effected pointed out we haven't done the same thing for hospitals. And it would be possible to say you don't get an update unless you're an X model, or you don't get a bonus unless -- whatever.

But actually that's not something I've heard discussed. I don't mean just here, but maybe it has been discussed here but I haven't heard it. But it could be,

you know, going forward, we could think along those terms. But why would one do it, with one important component of the delivery system and not with a much bigger component, really, in terms of dollars spent.

DR. CROSSON: And I think we -- aside from the global discussion about let's fix hospital payment, I think we've been trying to move in that direction by holding hospitals accountable for the per-Medicare beneficiary expenditures. It's a small amount but that's in there. And I think we weighted -- did we weight that more than the others? I can't remember?

MS. TABOR: [Off microphone.]

DR. CROSSON: It's not a weighted model. Okay. But it's a start.

DR. JAFFERY: Just a quick comment in response to what Larry said. Just to clarify that the differential payment, it goes -- I don't think I can say this -- so after the time when the advanced APM bonus payments end in 2026, 2025 --

MR. WINTER: '24 is the last year that they will be paid, yeah. 2025 -- after 2024 they stop.

DR. JAFFERY: Okay. So thanks. And it's after

that, if you're in an advanced APM model you get the physician incurring lots of points, 7.5?

MR. WINTER: Well, there's one year but there's no update for any clinicians. That's 2025. And then in 2026, there is a differential update for clinicians in advanced APMs. They get 0.75, and all of the clinicians get 0.25 percent update?

DR. JAFFERY: When would then presumably compound over time.

MR. WINTER: Yes.

DR. JAFFERY: So, to me, that's the bigger differential that pushes people in the out years more and more towards advanced APMs, as opposed to what we have through 2024, in some ways anyway.

DR. CROSSON: Okay. So we are sort of in Round 2. Kathy. Feel free.

MS. BUTO: Right. I've been waiting for that. I just wanted to say that all these updates we're talking about are really updates to fee-for-service payments.

DR. CROSSON: Yes.

MS. BUTO: And we call them A-APMs but they're really ACOs, aren't they, mostly?

DR. CROSSON: Mostly.

MS. BUTO: And ACOs are fee-for-service, although they are fee-for-service with incentives to do more coordination of care. So I'm really glad Karen brought up the idea of revisiting the way we pay physicians. I hope since it won't happen in this go-around that you'll consider doing some of what I think Warner was getting at, which is arrangements, even within the ACO or A-APM, that go to things like partial capitation.

We've talked about trying to increase incentives for primary care physicians. We've mainly talked about increasing their payment rates, and not changing the arrangements, giving them more flexibility, partial capitation, whatever the combination is. And I think the Commission could be a little more creative in that space, beyond just increasing rates, which is, I think, even in this chapter we talk about CMS's effort to increase the E&M code payments.

So I love it, but I really hope -- I think the next step is a bigger step than the one we've been taking.

DR. CROSSON: I completely agree with that, although I would point out, a little bit, we did try to do

this with primary care, and our recommendation was basically a partial capitation.

MS. BUTO: Right. It was a fairly small amount.

DR. CROSSON: It was small.

MS. BUTO: I think we could be more ambitious.

DR. CROSSON: Right.

DR. DeBUSK: On that, first of all, I totally agree. I'm glad we're -- I know this is the updated thing, and I'm sure like Jay and Jim are going nuts that we're talking about this and not voting on an update. But I completely agree. Talking about hospitals are paid and how physicians are paid is a central theme that I hope we do this spring and I hope we carry it on.

To your point, I think the primary care incentive bonus -- Jay, you mentioned it -- is fantastic. The one thing is it didn't have any -- it didn't have a lot of volume in it. It was a relatively small payment.

DR. CROSSON: Right.

DR. DeBUSK: I think if you were -- and I'm going to go out on a limb -- but if you were looking at the real risk involved in the patients that are in the panel, some type of management, some type of medical expense ratio,

where the groups that were managing these patients well were getting fairly large bonuses, I mean 20, 30, 40 percent of their compensation could be up to that. It could be through how they manage through this medical expense ratio. You could put more money in the primary care incentive bonus if you tiered it based on performance instead of turning it into something that everyone who meets a certain, you know, E&M mix or identifies as a certain specialty qualifies for.

So there's a way to do a qualified primary care incentive bonus that would have a lot more money in it.

MS. BUTO: I'm glad you're going to be here to do this, Brian.

[Laughter.]

MS. BUTO: I'm excited. The other thing I'd say is I think to hold our feet to the fire. It doesn't hurt us to say something about that kind of work in this kind of chapter and say, you know, this is what we're doing and these are the update recommendations that we provide. We are looking beyond this, and then say a few things about that. I don't think it would be a great risk, and since we're doing it anyway, I think it would be worth just

putting a placeholder in there.

DR. DeBUSK: Totally agree, just to say that we're interested in this idea, because we are crossing over into sort of a global payment, a risk-adjusted global payment tied to performance for primary care. That's a different day. I mean, I think that changes the way they behave.

DR. CROSSON: Karen.

DR. DeSALVO: I'm -- for this year I'll support the recommendations, though I do hope that we'll take up this work next year, and to that end, for next year, just two things. I don't remember if this is in the chapter so forgive me, but we really need to get a better handle on physician expenses in 2020 and beyond, because they've probably changed from what was thought before, including health IT and some differences in the kinds of team structure. What I know, anecdotally, is it's expensive to hire consultants to help you move to do MIPS and move to alternative payment models. So I'm not sure how much of an increase that really is after you have to do that work, as a practice.

But then related to the bonus thing is years ago,

when the patient-centered medical home movement was taking off, there was some talk about bonus not just for the clinician but for the team. And so as we're thinking about it and trying to drive team-based care and really encourage not just a lone doc taking care of patients but really thinking of them not only having partners but having teams, into next year maybe we can also think about structures that bonus an entire practice, not just support physician compensation to go up.

DR. CROSSON: Okay. Thank you.

DR. DeSALVO: I'll provide an aside on that. Allan Goroll from Harvard wrote some stuff about that.

DR. PAUL GINSBURG: Yeah, and I want to follow up Karen's comments, and this came up when Ariel, before, was answering a question. The information we have on physician practice expenditures, you know, other than their income, the rest, compared to what we could know is a big gulf, because the last survey was 2007, you said, Ariel?

MR. WINTER: Based on data from '07 and 08.

DR. PAUL GINSBURG: Okay, 2007 and 2008. I remember how long CMS waited for that 2007 survey, how long it had been since the previous one. And I think we should

take it upon ourselves to encourage CMS. You know, and compared to the many billions of dollars that we spend to pay physicians, that we can't afford a survey more often than once every 10 of 15 years seems to be not a good way to manage policy.

DR. CASALINO: On this point.

DR. CROSSON: Yeah.

DR. CASALINO: Yeah, and I think that Karen is right. Dealing with what used to be called pay for performance and now value-based purchasing, and the EHRs and everything, this is all -- there was some of this in 2007, but it's really accelerated. We're actually interviewing physician practices right now about the costs of dealing with MIPS, and there's no question that, I mean, new staff are being hired just to deal with these things, some to coordinate care but some to deal with just the data side of it.

So I think the expense picture might look different now than it looked in 2007, with almost all new categories. I think it's a good point, Paul.

DR. CROSSON: Our estimate is I remember it for the first year of MIPS for the physician community was $1

billion in expenditure across the country.

Okay. Not seeing any future -- I mean, any more comments, so we have a recommendation before you. There it is. All Commissioners in favor of the recommendation please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: Seeing none, it passes unanimously.

Thank you, Rachel and Ariel. Brian, thank you very much.

Oh, I forgot. What happened to Dana? Yeah, so what do I do? Out loud?

Yeah, just an amendment. We had one Commissioner who was not present for the vote. So the vote was 16 to 0 with 1 not present in voting.

DR. CROSSON: Okay. Now we're going to take up kind of double-ended discussion here. It's an update for outpatient dialysis facilities, as well as a policy recommendation, where we have a choice to make. Nancy and

Andy are here, and, Nancy, you have the floor.

MS. RAY: Thank you. Good afternoon. Today's presentation on assessing the payment adequacy of outpatient dialysis services consists of three seconds. First, I will answer some questions raised during the December meeting. Then I will summarize the indicators of payment adequacy that we reviewed in December. Lastly, I will present the draft update recommendation for your consideration.

The update analysis and recommendation will be included as a chapter in our March 2020 report. At the conclusion of our update discussion and vote, we will then turn to our discussion about refining the expanded ESRD transitional drug add-on payment, the TDAPA. The analysis about the TDAPA will be included in the June 2020 report.

As background, in 2018, there were roughly 395,000 Medicare fee-for-service dialysis beneficiaries. They were treated at about 7,400 dialysis facilities, and total dialysis spending was $12.7 billion in 2018.

So the revised chapter includes additional material about a number of issues raised at the December meeting. Dana, we have added more information about the

ESRD QIP. Several Commissions, including Kathy and Dana, we have added discussion about differences in outcomes between home and in-center dialysis patients and the retention of patients on home dialysis.

Warner, we have added additional information about the first two years of the ESRD ESCOs.

So now I will summarize 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 350 facilities between 2017 and 2018. Our analysis suggests that there were few facility closures in 2017, 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 2017 and 2018. And looking at volume changes, the growth in the number of dialysis fee-for-service beneficiaries and Medicare-covered treatments remained steady.

The 18 percent marginal profit suggests that

providers have a financial incentive to continue to serve Medicare beneficiaries.

Moving to quality, the percent of dialysis beneficiaries using home dialysis has modestly increased from 10 percent to 12 percent, between 2013 and 2018. Hospital admissions has modestly declined, and mortality and percent of hospitalized beneficiaries with a readmission have held steady.

Regarding access to capital, indicators suggest it is robust. An increasing number of facilities are for profit and freestanding. Private capital appears to be available to the larger and small organizations.

Moving to our analysis of payments and costs. In 2018, the Medicare margin is 2.1 percent. Between 2017 and 2018, the TDAPA has increased the Medicare margin across rural and urban facilities and small and large providers by between two and three points.

Brian, the increase in the margin is due to an increase in payments per treatment between 2017 and 2018 by 11 percent, while cost per treatment increased by 8 percent. The 2020 projected Medicare margin is 2.4 percent, a small increase from the 2018 margin.

So that leads us to the draft recommendation. It reads:

For calendar year 2021, the Congress should update the calendar year 2020 Medicare end-stage renal disease prospective payment system base rate by the amount determined in current law.

Regarding implications for beneficiaries and providers, we anticipate that beneficiaries will continue to have good access to care. Relative to current law, this recommendation will have no effect on reasonably efficient providers' willingness and ability to care for Medicare beneficiaries.

With that I turn it back to Jay.

DR. CROSSON: So without objection I think we're going to take these two separately. Seeing none, we will take this, as we decided in December, as an issue to vote on in our expedited voting process, which means that I will ask if there are any questions about anything that has changed between now and the December meeting relative to this update.

Seeing none, we will project the recommendation.

All Commissioners in favor of the draft recommend

please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: We are still missing one Commissioners. So we have 16 positive, 0 negative votes, and 1 Commissioner not present for the vote.

Okay. Andy? Who is up?

DR. JOHNSON: We are now going to discuss a new policy affecting payment to dialysis facilities for new ESRD-related drugs. In today's presentation we will review the transitional drug add-on payment adjustment, or TDAPA, discuss related issues, and present policy options for Commission consideration.

We are taking up this issue based on Commission interest during the December meeting. We plan to return to this topic in the spring and include it in a June report chapter.

One final note before I begin, in recent meetings Nancy has discussed the impact of TDAPA payments for

calcimimetics. Today's discussion will not address TDAPA policy for calcimimetics because the policy is a special case and the TDAPA period for calcimimetics is likely to end soon.

Today's discussion will focus on TDAPA policy for new ESRD-related drugs that are not yet available.

Prior to 2011, Medicare paid for dialysis services through a composite rate covering certain items and services, but many ESRD-related drugs were paid separately. The Medicare Improvements for Patients and Providers Act, or MIPPA, established the ESRD bundle of items and services and required all ESRD-related drugs to be included in the bundle, specifically citing drugs in the composite rate, erythropoietin-stimulating agents, or ESAs, and all other drugs and biologicals used to treat ESRD. The only exception for ESRD-related drugs is those that are oral only. Those drugs have been excluded from the bundle by law until 2025 or until a non-oral form is available.

Since 2011, Medicare has paid dialysis facilities a single rate per treatment that covers all items and services in the bundle, including equipment, supplies, labor, labs, and drugs using dialysis treatment.

In determining which drugs should be included in the bundle, the original bundle, in addition to the mandated composite rate drugs and ESAs, CMS reviewed dialysis claims and categorized all ESRD-related drugs into 11 functional categories. The functional categories are listed in your mailing material. CMS identified the ESRD-related drugs by category to allow the agency to respond to changes in drug therapies over time by adding new drugs in one of the functional categories to the bundle upon market entry. CMS stated, "We did not finalize a specific list of drugs and biologicals because we did not want to inadvertently exclude drugs that may be substitutes for drugs identified, and we want the ability to reflect new drugs and biologicals as they become available."

With a policy based on functional categories in place, one issue remained: How would the ESRD prospective payment system address new ESRD-related drugs? This depends on whether the new drug is in one of the functional categories or not.

Two policies have been developed to address new ESRD-related drugs. We will start by talking about the policy for new drugs that are not in an existing functional

category, shown in the center column. These drugs are, by definition, outside of the current ESRD bundle, and the cost of providing these drugs is not included in the base payment rate.

The Protecting Access to Medicare Act, or PAMA, directed the Secretary to establish a drug designation process that would determine how to include new injectable and intravenous products in the bundle.

In response to PAMA, the Secretary established the first transitional drug add-on payment adjustment policy. For 2016, new drugs that are ESRD-related but not in an existing functional category would receive a TDAPA equal to the average sales price for at least two years.

After that, the new drug would be included in the bundle by modifying an existing functional category or adding a new one. In addition, the ESRD base rate would be updated to account for the expansion to the bundle, using the data collected during the two-year TDAPA period.

A second TDAPA policy was added later addressing new drugs that are in an existing functional category, shown in the right column. This policy will be the focus of the remainder of this session.

As a reminder, drugs in a functional category are included in the bundle, and payment for these drugs is covered under the base rate.

When establishing the bundle in 2011, and in response to PAMA in 2016, CMS stated that no TDAPA would be paid for new drugs in an existing functional category. Such drugs would be included directly into the bundle with no update to the base rate.

However, through two subsequent rounds of rulemaking, CMS expanded the TDAPA policy to include some of these drugs.

Starting in 2020, new drugs in a functional category that use certain FDA approval pathways are eligible for a TDAPA. Eligible drugs include those with new molecular entities, new active ingredients, and biosimilars, among others.

CMS determined that biosimilars are eligible for a TDAPA because the technology used to develop biosimilars is sufficiently innovative.

Examples of drugs excluded include those that are considered "new" due to a change in pill size or inactive ingredient, those that were previously marketed or

available over-the-counter, and also generics.

For new drugs in an existing functional category, facilities will receive a TDAPA equal to the average sales price for two years in addition to the full base rate. After that, the drug will be included in the bundle with no change to the base rate.

There are two main issues with paying a TDAPA for drugs in an existing functional category.

First, paying separately for new ESRD-related drugs is a form of unbundling the ESRD bundle. It reduces the competition that would occur if all drugs with the same function were paid under a single rate, and it fails to provide an incentive for manufacturers to lower launch prices.

An example showing the value of maintaining the bundle occurred in 2015 when an ESA substitute entered the market. Within one year, one-quarter of patients had switched to the new, lower-cost drug and the total ESA costs had declined.

A second issue is that the TDAPA payment is duplicative of the payment for drugs already included in the bundle. A patient needing a drug for a certain

function will either take a drug already included in the bundle, and the facility will receive the base payment rate, or the patient will take the drug receiving a TDAPA, and the facility will receive the full base rate plus the TDAPA.

Not only is the TDAPA duplicative, it creates a financial incentive to provide TDAPA-covered drugs over drugs in the bundle and potentially promotes the overuse of TDAPA-covered drugs.

There are also issues with the eligibility criteria to receive a TDAPA. Most importantly, the TDAPA policy does not apply substantial clinical improvement criteria and, therefore, will increase payment for drugs that offer no clinical improvement over available drugs.

The policy fails to protect the well-being of beneficiaries and fails to ensure good value for Medicare and taxpayer spending.

CMS does apply a significant clinical improvement standard in other cases, such as to new technologies under the inpatient and outpatient payment systems, and to new equipment and supplies under the ESRD payment system.

Finally, paying a TDAPA for biosimilars negates

their primary value by removing them from the bundle for two years. Biosimilars are not clinically superior to their originator biologic, and they would not meet a significant clinical improvement criteria. However, biosimilars can foster lower drug prices through competition when included in a bundle.

We are presenting two policy options that would replace the current TDAPA policy for new drugs in an existing functional category. Commissioners can choose one of these options. The first option is to eliminate the TDAPA for new drugs in a functional category. When these drugs enter the market, they would immediately be included in the ESRD bundle with no changes the base rate.

A second option is to limit TDAPA eligibility by applying significant clinical improvement criteria to new ESRD-related drugs. This option would also propose to avoid duplicate Medicare payments by reducing the TDAPA payment by the amount paid through the base rate for drugs in the same functional category.

Under either option, the TDAPA policy for drugs that are not in an existing functional category would remain in place.

The set of items and services covered by the ESRD bundle has been fairly stable over time. In recent years, a few new drugs have been incorporated directly into the bundle.

However, the TDAPA is intended to provide an incentive to create new ESRD-related drugs, and CMS recently introduced a similar ESRD transitional add-on payment adjustment for new and innovative equipment and supplies.

The add-on payment for equipment and supplies requires that the new items meet significant clinical improvement criteria.

Some stakeholders are concerned that over time the base rate may become insufficient to support new drugs, equipment, and supplies, particularly if the new items meet a clinical improvement standard.

As you know, the Commission monitors dialysis costs and payment adequacy and makes recommendations to Congress every year. If, in some future year, Nancy reports that payments to dialysis facilities have become inadequate, the Commission could consider a recommendation to address the underlying issue.

If warranted, one option the Commission could consider is rebasing the ESRD PPS. Rebasing is the process of calculating a new base rate using the current set of bundled services, incorporating their utilization patterns and prices.

Currently, rebasing the ESRD PPS requires congressional authority. In 2014, Congress required the Secretary to rebase the ESRD PPS due to changes in drug utilization. In this case, rebasing with lower overall costs led to a significant reduction in the base payment rate.

However, if new technology increases overall costs, rebasing the payment system could drive up Medicare payment rates. That is the reason we are now discussing rebasing only after an issue is identified.

To review, the current policy does not apply a clinical improvement standard and duplicates Medicare payment for drugs already included in the bundle. The policy options addressing new ESRD-related drugs in a functional category are, one, to eliminate the TDAPA or, two, limit TDAPA eligibility using significant clinical improvement criteria.

Neither option addresses the TDAPA policy for new drugs outside of the bundle. As always, we will continue to monitor changes in dialysis cost and payment adequacy each year and report any issues to the Commission.

For today's discussion, we seek input on these policy options, and depending on the feedback, we can work toward a recommendation this spring.

Thanks, and I'll turn it back to Jay.

DR. CROSSON: Thank you very much, Andy.

We're now open to clarifying questions. Kathy.

MS. BUTO: Do we have any data -- I should ask this question first. I was trying to figure it out. Has the policy where new drugs that fall within an existing functional category, do we have any experience with that policy and whether or not there's been a wholesale shift to the new drug since the base payment rate is not going to be reduced? Any experience with that or is it too new a policy?

MS. RAY: So under the TDAPA, the only drugs that have gotten the TDAPA to date are the two calcimimetics.

MS. BUTO: Oh, okay. So no drugs that fall into an existing functional category.

MS. RAY: That's correct.

DR. JOHNSON: Since the bundle was implemented, there have been new drugs that fell into a functional category, and without --

MS. BUTO: They have just been folded in?

DR. JOHNSON: Yeah, prior to any TDAPA policy, they were folded in.

MS. BUTO: Thank you.

DR. CROSSON: Brian.

DR. DeBUSK: It's sort of unfair because it's a clinical question, but could you give us a feel for are there barriers, I mean, are there certain categories, drug categories now in the ESRD bundle that, say, need a breakthrough or that -- I mean, are we -- I know it's an unfair question. Neither of you are doctors. But are these adequate drugs? Or are there drugs there that are still woefully -- say lots of side effects or difficult to administer?

DR. CROSSON: Just a suggestion, but you've got one right next to you.

DR. DeBUSK: Oh, I've already pinged him.

[Laughter.]

DR. DeBUSK: He dodged the question or else I would ask him.

DR. CROSSON: I saw he wasn't jumping up and down.

DR. DeBUSK: I would think you'd know a lot about the clinical aspects of this, so I'm sure he's going to weigh in. But he'd be the perfect person, yes.

DR. CROSSON: Yeah, I mean, I'm not the one to ask. Is there anybody here who might want to --

[Laughter.]

DR. JAFFERY: Yeah, I mean, I think that's a difficult question to answer. Are there opportunities for breakthrough in any of these functional categories? I don't know. You know, maybe some of the -- maybe phosphate binders. I don't know. There's nothing that jumps out that says this is more or less an opportunity.

MS. RAY: So the only thing that I can mention -- and, again, as we've been informed from stakeholders, there is a new drug in clinical trials that has an indication. I'm going to botch the pronunciation: pruritus, itching.

DR. CROSSON: Itching.

MS. RAY: Yes, yes. And I believe that drug has

an FDA breakthrough designation, at least according to the manufacturer's website.

MS. BUTO: Does it fall into an existing functional category, Nancy?

MS. RAY: It would, yes. In fact, it would probably fall into a functional category that's in the existing composite rate bundle.

DR. CROSSON: But it doesn't sound like, Jonathan, that this is a field that's rife for the introduction of new highly expensive pharmaceuticals, for example.

DR. JAFFERY: Yeah.

DR. CROSSON: Yeah, okay. Jon?

DR. PERLIN: Yeah, I think it's a great question, but it's a great question within a limited context, which is how we resolve this TDAPA. The work we do is not value-neutral. When I think of Medicare beneficiaries with end-stage renal disease, you know, I ask, where are the breakthroughs and care models that prevent the deterioration of established kidney disease? Where are the care models that prevent actually acute kidney injury that leads to chronic kidney disease? And where are the care

models that lead to definitive renal replacement, transplant and such? And so, you know, not this year, but as we go forward, I think those are some of the things that we're going to have to grapple with because, really, this is a very difficult disease. You know, I think this conversation speaks to the difficulty around it. But I think there's a bigger issue that has to do with the care of beneficiaries, the integrity or the continuity of care across many elements of the service.

DR. CROSSON: Which is one of the reasons we included hypertension management in the MA performance set.

Okay. Jonathan.

DR. JAFFERY: Yeah, just to build on what Jon said, I certainly agree with that, and to me that's one of the trickiest things with grappling with ESRD payment policies that we're doing -- we're talking about something that's predominantly a Medicare payment -- Medicare payments, where a lot of the real opportunity is a little bit upstream, or more than a little bit upstream, where it's a mix of payers, and Medicare is only one of a number of payers. And even if you think about something like a drug to treat pruritus, which would be a symptom that might

drive somebody who's on the border of starting dialysis to, in fact, initiate dialysis, that might have more utility -- or I shouldn't say that necessarily, but that might have some significant utility that would be helpful in that pre-ESRD space, but that's very different from what we're talking about here, which is this unique -- we've got these bundles, and now we are, like you said, thinking about potentially unbundling some of it.

DR. CROSSON: Pat.

MS. WANG: You know, just to underscore the point, I thought it was -- the statistics in the report on who suffers from ESRD in the Medicare program were really striking, about your point, 70 percent LIS, a disproportionate number under the age of 65. So really what you're talking about is the importance of Medicaid and other coverage for folks -- you know, they don't even get to 65, disproportionately African American, health disparities, socioeconomic -- I mean, it just underscores that by the time Medicare gets folks, it's a little late.

I wanted to ask a question about the SCI process. How would that work? Is this something that would be burdensome on CMS? Would it add value to really ask CMS to

be making judgment calls about what's substantial clinical improvement? Is the lemon worth the squeeze given that there aren't a ton of new drugs coming down the pipeline?

MS. RAY: Sure. So CMS already implements a substantial clinical improvement criteria in the inpatient setting for the new technology add-on payment, and that's done for new drugs and new devices. And there they look at whether or not the new technology substantially improves the diagnosis or treatment of the patient. So there is a process in place. There's also a similar substantial clinical improvement criteria for outpatient devices as well.

MS. BUTO: Nancy, I don't think very many drugs -- maybe one drug has passed that test in the inpatient side. I'm looking for Jeff or somebody in inpatient. It's rarely -- how many? Eight, okay. In the last like 15 years since it was enacted, I think.

[Comments off microphone.]

MS. BUTO: Oh, just in the year 2020. Okay.

DR. CROSSON: So it would be reasonable to say I think what we're saying here is if the Commission were to gravitate towards Option 2, we would assume, all things

notwithstanding, that this would be something that CMS could theoretically do, because there are not going to be hundreds of these drugs coming forward in any given year.

MS. RAY: One would think so, yes.

DR. CROSSON: Okay. Seeing no further questions, we'll move to the discussion. You have the discussion slide up there, which I think presents the options, and Kathy's going to lead off.

MS. BUTO: Okay. My take on this is that there isn't a strong justification to TDAPA for drugs that already have a functional category. In other words, status quo, they should be able to be paid as part of the base.

I'm also looking at the 18 percent marginal profit that facilities are enjoying, and I'm aware of the fact that probably the bigger issue, in a way, to me, is the fact that biosimilars will not get special treatment. One could argue that if they got special treatment, facilities would use them more often. Yes, but it would cost the program twice as much or one and a half times as much, because there's money in the base, and then you'd be paying for the biosimilar.

I think that issue is also an issue in the

outpatient department. In other words, I think biosimilars are eligible for separate payment in the outpatient department, even though there's a drug already being paid for under OPPS, so, I guess, again, setting up in that case not so much something is in the base versus something outside, but an issue of a level playing field.

Andy?

DR. JOHNSON: Yeah. And I think this is what you meant, but just to clarify that biosimilars are eligible for a TDAPA. But the generics are not eligible for TDAPA.

MS. BUTO: Right. Right, right.

So, I mean, my point is that's another reason why I would not allow TDAPA for drugs that fall within an existing functional category because then -- I think you pointed out in your example the biosimilar that was available then was able to lower the cost of treatment because it was considered as part of the bundle. That's my sense.

The issue of substantial clinical improvement might be another way to go, but I would reserve that for actually drugs that are seemingly new, because even though they don't have a functional category -- and I know we're

not talking about them here -- there may be drugs that, in a sense, are a substitute for something in a functional category. I don't think we know yet. So it's something to think about as you get to that issue is whether substantial clinical improvement ought to be a criteria for drugs that are outside a functional category.

Again, I just go back to the fact that the margins are pretty healthy, and there aren't very many drugs involved probably in the pipeline that have to be considered here, so it seems to me a place where we should be, anyway, as a Commission.

DR. CASALINO: Kathy, you're arguing for Option 1?

MS. BUTO: Yeah, Option 1.

DR. CROSSON: Jonathan?

DR. JAFFERY: Yeah. Thanks. Thanks for bringing this work today, and I would tend to agree with Kathy.

And I think the bundle -- we've seen a few things in this bundle that have been successful. You give the example of the newer ESA, but even the initial one we saw, pretty dramatic changes in utilization of IV iron versus ESAs, which actually had probably pretty important clinical

benefit too, now with some of the stuff we know about cardiovascular risk and ESAs. That was a pretty rapid switch in practice that I think we attributed to probably both those things.

I guess one thing that maybe -- I want to make sure I understand this correctly, and this may -- if I do, then maybe it's a slightly different suggestion than 1 or 2.

While I would go with what Kathy was saying about eliminating the TDAPA here, where it says new drugs would be included with no update to the base rate, I wonder if it would be possible to not have a TDAPA but still allow an update or even encourage it.

And an update could potentially go in both directions. So if it showed clinically -- clinical superiority, maybe we wouldn't increase it if its cost was higher. If we saw something like a biosimilar or a number of biosimilars come in, maybe there would be an update that would decrease it, somewhere between the reference biologic and biosimilar.

So it's maybe a modified recommendation around eliminate it but allow or even encourage updates at the

time, every so often or at the time of enter into the market.

MS. BUTO: Jonathan, I think that was the rebasing approach that Andy and Nancy were talking about, which is every X amount of time, you go back to look to see where costs had gone up or gone down.

DR. CROSSON: I think he's talking about something different.

MS. BUTO: Are you talking about another passthrough?

DR. CROSSON: Drug-specific --

MS. BUTO: Just specific to drugs?

DR. JAFFERY: Correct, yeah.

MS. BUTO: So that sounds more like Option 2, I think.

DR. JAFFERY: But my understanding with Option 2 is there would be a separate payment for that specific drug, that new drug that comes, and you'd have, let's say, a two-year period where you get the bundled rate, and then you'd get a separate payment specifically if you use that drug, which would drive the market towards using that new drug. And you'd get both.

What I was suggesting is that you would say, "No. This new drug comes in. We'll include it in the bundle," but at that point, we would reassess and see is that bundle adequate. And we might say -- CMS might say, "Well, it's really just a me-too drug or a biosimilar, and so we are going to leave the bundle alone, or we might even decrease it." Or they'll say, "We're going to include it, and it's actually got clinical superiority. And so we do think that there's some value in encouraging the use of that drug."

MS. BUTO: If I could just make a comment on that. The only example that comes to mind of something like that is when TPA was approved. There was a movement to get TPA added to the inpatient PPS system as sort of a passthrough, and at the time, Glenn Hackbarth was the Deputy Administrator. We resisted doing that, and it turned out, even though it was a very expensive drug, that overall costs related to conditions treated by TPA, heart attack, et cetera, went down.

So because it was an effective drug, it had the effect of reducing costs in other ways to the whole bundle. So the issue with making adjustments for something in a bundle, but if you're just doing a piece of it is, is the

rest of the bundle might change too. So it's just something to think about.

DR. JAFFERY: So now are you arguing for TDAPA?

[Laughter.]

MS. BUTO: I'm arguing not to make any changes, except to rebase periodically, to capture all those changes and costs, because there are going to be changes in supplies, changes in drugs, and maybe some different ways to achieve adequacy of dialysis.

DR. CROSSON: Okay. Paul, you just wrote yourself down.

DR. PAUL GINSBURG: Yeah.

I suppose Kathy's perspectives on this issue, and I wanted to bring up one more issue that makes me particularly cautious about changing policy.

There's a situation that I think is somewhat unique to ESRD where Medicare, of course, is such a large part of the market in ESRD. So there's an opportunity for a new drug that is specific to ESRD to come in and have a virtually unrestrained average sales price, which then gets brought into the ESRD system. And just the chance of that happening is reason to be very cautious in any of these

policies, which would automatically have a passthrough and then actually drive up the price of the bundle.

So that's why I agree with Kathy in supporting No. 1.

DR. CROSSON: Pat. Pat and then Brian.

MS. WANG: I see a lot of appeal to Option 1 and the comments that Kathy and Paul have just made, and perhaps I should have asked this in Round 1. The slight hesitation that I have is for the very fact, Paul, that you just mentioned, that Medicare is sort of like the biggest purchaser. Will it discourage manufacturers from doing more R&D for drugs to be part of the ESRD treatment?

I don't really understand what the rationale was behind adding all of these duplicative payments, other than perhaps a fear that there wasn't enough new launches in this area, and it was meant to be like an extra big bonus to incentivize manufacturers to participate and develop stuff here. So that would be my only concern, and I guess that I would just -- and that would sort of suggest that maybe Option 2, even though it's a little bit squishier, would hedge that danger.

MR. RAY: So just to give some information, when

CMS expanded the TDAPA and the two rulemaking processes, they did argue that they were doing so to encourage innovation in this area for both drugs in 2018 for the 2019 final rule and for equipment and supplies for the 2020 payment rule.

DR. CROSSON: Brian?

DR. DeBUSK: I was actually going to echo Pat's comment too. I want to believe in 1, and you want to lean toward 1. So, Kathy, I'm with you.

The concern, though, is Medicare is such a big part of this. I mean, Medicare could single handedly stop a would-be innovation in one of these 11 categories.

My thought, again, I'm still learning toward 1, and I don't even know if this is a reasonable ask of you guys. But are there people who have looked at those 11 categories and looked at what are the needs by category? I mean, is there the hope of a drug that improves quality of life or that reduces mortality? Is there a glaring need there that maybe we could inadvertently stifle? Because, again, if we do shut that down, it's not like the commercial payers are going to pick it up and fix it or the MA plans are going to fix it. I mean, MA is the lead.

And, again, maybe it's an unfair question, but just something to give us a color for how mature the drugs in this segment, when's the last drug -- when maybe was the last update in any of these categories? If these categories haven't been changing in the last 20 years, they're probably not going to change in the next two. But if this is a vibrant sector, I just wish we could capture that somehow.

DR. CROSSON: On that, well, Paul had first come in and then Bruce.

MR. PYENSON: If you look at the 11 categories, at least the most expensive ones are also used to treat CKD stages 1 through 4 and 5 pre-dialysis. So it's not as though -- and those populations are vastly bigger than end-stage renal disease.

I'd also point out that commercial payers are not insignificant. You can get a sense of that. The Medicare margins are quite a bit lower than the total margin. They're all positive, but there's lots of money flowing from not only commercial payers but also for Medicare Advantage currently, even before the rule changes for 2021, allowing dialysis patients to enroll.

So I think it's not as, perhaps, monopolistic from a Medicare restraining the market as it could be.

DR. CROSSON: And you're saying there's still enough money there to stimulate innovation?

MR. PYENSON: There seems to be no shortage of money.

DR. CROSSON: No shortage of money.

DR. PAUL GINSBURG: This is when I was going to comment and remind people that the United States is not the only high-income country in the world that treats ESRD. So there's still an important market abroad, although there is a potential to set a price in the United States, many multiples of the price that's set elsewhere.

DR. CROSSON: Kathy?

MS. BUTO: Yeah. I was going to mention that the first erythropoietin drug was approved as an orphan drug for ESRD, but its greater use was for cancer and other things. And, of course, I guess sports doping and other things. So the point is -- and I'll go back to what Bruce said. I think the manufacturers now think that the chronic kidney disease population, which is growing, is the big market. It's pre-dialysis, but some of the same drugs are

needed.

And, Jonathan, you would have much more insight to that.

DR. JAFFERY: Yeah. The ESAs are exactly in that category. Clearly, injectables are not things that are easy to give, but sub cu or oral medications clearly are used a lot in pre-ESRD, CKD mostly 3, 4.

DR. CROSSON: So we seem to be not of one mind here. I just want to test something. So Jonathan's suggestion was basically Option 1, but that we -- if I get this right, that CMS would t hen have the ability automatically, would have the ability to rebase the bundle based on the introduction of a drug that either demonstrably -- and this is unrelated to clinical effectiveness, but demonstrably changed the cost profile for managing the bundle. That was your proposal, I think, right?

DR. JAFFERY: Yeah. I mean, I think there was a part about demonstrably changing clinical outcome, but that would be, I think, folded into the -- that would be that CMS could increase it if they felt that was the way.

DR. CROSSON: One of the criteria that CMS could

use to reprice the bundle.

DR. JAFFERY: Yeah.

DR. CROSSON: So would that be enough to resolve the issue about -- if we went purely with No. 1, would that be enough to resolve the issue about creating an economic barrier to innovative drugs? It seems to me, it might.

DR. JAFFERY: That's what I was trying to get at. I think I'd leave it to others to decide if they feel it would.

DR. CASALINO: CMS periodically rebases on some quasi-regular schedule or --

DR. JOHNSON: Not right now, no.

DR. CASALINO: How hard would it be to get CMS to rebase? I guess, is one question, and the corollary question is -- Kathy was pointing out, and I think this really needs to be emphasized. The drug could still be a lot more expensive like TPI, but if it saves dramatically another cost, which it could, putting it into the bundle could actually make the bundle cheaper and not more expensive.

So this rebasing would not be a trivial process. It would be doable, but it would require some calculations.

But is it a realistic expectation? If you're a manufacturer, are you thinking, "Okay. Yeah. We'll get thing rebased, and we'll get well compensated," or it's just a very hard thing to get to happen.

DR. CROSSON: All right. What we've got here is we have a situation right now that we think is not the right policy. So we want to pick something that we think is a better policy.

The pure Option No. 1 creates this concern, and maybe the concern isn't as great as some have made it out to be.

The other two options create a requirement for CMS to do some level of analysis to determine whether or not to allow the TDAPA based on its clinical efficacy, which would require one level of analysis, or the other one would be to do the -- do something essentially similar but based on a more comprehensive analysis of the impact of the introduction of the new drug on the cost of the bundle, which could be just the impact of the drug itself or could be the impact of the drug itself combined with other clinical changes in terms of the total cost of care for that bundle, which could, of course, take more than a

trivial amount of time to ascertain, it would seem to me.

MS. BUTO: I was going to say you couldn't figure that out at the moment of introduction.

DR. CROSSON: No, you couldn't. You couldn't.

MS. BUTO: And so that would have to be a rebasing issue, it seems to me.

The other thing is the manufacturer is going to have every incentive if you potentially would allow greater cost for that launch price to be high.

DR. CROSSON: It would be higher.

MS. BUTO: I'm reacting based on what I know --

DR. CROSSON: Coming back to where you were in the beginning.

MS. BUTO: -- the behavior has been in the past.

DR. JAFFERY: Can I ask a question?

DR. CROSSON: Go ahead, and then Larry.

DR. JAFFERY: So if there is no TDAPA, if we go with Option 1, and let's say we had a drug introduced that's like the example of TPA -- so the way you described TPA was it was a passthrough or it wasn't going to be, but so if we had a --

MS. BUTO: It wasn't a passthrough.

DR. JAFFERY: It wasn't a passthrough, but I guess what I was hearing from you was that maybe that was not the best approach overall because, actually, the use of the drug ended up lowering overall costs.

MS. BUTO: No. It was a great decision because if we had added the cost of TPA to the DRGs, it would have raised the cost, the relative weight of those DRGs, when, in fact, the DRG weight dropped. So it would have made exactly the wrong decision was my point.

DR. JAFFERY: So trying to balance that with driving the use of a new drug, I mean, I guess that's what we're trying to grapple with here.

MS. BUTO: The problem is this is a great area of uncertainty when something first comes in, and one thing that could happen is you could imagine maybe there's an exceptions process where there really is reason to think the complication rates are so much less or, you know, whatever it is, more patient will benefit from it, even though it's in a functional category. And you really want to use that or encourage use. Then maybe there's an exception to an SCI kind of thing.

But it's hard to rebase on the front end when you

don't know what the reduction in costs might end up being once the drug is -- if that happens or if all the other costs will go up.

DR. JAFFERY: Yeah. And I wasn't envisioning being able to rebase on that broader impact because I don't know that that's realistic. Again, on the cost, I guess would the exceptions process then allow for a separate payment, and how is that different? If not, then how is that different from updating the bundle?

DR. CROSSON: Larry.

DR. CASALINO: I'm just trying to understand. Would it be correct to say that Option 2 as written would not require rebasing, although when rebasing happens, rebasing would include whatever comes up with that drug. And Option 2, as Jonathan is proposing, is kind of "immediate rebasing." Is that a correct distinction?

DR. CROSSON: It's --

MS. BUTO: I think it's just an add-on, not rebasing. Rebasing usually means that some costs might come down.

DR. CASALINO: So --

DR. JAFFERY: I'm not suggesting an add-on.

MS. BUTO: Oh. I think that's what TDAPA is.

DR. JAFFERY: I understand. That's why I'm saying I was looking at a different -- I want to be clear. I'm not suggesting Option 2. I was suggesting -- I think Jay described a third pathway, which was that it was simply rebase which could cause the bundle to go up or down without a separate payment for the new drug.

MS. BUTO: Okay. So you might wait a year or so before you decide on the rebasing, or -- I'm just saying it's hard to do that on the front end. That was my only point, because you don't know what the costs are going to be.

DR. CROSSON: So that's because we've expanded on Jonathan's model. Initially, his model was just based on the cost of the drug, and then we've said, well, wait a minute, but there are other considerations in terms of the impact of the drug on the total cost of the bundle, which wouldn't come until later. So that's a fourth alternative, which is probably so cumbersome as to not be realistic.

DR. JAFFERY: But you could do an update on the front end just based on the cost of the drug potentially.

DR. CROSSON: Yes.

DR. JAFFERY: No, it's not Option 2.

[Comments off microphone.]

DR. JOHNSON: I'm not sure we'd know the cost of the drug if it's truly new coming right in. I think that's part of the issue with figuring out what to do with the update. And if there is money -- is the suggestion -- I'm just trying to understand -- then to provide some other amount, a separate payment but a different amount than the TDAPA --

DR. JAFFERY: Well, so not knowing the cost of the drug up front is a separate issue that I don't think we talked about or considered entirely. But, no, I'm not suggesting at all that we consider a separate payment. What I would not want to do is try and avoid, I think, what, Kathy, you've said in the first place with trying to not drive the incentive of you're already getting a hundred bucks, we're going to keep giving you a hundred bucks, you're getting a hundred bucks to use Drug A; now you're going to use Drug B, we will keep giving you the hundred bucks, and we'll give you whatever, another 50 bucks, for Drug B. Drug B comes out. It's included. We're not sure if it -- if Drug B is clinically superior to anything -- to

Drug A, and, in fact, is more expensive, we might then evaluate -- we could evaluate it and maybe increase the $100 payment to $125. If, in fact, Drug B is a biosimilar and it's actually 50 bucks, we might decrease the payment to $75.

DR. JOHNSON: Correct me if I'm wrong, but that sounds like choosing Option 1 where there's no TDAPA, the new drug gets folded directly into the bundle, and then a year or a couple years down the road you figure out what has happened to the cost of the bundle? Has it increased because this new drug is expensive? Does this new drug offset other costs? And then consider rebasing if that's warranted. Is that --

DR. CROSSON: So Jonathan was saying do it right away. That's another version, which is more consonant with the issues that Kathy was describing. Now we have five options.

MS. BUTO: Andy, I think the difference between 2 and what he's saying is you add the dollar amount to the bundle, regardless of whether they're using the new drug. Okay?

Number 2 requires you to use the new drug, right,

to get that additional payment?

DR. JOHNSON: Correct. It is a TDAPA payment when you use --

MS. BUTO: So the money goes in, but then the plan or the facility can make the decision to use a cheaper alternative, even though that additional money is in there. Is that --

DR. JAFFERY: Potentially. I guess I would also emphasize that -- we keep coming back to the example where the cost of the bundle goes up, and that's what I was trying to get at a place where we could take drugs that are coming in the market that are competitive and not necessarily clinical improvements and lower cost as well.

MS. BUTO: But don't you -- I mean, I'm not a pricing expert, but once the rule is known, and the rule is there will be an add-on, it's not tied to the use of your drug, why wouldn't the new manufacturer want to come in at the highest and some sort of parity pricing to what's in the bundle so that -- in other words, when would you ever get a lower cost with a new drug if that's the rule? Because there's no benefit to them necessarily to have the whole bundle go down, right? So why wouldn't they price

kind of at parity?

DR. CROSSON: Okay. Are you going to get us out of this, Bruce?

MR. PYENSON: Yes, get us out of this. For months at MedPAC we've been talking about the importance of accountability and risk, and I've been listening to this conversation about how to take risk away from a situation, which strikes me as very strange given, you know, the consensus that we had that accountability and risk is a good thing. So I think there are -- correct me if I'm wrong. There's already protections in place. There are some outliers and things of that sort that are there, and so I'm puzzled at the direction of the conversation given our previous enthusiasm for risk.

DR. CASALINO: What [off microphone]?

[Laughter.]

DR. CROSSON: Moving on to the next topic. I think -- yeah, so all right. Let me -- yeah, I think we've gone about as far as we -- I think -- I'm going to do something we don't normally do, which is a straw poll here, because I think we have to get some direction for the staff, assuming that what we want to have -- Jim, what you

want to have is something that we can vote on. So after all this discussion, I'm going to ask for a show of hands -- you're not committed to this, but for Option 1, Option 2, or some variant of what Jonathan has proposed as a third option.

DR. CASALINO: Could we just hear a statement once more of what the third option is? Just a statement.

DR. JAFFERY: I'm not sure I can do this anymore.

[Laughter.]

DR. JAFFERY: And Kathy's last point was a fair one that I would need to think through a little bit more. But the idea was that there would not be any added transitional payment, but at time of introduction of the new drug, the bundle would be reevaluated and potentially rebased.

DR. CROSSON: Okay. So that's Option 3. So all those Commissioners who are predisposed to Option 1, please raise your hand.

[A show of hands.]

DR. CROSSON: Number 2.

DR. JOHNSON: Can we pause on the comments, too? Because I have some concern that Option 3, we wouldn't have

the data to update the bundle at the time that the new drug enters the market.

DR. CROSSON: Yeah, we've had this before. I can't quite understand. If the drug is entering the market, it has to enter at a price, right?

MS. RAY: Right, but, for example, CMS -- the rebasing of the bundle that happened in 2014, that used three years' worth, or maybe even more than that, of prior data, because you want to see how practice patterns change over time. You know, does one drug start substituting for another drug? Does one drug drop out? And so forth. And in this case, it was ESAs, and ESAs had to be titrated down. It wasn't an immediate drop.

DR. CROSSON: Yes. I get it, Nancy. I think Jonathan was basically -- or at least I was just thinking a drug costs ten bucks, you know, we add ten bucks or subtract ten bucks. And what you're talking about is utilization, utilization versus other things, all of that complexity. I understand that.

DR. JAFFERY: So if it's not feasible, clearly it's not a reasonable option, and I would go back to supporting Option 1 in the absence of that being feasible.

MS. MARJORIE GINSBURG: [off microphone] Option 3?

DR. JAFFERY: No, and we can discuss this over dinner.

[Laughter.]

DR. CROSSON: Okay.

MS. BUTO: Jay, not to make this worse, but --

DR. CROSSON: But go ahead.

MS. BUTO: We could have Option 3 where it's always just the add-on for the drug into the bundle, if that's what -- we just have to recognize -- I wouldn't support that, but you'd have to recognize that it's never going to go down until you rebase. But if you want to leave the flexibility for a new drug, that would be the way to add to the bundle.

DR. JAFFERY: So we'll call that "Option Q"?

DR. CROSSON: It's rare for a Commissioner to pose an option and then say they oppose it, but --

[Laughter.]

MS. BUTO: Trying to be fair here.

DR. CASALINO: We should vote on how many people want to discuss this at dinner with Jon.

DR. CROSSON: Warner.

MR. THOMAS: Just a comment, I think, going to Larry's point about risk and trying to put risk to providers. And I think it's an area that, if I remember in the reading, it's got an all-in margin of 20 percent. It's got an extremely healthy Medicare margin. It's got tremendous consolidation amongst -- you know, two providers have nearly 80 percent or 75 percent of the market. I think probably putting more risk here and limiting some of these things probably makes a lot of sense. And, look, if it has a material impact, that may not be a bad thing. If it gets new entrants into the market, that's probably a good thing.

So we ought to put this conversation in the context of the total industry here and the 20 percent all-in margin of this area.

DR. CROSSON: Well said. David, you've been trying to get in.

DR. GRABOWSKI: Yeah, I was just going to say, I like Jonathan's idea if it's rebasing downstream, and I think we would do that anyway; even if things got out of whack, I think we would want to revisit kind of what we're

paying for each of these bundles. So I would hope, even if we're voting for 1, we're not going to just let this go on indefinitely, that at some point we'll go back and revisit. But I don't think we can do it instantaneously just given, as Nancy and Andy have been saying, there's offsets there and utilization and it's really hard to measure. But downstream I think we could definitely readjust the bundles, and I would hope we would.

DR. CROSSON: Okay. Pat.

MS. WANG: I just want to say I don't think that the issue of risk is on the provider. It's the risk that manufacturers won't see enough in it for them. I think that this TDAPA is designed to incentivize manufacturers to get in because they know they're going to get paid a lot of money. And so I think Option 1 is the right way. The only thing I would say is maybe there should be an exceptions process as long as it's not something you can drive a truck through, because let's say that there is another TPA that comes along and it's really expensive, at least in the beginning. You would want that to be -- you would want a manufacturer to feel like that's going to be recognized sooner than the next updating of the bundle. I think

updating on the front end, for all the reasons people have said, it's a really neat idea. I think it's really complicated, and what happens if you have two or three new drugs? Are you going to be juggling all this stuff to figure out what the proper update is?

So that's my perspective on risk.

DR. CROSSON: So I think what I'm hearing from you is support for Option 1 with perhaps in the text some discussion about a rare but available exception process on the part of CMS, different from what they're doing now, and then suggestion for periodic rebasing, if there's going to be a lot of turnover in drug use in the industry.

Okay. So let's try this again. Commissioners who are predisposed to Option 1, raise your hand.

[A show of hands.]

DR. CROSSON: Option 2? Option 2, one.

Option 3?

[No response.]

DR. CROSSON: Okay. So I think that should provide some direction. Okay. Thank you very much. An important issue, and thank you for bringing it to us so clearly so we could make some judgments.

[Pause.]

DR. CROSSON: Okay. Now we're going to move on to a portion of the agenda where we have reached consensus, we believe, on updates, and so we're going to go through an expedited presentation and voting process, and we're going to start with a bundle of post-acute care, and, Carol, you're going to introduce that for us?

DR. CARTER: I am going to lead off.

In response to Commissioner comments at the December meeting regarding the broader direction of post-acute care, we've included a short introduction to the PAC update chapters, and that was all mailed to you. The chapter makes three points.

First, payment levels in the three settings are high relative to the cost of care and need to be lowered.

Second, it commends CMS on the revised PPSs for home health care agencies and skilled nursing facilities that will increase the equity of Medicare's payments, but we note that the provider responses may warrant revisions in the future. The changes encouraged by the revised PPSs are consistent with an eventual unified payment system across all post-acute care.

Finally, we note that the reporting of the functional assessment data may be biased in ways that raise payments. Our work raised serious questions about tying payments to these data and underscored the importance of improving the consistency and accuracy of this information.

And now we'll turn to the setting-specific update recommendations. These presentations will be abbreviated, but the material in the chapters was fully discussed at the December meeting.

All right. We'll begin the update discussions with skilled nursing facilities. This chapter includes information that was requested at the December meeting.

Jonathan, you asked to see information about the variation in occupancy rates, and I included that.

Amol, you asked about where small SNFs were located, and we included that information.

I also added new information on the second-year performance under the VBP because that was released just after the last meeting.

Here's a reminder of the SNF industry in 2018. There were about 15,000 providers, most of which also provide long-term-care services. About 1.5 million

beneficiaries or about 4 percent of fee-for-service beneficiaries used SNF services, and program spending, $28.5 billion.

Medicare makes up a small share of most nursing facilities' volume and revenue, about 10 percent of days and about 18 percent of revenues. Both of these have declined in recent years, in large part because of the expanded enrollment of beneficiaries into Medicare Advantage plans.

The indicators on the adequacy of payments are all positive. Beneficiaries appear to have access to services. Supply was stable, and the volume declines paralleled the changes in inpatient hospital care, which is a requirement for coverage. The marginal profit was high.

With regards to quality of care, the risk-adjusted rates of discharge to community and the two readmission measures are moving in the desired directions. All three improved between 2017 and 2018.

SNFs have adequate access to capital, and this is expected to continue in the coming year. The total margin reflects how -- the low payments made from other payers. Medicare margins in 2018 were high and are expected to

remain so through 2020. The Medicare margin for efficient providers was very high, indicating that Medicare's payments are too high.

This leads us to the draft recommendation, and I've reworded it slightly so that it matches the structure of the other recommendations, but its content is the same as what you discussed in December. It now reads: For fiscal year 2021, the Congress should eliminate the update to the fiscal year 2020 Medicare base payment rates for skilled nursing facilities.

The level of Medicare payments indicate that a reduction would be needed to more closely align aggregate payments to aggregate costs. However, we expect the SNF industry to undergo considerable changes as it adjusts to the redesigned PPS. Given the impending changes, the Commission will proceed cautiously in considering recommendations to lower payments. A zero update would begin to align payments with costs while exerting pressure on providers to keep their cost growth low.

In terms of implications, spending would decrease relative to current law by between $750 million and $2 billion for fiscal year 2021 and by between $5 billion and

$10 billion over five years. 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.

And with that, I'll turn this back to Jay for your vote.

DR. CROSSON: Thank you, Carol.

So I'll invite questions on any of the material that's new since the December meeting. Paul.

DR. PAUL GINSBURG: I just wanted to thank Carol and Evan and others for writing the introductory thing to cover all the post-acute care. I think it was very effective.

DR. CARTER: Thank you.

DR. CROSSON: Agree. Seeing no questions we'll proceed to vote on the recommendation before you. All Commissioners in favor of the recommendation please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: It passes unanimously.

Now Evan is going to take us through home health.

MR. CHRISTMAN: Thank you, Jay. As he mentioned, we're going to go through home health, and again, as Carol mentioned, this is a shortened version of the presentation we gave in December. You have an updated chapter that adds a few points of interest that were raised by Commissioners. If you have any questions about that I'll gladly take it.

Just as a reminder, Medicare spent $17.9 billion on home health services in 2018, and there were over 11,500 agencies. The program provided about 6.3 million episodes to 3.4 million beneficiaries.

Turning to our framework, here is our summary of the indicators. Most beneficiaries live in an area served by home health. Episode volume declined slightly. Home health agencies had significant positive marginal profits of about 18 percent in 2018.

For quality measures, the functional measures we follow that track improvement in walking and transferring continued to rise in 2018, although some of this increase may be attributable to coding practices. The rates of

hospitalization or ER use did not change significantly.

For access to capital, we see that it is adequate. Large for-profit home health agencies continue to expand and acquire new businesses, and the financial performance of the sector under Medicare is strong, and these are some of the highest margins you will see for this cycle. The margins in 2018 were 15.8 percent, and we estimate that they will be 17 percent in 2020.

That brings us to the recommendation. The recommendation reads:

For 2021, the Congress should reduce the calendar year 2020 Medicare base payment rate for home health agencies by 7 percent.

We would expect that this would be a decrease relative to current law by $750 million to $2 billion in 2021, and over $10 billion over five years. We expect that access to care should remain adequate. These lower payment levels should not affect the willingness of providers to serve beneficiaries. However, they may increase cost pressure for some providers.

That completes my presentation.

DR. CROSSON: Thank you, Evan. We'll now invite

questions on anything the Commissioners feel has changed since the December meeting.

[No response.]

DR. CROSSON: Seeing none, we will proceed to vote on the recommendation. All of the Commissioners in favor of the draft recommendation raise your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: Seeing none, it passes unanimously. And now we're going to move on to IRFs, and Jamila is going to -- we've got rapid changes of staff here going on.

DR. TORAIN: Good afternoon. Now we will review the indicators for IRF using the same framework you saw in other sectors.

Here is a reminder of the IRF industry in 2018. There were about 1,170 IRFs, 75 percent were hospital-based, only 25 percent of IRFs were freestanding, but these IRFs tend to be bigger so they accounted for about half of Medicare discharges.

There were about 408,000 stays for 364,000 beneficiaries, and program spending in 2018 totaled $8 billion, and Medicare accounted for about 59 percent of IRFs discharges. The average length of stay was 12.7 days in 2018.

In summary of the materials we discussed in December and were included in your mailing materials, we found that the IRFs payment adequacy indicators were positive. With regard to the beneficiaries' access to care, given that the IRFs' occupancy rate was 66 percent and beneficiaries can receive care in other settings, IRFs' capacity appears to be more than adequate.

With regard to quality of care, our risk-adjusted outcome measures have improved slightly over time.

With regards to IRFs' access to capital, these facilities maintain good access to capital markets. The all-payer margin for freestanding IRFs was a robust 10.7 percent in 2018.

With regard to Medicare payments and IRF cost indicators, they were positive. In 2018, the Medicare margin was 14.7 percent, and we project a margin of 12.7 percent in 2020.

So to summarize, we observe capacity appears to be adequate to meet demand and that providers should have an incentive to take more beneficiaries that qualify for IRF-level care given the strong marginal profits for both freestanding and hospital-based facilities.

That brings us to update for 2021. As we did last year, the draft recommendation reads:

For 2021, the Congress should reduce the fiscal year 2020 Medicare base payment rate for inpatient rehabilitation facilities by 5 percent.

To review the implications, spending would decrease relative to current law by between $750 million and $2 billion in 2021, and by between $5 billion and $10 billion over five years. We anticipate no adverse effect on Medicare beneficiaries' access to care given IRFs' high Medicare margins, although the recommendation may increase financial pressure on some providers.

The draft would also include a reiteration of 2016's recommendations to address concerns about coding and expanding Medicare's IRFs' high-cost outlier pool.

And with that I will turn it back to Jay.

DR. CROSSON: Thank you, Jamila. Questions on

any changes since the December discussion?

[No response.]

DR. CROSSON: Seeing none, we will proceed to vote on the recommendation. All of the Commissioners in favor of the recommendation please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Jon, did you vote? Gotcha. Sorry. Abstentions?

[No response.]

DR. CROSSON: Seeing none, it passes unanimously.

Thank you, Jamila. Now Stephanie.

MS. CAMERON: I'm back. Now we turn to assessing payment adequacy and updating payment for long-term care hospitals.

As you'll recall, total Medicare spending on care furnished in 375 LTCHs was approximately $4.2 billion in 2018. This total spending accounted for payments for just over 100,000 Medicare cases. The average Medicare payment per case was about $40,000 across all cases, and approximately $47,000 across the cases meeting the criteria

for payment under the LTCH PPS.

In summary of the materials that we discussed in December and that were included in your mailing materials, occupancy rates across the industry have decreased slightly. Although growth in the volume of LTCH services per beneficiary declined, this decline is in large part from the implementation of the dual payment rate structure, and LTCHs admitting more patients meeting the LTCH PPS criteria, which aligns with the goals of the policy.

In terms of quality, unadjusted mortality and readmission rates appear to be stable, while adjusted infection rates continue to be lower than expected.

The effect of fully implementing the dual payment rate structure will continue to limit industry growth and access to capital in the near term. The aggregate margin for LTCHs with a high share of cases meeting the LTCH PPS criteria increased to 4.7 percent in 2018. Our projected margin for these LTCHs in 2020 is 3.7 percent.

There is no statutory update for Medicare payments to LTCHs. However, CMS historically has used the LTCH market basket as the starting point for establishing the LTCH update.

Therefore, we make our recommendation to the Secretary. The draft recommendation reads:

For 2021, the Secretary should increase the fiscal year 2020 Medicare base payment rate for long-term care hospitals by 2 percent.

This 2 percent update is expected to reduce federal spending relative to the expected regulatory update by less than $50 million in 2021, and less than $1 billion over five years, given the current projections of market basket and productivity. We anticipate that LTCHs can continue to provide Medicare beneficiaries who meet the LTCH PPS criteria with access to safe and effective care.

And with that I turn it back to Jay.

DR. CROSSON: Thank you, Stephanie. Questions about any material that's changed in the last month since the December presentation?

[No response.]

DR. CROSSON: Seeing none, we will proceed to vote on the recommendation. All of the Commissioners voting in favor of the recommendation please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: Seeing none, it passes unanimously. Thank you, Stephanie.

DR. CROSSON: Now we are going to turn to the question of the update for hospice services, and Kim is going to take us through that material.

MS. NEUMAN: Good afternoon. Next, we will review the indicators of hospice payment adequacy and discuss a draft recommendation for the fiscal year 2021 hospice update that also involves a policy to modify the hospice aggregate cap.

The information on payment adequacy that I will summarize was discussed in detail in your mailing materials. We revised those materials in response to your December conversation. For example, Larry, we added the issue of what is an appropriate benchmark for performance on the hospice CAHPS survey. Karen, we added information on hospice quality studies by OIG and GAO. And Brian, we added more discussion on factors that may lead to

differences in length of stay across providers.

So a few key facts about hospice. In 2018, over 1.5 million Medicare beneficiaries used hospice services, including more than half beneficiaries who died that year. Over 4,600 Medicare hospice providers furnished services to those beneficiaries, and Medicare paid those hospice providers about $19.2 billion.

So now turning to our indicators of hospice payment adequacy, which are strong, in terms of access to care, the supply of hospice providers continues to grow and hospice use has increased, with the share of Medicare decedents using hospice and average length of stay rising in 2018.

Marginal profit was 16 percent in 2017, which suggests providers have an incentive to accept new Medicare patients.

Quality data are limited. Process measures are mostly topped out, and performance on the hospice CAHPS survey was stable in the most recent years.

A study by the Office of Inspector General identified a group of about 300 hospices in 2016, that the OIG labeled as poor performers, based on survey and

complaint data.

In terms of access to capital, the continued growth in the number of providers suggests that capital is accessible. And as far as margins, for 2017, we estimate an aggregate Medicare margin of 12.6 percent, and for 2020, we project an aggregate margin at the same level, 12.6 percent.

So next we'll switch gears and talk about the hospice aggregate cap. As you will recall, the cap limits the total payments a hospice provider can receive in a year. The cap is an aggregate limit, not a patient-level limit. In 2020, the aggregate cap was about $29,965, and it is not wage adjusted.

As we've observed over the years, hospice margins increase with length of stay, and we see that in the chart, as we move from left to right, margins increase as hospices have more long-stay patients. The margin providers in the highest length of stay group dip a little bit, and that's because of the hospice aggregate cap.

The hospice aggregate cap reduces payments to hospices with long stays and high margins. For example, in 2017, we estimate that approximately 14 percent of hospices

exceeded the cap, and those providers had a high average length of stay and a margin of 21 percent before application of the cap.

Because the hospice cap is not wage adjusted while hospice payments are wage adjusted, more hospices exceed the cap in high wage index areas than low wage index areas.

So a policy to wage adjust and reduce the cap by 20 percent would improve the equity of the cap across providers and generate savings by focusing payment reductions on providers with long stays and high margins.

And so this next slide shows our simulation of the effects of the policy to modify the cap using historic 2017 data, assuming no utilization changes. And we've discussed, with a cap policy change, the share of hospices exceeding the cap is estimated to increase the yellow bar in the chart. These new above-cap hospices are providers that have long stays and high margins, and they are disproportionately for-profit and freestanding providers.

Many hospices, though, those in the blue bars, would remain well under the cap and would not experience payment reductions under the cap policy change.

So given the margin in the industry and our other positive payment adequacy indicators, the analysis suggests that hospice aggregate payments exceed the level needed to furnish high-quality care. In other sectors, in this situation, the Commission has generally considered across-the-board payment reductions, but, in this case, the hospice cap policy we just discussed provides an opportunity to focus payment reductions on a subset of providers with high margins and disproportionately long stays.

So with that in mind, we have developed a two-part draft recommendation. The draft reads:

The Congress should, for fiscal year 2021, eliminate the update to the fiscal year 2020 Medicare base payment rates for hospice, and wage adjust and reduce the hospice aggregate cap by 20 percent.

In terms of implications, the draft recommendation would reduce spending relative to current law by between $750 million and $2 billion over one year, and between $5 and $10 billion over five years.

In terms of beneficiaries and providers, we expect that beneficiaries would continue to have good

access to hospice care, and we also expect that providers would continue to be willing and able to serve Medicare beneficiaries.

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

DR. CROSSON: Thank you, Kim. I'd invite questions from Commissioners on any material that has changed since December. Marge.

MS. MARJORIE GINSBURG: This is just a question on page 62 of the report. It says this would lead to savings for beneficiaries and taxpayers. I'm not sure how it would lead to savings for beneficiaries. Taxpayers, yes, but I wasn't sure what the reference was to beneficiaries.

MS. NEUMAN: In this case, since the Medicare program pays almost the full chunk, right -- there's very limited cost-sharing -- I think you're right. We should change that to focus on taxpayers. Thanks.

DR. CROSSON: Good pick-up there. Okay. Other questions? Karen. Comment?

DR. DeSALVO: Thank you guys so much for the work. I'm supportive of the recommendation. I just wanted to underline something that's come up in the conversations

about hospice as we've had it, which is that there seems to be a new type of service or benefit that Medicare program can't necessarily meet for people who have cognitive issues or neurological disorder.

And so I'm not going to presume to put it on the work plan for next year, but it would be important, I think, to start thinking about as the epidemiology has changed and people are increasingly having neurological and other kinds of illnesses. We may not have the kind of services or benefits package that's meeting those needs, and there may be a little bit of that in there, but I would just encourage us to consider understanding what are the needs that maybe we're not meeting that are being used in the hospice program instead.

DR. CROSSON: And how could that otherwise be met?

DR. DeSALVO: Exactly. What should we perhaps build? I mean, it's a similar theme with home health, where it started as opposed to acute care, but really, it's evolving into a primary care, and in some cases a primary care alternative, as the world has evolved. But in this case, I think it has a lot to do with beneficiary needs

more than technology or practice behavioral issues.

DR. CROSSON: Beneficiary and family needs, yes.

DR. DeSALVO: Mm-hmm.

DR. CASALINO: So understanding that hospice and home health basically being used as a substitute for something that should exist but doesn't, to take care of people with cognitive--

DR. DeSALVO: Alzheimer's, other forms of dementia, dementia, and yeah, neurological disorders. I mean, it seems to be that's what some of the data is telling us.

DR. CASALINO: Are you aware of proposals of this kind for what that kind of thing could be?

DR. DeSALVO: I'm not, and I'm so hesitant to say it because it just feels huge to think about creating long-term care support for Medicare beneficiaries, but I think the reality is we're probably not meeting the needs of beneficiaries and families. And as the causes of morbidity and mortality shift as we get better at treating, you know, cardiovascular disease, et cetera, people are living longer and having other issues that we -- the program's not really seemingly able to meet those needs.

DR. CROSSON: And I agree it's reasonable to call that out because it's what's happening, and also, I think we've seen the development of for-profit organizations taking advantage of the situation.

DR. NAVATHE: It might be interesting. I don't know that this would be fruitful but to go and look through like PTAC proposals and see if there's anything that might be trying to address some of these needs.

DR. CROSSON: I'm not aware of it, but it's possible, yes.

Jon?

DR. PERLIN: I'm glad Karen brought up the home health because I was just about to say exactly that.

I think not within the body of this work, which I totally support, but on the difference between the use of these programs from how they were originally envisioned to the realities of today is something we really should address because they're not necessarily bad things. They're good things.

So, for example, the discussion last time about home health was, I think, very instructive, because in point of fact, it wasn't really that we're not doing what

it was intended to do, provide post-acute care, but we don't have a mechanism to really support what it might do, what it is doing in certain circumstances, which is really pre-acute or preventive care. And that would be a good thing.

DR. CROSSON: Yeah. Broadly speaking, I think it's our responsibility to point out to the Congress when we observe that something that was instituted and then rolled out through CMS has substantively changed, for better or worse.

DR. DeSALVO: Is it too difficult to do that in this chapter to sort of signal that perhaps there may be some people who are not using -- some for-profits, rather, who are not using the program properly, but that perhaps it's a signal that there are some unmet needs for beneficiaries, or is that -- is it a little too late to signal that in the chapter?

DR. MATHEWS: We've consistent in both this chapter and the home health chapter over the years used phrases along the lines of they're becoming a "de facto long-term care benefit." But the clause that usually follows that phrase is "in a way that was not intended when

the benefits were established."

What you're asking for is a little bit different, and this might be something we need to think about in one of our future planning sessions.

DR. CROSSON: Kathy?

MS. BUTO: I think this reminds me of a conversation that we had with disability advocates about the Medicare benefit, some years ago, and the fact that they actually said, "Look, we know there's a cost issue. We aren't trying to redesign the benefit to be long-term care necessarily." But is there a way to think about different benefit packages that beneficiaries could opt into? You might be able to do it in the context of a per member per month kind of Medicare, special Medicare Advantage kind of thing for people with dementia or Alzheimer's, for people with -- but it has to be you've got to cross that bridge of medical versus social and support services.

So I think it's a bold and sort of really big issue but one the Commission obviously has some appetite to delve into.

But I would throw disability into that bucket.

They've been after it for a while and actually engaged in a demonstration program to see about some sort of capitated benefit that would allow them to make decisions about the right mix of, say, personal care, medical, and other support services.

DR. CROSSON: Yes, Pat.

MS. WANG: Since I have been on the Commission, the landscape report on Medicare that gets produced every year, I have always been struck by that table that says in 2000 whatever, you know, these were the top ten conditions experienced by Medicare beneficiaries, and this is today. Since I've been here, Alzheimer's and dementia has been on the second table but not on the first. Along these lines, it might be a good idea even to think about in that report noting that fact because this is -- really, this is a huge issue for the Medicare program, and it could sort of give a foundation for future discussions.

I have thought -- and I haven't said anything, but I have always been struck by that and wondered what is the Medicare program doing to prepare for this. It could lay a little bit more of a foundation for future discussions.

DR. CROSSON: Thank you.

Jon?

DR. PERLIN: I'm glad we're having this conversation because it really highlights the difference between sort of unnecessary rigidity to prevent abuse, abuses, versus creative solutions. I just think, to the VA experience -- for example, VA has a program that's very robust called the Caregiver Support Program, wherein family members receive a stipend so that essentially the de facto employment is the care of a dependent, often a dependent elder.

What is notable about that is that that's a substitute for not only potentially more expensive services but potentially less desirable services that disrupt the family unit as it is.

DR. CROSSON: Okay. Good thoughts for future work.

Seeing no further comments -- yes, Marge.

MS. MARJORIE GINSBURG: I'm sorry. I have one other comment about the recommendations. I had originally written that it was unclear in the writing whether you were talking about one recommendation or two, and now I see that

you've separated them.

So my question is I see these as two very different standalone recommendations that aren't necessarily linked. Is it to our advantage to present them as two separate entities or two parts of one?

DR. MATHEWS: Let me make a run at that. Thinking about consistency with the payment adequacy indicators across the sectors where we look at access, quality, financial performance, when we look at the preponderance of the indicators for hospice, we as a Commission might be in a position where we would say an across-the-board 3 percent reduction in payment rates is warranted, and we're looking at minus 5 for home health -- or I'm sorry -- minus 5 for IRF, minus 7 for home health. Again, there's a little bit of magic here, but if we were to come up with that kind of update recommendation, that might be where we are talking about for hospice.

But as Kim said, in this instance, we happen to have a corresponding policy related to the cap that produces roughly 2.8 percent savings, and so it achieves the same goal in terms of reducing the amount of dollars that are going into the hospice sector, but it does so in a

much more targeted way than an across-the-board payment reduction would.

As Kim said, it's going to be taken out of the hospices with the longest length of stay, which happen to be the ones that are most profitable under Medicare's payment system.

So, in my mind at least, these are integrally coupled, even though conceptually you are correct. We could make an update recommendation that could be minus 3 and through the cap thing separately or you could combine them in the way we've done here.

MS. MARJORIE GINSBURG: I just need to hear the rationale.

DR. CROSSON: Good question, Marge.

Okay. Seeing no further comments and questions, we'll proceed to vote on the draft recommendation before you. All Commissioners in favor, please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: Seeing none, it passes unanimously.

Thank you, Kim.

And for the last presentation and discussion, we have Dan her who's going to present ambulatory surgery centers.

MR. ZARABOZO: Right. Okay. So for your updated chapter on ASCs, we've added some text in response to the Commissioners' discussion from the December meeting.

Bruce, we added a sentence about the number of ASCs that billed Medicare for at least one surgical service in 2018.

Brian, we enhanced the discussion about the potential effects of physician ownership of ASCs.

And, Dana, we added a comparison of ASC performance to HOPD performance on poor quality measures that are in both the ASC quality measure program and the HOPD quality measure program.

Okay. So important facts about ASCs in 2018 include that Medicare fee-for-service payments to ASCs were nearly $4.9 billion. The number of fee-for-service beneficiaries served was 3.5 million, and the number of Medicare-certified ASCs was about 5,700.

Also, the ASC payment rates received an update of 2.6 percent in 2020.

In terms of payment adequacy, we find that beneficiaries' access to ASC services is improving. In 2018, the volume per fee-for-service beneficiary increased 2.2 percent. The number of fee-for-service beneficiaries served increased 0.9 percent, and the number of ASCs increased by 2.6 percent. In addition, Medicare payments for fee-for-service beneficiary increased 7.4 percent.

Also, the growth in the number of ASCs suggest that access to capital has been good. Moreover, there's been a fair amount of acquisitions and partnerships with ASCs by corporate entities, which requires access to capital.

On quality, the measures of quality showed improvement from 2013 to 2017, but we do have some issues with the quality measures. We believe that CMS should add more claims-based outcomes measures, and we are concerned about CMS's decisions to delay the use of a CAHPS-based patient experience measure.

Then, finally, a limitation of our analysis is that we can't assess margins or other cost-based measures

because ASCs don't submit cost data, even though the Commission has frequently recommended that these data be submitted.

So, once again, we have this draft recommendation. The Secretary should require ambulatory surgical centers to report cost data.

The importance of this recommendation is that the Commission has recommended this policy for a decade. At the same time, CMS has been largely neutral on committing to collecting cost data from ASCs.

Collecting cost data, which Medicare does for other providers, would improve the accuracy of the ASC payment system. The Secretary could limit the burden on ASCs of cost collection 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.

To motivate the collection of cost data, we have a second draft recommendation with slightly different language from December: "For calendar year 2021, in the

absence of cost report data, the Congress should eliminate the update to the calendar year 2020 conversion factor for ambulatory surgical centers."

Given our findings of payment adequacy and our stated goals, eliminating this update is warranted. This is consistent with our general position of recommending updates only when needed.

The implications 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.

And now I turn things back to the Commission for discussion and voting.

DR. CROSSON: Thank you, Dan.

So are there questions from Commissioners on anything they feel has changed since December?

I see Bruce.

MR. PYENSON: Dan, your estimate of under a

billion dollars over five years, does that assume a one-year policy change, and after that, the normal updates occur?

MR. ZARABOZO: Yes.

MR. PYENSON: Is how we typically do this sort of change?

MR. ZARABOZO: My understanding is yes.

MR. PYENSON: Thank you.

DR. CROSSON: Other questions?

[No response.]

DR. CROSSON: We'll take the recommendations individually.

On the first recommendation, all Commissioners in favor of the recommendation, please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: Seeing none, it passes unanimously.

On the second recommendation before you, all Commissioners voting in favor, please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: Seeing none, it passes unanimously.

Thank you, Dan. That's the end of the agenda for today.

We now have an opportunity for public comment. If any of our guests wish to make a comment, please proceed to the microphone. I will give you instruction in one moment. I see several individuals.

[Pause.]

DR. CROSSON: So this is an opportunity to provide input to the Commission. It's not the only opportunity. The staff makes itself available on a regular basis to individuals and organizations who wish to have input.

Having said that, we do invite you to make a comment. We would ask you to identify yourself and any organization you represent, and please limit your comments to two minutes. When this light goes out, the two minutes

will have expired.

MS. LESTER: Hi, and thank you. My name is Kathy Lester. I'm here on behalf of Kidney Care Partners, which is a coalition of health care providers, nurses, physicians, other health care providers, dialysis facilities, manufacturers, and patient advocates. We have more than 30 members of the kidney care community as members of KCP.

I want to thank the Commission for really looking at the issues of innovation in the ESRD program. Some of you had asked the question: has there been innovation in this sector? And I think if you asked our patient members, they would say very little. There has been very little change since the bundle was first created until the '90s when ESAs came in, and when you saw the discussion of drugs that were going into the bundle, you were hearing them in that ESA category.

But when you look at the innovation pipeline that we have, there are very few, but I think those came about because there was a hope under the new ESRD PPS system. There would be opportunities to think about adding cost.

Nancy raised the issue of the anti-pruritic drug.

That may or may not be within a functional category. I don't think we'll know that until the FDA writes the label and approves it, but that drug, if it were in, would be competing against Benadryl.

There's less than a dollar in the bundle for that functional category. So it's hard to see how a new product that would have such a dramatic impact potentially on a disease where patients are itching themselves, getting infections, and now not qualifying for transplants could compete when there is simply no money in the bundle. There's no other product or category that could be offset because there is no other treatment option for the pruritic.

So it's an example of why we think TDAPA was created, to have a study period, to understand those truly innovative products, and the community agrees with many of the conversations and comments you made today. TDAPA needs to be narrowed. It should focus on drugs that provide clinical improvement to patients in a substantial way.

So we really do encourage you to look at that patient option. I think one of the Commissioners suggested looking at the functional categories, seeing what is in

there, if there have been changes, what the costs are in terms of dollars, but also what are the options for patient outcomes?

So, again, very much appreciate your looking at the issue, and we also agree that looking upstream is where you're going to find savings in this patient population. The ESRD program is a one EMSR TRG, and there really aren't ways to shift across that.

So, again, we always thank you for your attention and focus on this area and look forward to future conversations.

DR. CROSSON: Thank you.

MS. ACS: Hello. My name is Annie Acs, and I am the director of Health Policy and Innovation at the National Hospice and Palliative Care Organization.

On behalf of NHPCO and our president and CEO, Edo Banach, I respectively submit comments on MedPAC's recommendation to Congress to wage-adjust and reduce the hospice aggregate cap by 20 percent.

NHPCO is the nation's largest membership organization for hospice providers and professionals who care for people affected by serious and life-limiting

illness. Our broad community of members include local hospice and palliative care providers, networks serving large regions of the United States, individual professionals, and NHPCO's members provide care in more than 4,000 hospice and palliative care at locations and care for over two-thirds of Medicare beneficiaries served by hospice.

In addition, hospice and palliative care members employ nearly 60,000 0professionals and hundreds of thousands of volunteers.

NHPCO notes that with the recommendations approved today, including increases to hospital payments, MedPAC is relaying a message to Congress and to all Americans that they encourage care to be provided in acute care settings, while discouraging person-centered care in less costly settings, like in the home or wherever beneficiaries and their families may consider home.

For almost 40 years, hospice has demonstrated value to both the Medicare program, and today more than half of all Medicare decedents received hospice care.

With more Americans choosing to die at home, we must prioritize payment for home-based care. As we have

previously stated, the recommended modifications to the hospice aggregate cap will negatively impact access to care and potentially drive people to more expensive care settings.

We are especially concerned for people living in rural and underserved areas, as we have heard from hospice providers across the nation that these dramatic cuts could result in unintended hospice closures, particularly in low-wage index and underserved areas.

We strongly believe that structural reforms to the hospice benefit, including value-based payments, should be explored in future MedPAC discussions. Today's recommendations are not structural and are not targeted to improve quality.

DR. CROSSON: Please conclude your remarks.

MS. ACS: Thank you.

On behalf of NHPCO, I thank you for your service, and we will continue to offer our assistance to MedPAC in your important role in advising Congress.

Thank you.

DR. CROSSON: Okay. Seeing no other speakers at the microphone, we are adjourned until 8-30 tomorrow

morning.

Thank you to all the staff. Thank you to Commissioners.

[Whereupon, at 4:52 p.m., the meeting recessed, to reconvene Friday, January 17, 2020, at 8:30 a.m.]

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 17, 2020
8:29 a.m.

COMMISSIONERS PRESENT:

FRANCIS J. CROSSON, MD, Chair
PAUL GINSBURG, PhD, Vice Chair
KATHY BUTO, MPA
LAWRENCE P. CASALINO, MD, PhD
BRIAN DeBUSK, PhD
KAREN B. DeSALVO, MD, MPH, Msc
MARJORIE E. GINSBURG, BSN, MPH
DAVID GRABOWSKI, PhD
JONATHAN B. JAFFERY, MD, MS, MMM
AMOL S. NAVATHE, MD, PhD
JONATHAN PERLIN, MD, PhD, MSHA
BRUCE PYENSON, FSA, MAAA
JAEWON RYU, MD, JD
DANA GELB SAFRAN, ScD
WARNER THOMAS, MBA
PAT WANG, JD

AGENDA PAGE

P R O C E E D I N G S

[8:29 a.m.]

DR. CROSSON: Good morning, and we welcome our guests to the Friday morning meeting of MedPAC for its January session.

This morning we have two items of business. The first one will be the likely conclusion to a body of work that's been going on for a year or so in response to a specific set of questions that we were provided by Members of Congress, and we have Kim and Nancy and Shinobu here, and Kim is going to begin. Thanks.

MS. NEUMAN: Good morning. As you'll recall,

in August 2018 the Chairman of the Committee on Energy and Commerce asked MedPAC to develop a report on two topics: the first was hospital consolidation and physician integration, and the second was hospital financial incentives under the 340B drug pricing program. The mailing materials you received for this session covers both topics.

Findings on the first topic, consolidation, were presented at the November Commission meeting. The section of the mailing materials on consolidation is similar to

November and includes updates to reflect your conversation at the meeting.

Work on the second topic related to the 340B drug pricing program is new and will be the focus of our presentation today.

Specifically, we have been asked to examine whether the 340B drug pricing program creates incentives for hospitals to use more expensive drugs and the implications for beneficiary cost sharing.

Before we get started, I would like to thank Jeff, Dan, and Rachel for their contributions to this work on 340B. In addition, I'd like to note that Acumen LLC performed work under contract for this project.

So first some background on how the 340B program works and how Medicare pays for drugs.

The 340B program offers nonprofit hospitals that serve a large share of low-income patients the opportunity to purchase outpatient drugs at substantially discounted prices.

Manufacturers are required to sell drugs to 340B hospitals at a price no greater than the 340B ceiling price. The ceiling price is discounted in two ways. There

is a basic rebate, which you can generally think of as a percentage discount -- 23 percent for brands and 13 percent for generics.

In addition, the ceiling price also incorporates an additional discount, referred to as "the inflation rebate," when a product's price has increased faster than inflation over time. With the inflation rebate, the more a product's price increases over time, the greater the discount a hospital receives.

Medicare Part B covers drugs administered in physician offices and outpatient hospitals, including drugs furnished by 340B hospitals.

Medicare generally pays for Part B drugs based on the manufacturer's average sales price, or ASP. This is an average price across purchasers and does not reflect 340B discounts.

Before 2018, Medicare paid outpatient hospitals the same rate regardless of whether they participated in the 340B program, generally ASP+6 percent.

When Medicare paid 340B hospitals the same payment rate as other hospitals, 340B hospitals earned substantial profit margins because they purchased drugs at

heavily discounted prices.

Beginning 2018, Medicare lowered the payment rate for 340B hospitals for some Part B drugs to ASP-22.5 percent. That reduced rate reduces but not necessarily eliminates the profit margin 340B providers earn on Part B drugs.

Although the mechanics of payment for drugs work differently under Part D, some hospitals earn rebates on Part D drugs dispensed through in-house or contract pharmacies.

So how might the 340B program influence prescribing patterns?

First, 340B hospitals may face incentives to select higher-priced drugs. This could occur if expensive drugs offer 340B providers greater margins than less expensive therapeutic alternatives.

Because of the way the 340B ceiling price is structured with a basic rebate and an inflation rebate, higher-priced products may offer providers a higher margin, but it's not necessarily always the case. Nancy will discuss more of what's known empirically about this shorting.

A second way the 340B program could influence spending is by creating incentives to furnish more drugs. The availability of discounts on a wide range of drugs for 340B providers could encourage the use of more drugs in general.

MS. RAY: Empirical evidence on 340B effects on drug prescribing, including whether it leads to the use of more costly drugs, is limited.

The OIG used the 340B ceiling price to look at the profitability of drugs furnished by 340B hospitals and found that among five cancer drugs, some lower-priced drugs offered higher margins (defined here as the difference between a drug's Medicare payment and its 340B ceiling price) than higher-priced drugs and that some higher-priced drugs offered higher margins than lower-priced drugs.

For example, Drug 2 had a lower Medicare payment amount but a greater margin than Drug 1. Whether there were financial incentives to use these five products would depend on which, if any, of these products were therapeutic alternatives for one another. The OIG report does not provide information on the names of the products or whether they are alternatives for one another.

Other studies have focused on differences in drug spending between 340B and non-340B entities. These studies have generally found higher drug spending among 340B entities compared to non-340B entities.

For example, GAO found that in 2012, per beneficiary spending for cancer drugs was 44 percent greater at 340B DSH hospitals compared to non-340B DSH hospitals. GAO concluded that neither health status nor hospitals' teaching status accounted for the higher cancer drug spending at 340B hospitals.

However, some stakeholders have critiqued this and other studies for not sufficiently controlling for patients' characteristics. GAO's study did not include Part D spending, and it did not examine 340B effects by cancer type.

MedPAC's analysis addresses the question of whether 340B status is associated with higher cancer drug spending. We could not replicate the OIG analysis because we do not have access to the 340B ceiling price. We focus on cancer because it accounts for three quarters of outpatient drug spending.

A couple of key points about our analysis:

We look at average cancer drug spending per month for patients with a cancer diagnosis. We are, we believe, the first researchers to include both Part B and Part D spending.

We conduct our analysis by type of cancer since drug regimens and spending differ by cancer type. Our analysis includes the five different cancer types listed on this slide.

We include in our analysis cancer patients treated across several settings -- 340B hospitals, non-340B hospitals, and physician offices. And our analysis covers the pre-2018 period when 340B hospitals were generally paid ASP+6.

We found that the cancer type influences drug spending. Among the five cancer types, average drug spending ranged from $1,800 per beneficiary per month for prostate cancer to $5,200 per beneficiary per month for leukemia and lymphoma.

Spending varies less by location of care than type of cancer. Compared to non-340B hospitals, average cancer drug spending at 340B hospitals was 2 to 5 percent higher. We found mixed results comparing 340B versus

physician offices. With the exception of prostate cancer, spending at 340B hospitals ranged from 1 percent lower to 7 percent higher compared to physician offices.

For prostate cancer, spending at 340B hospitals was roughly 70 percent greater than at physician offices. This difference may stem from differences in the mix of drugs.

Like other researchers, we found that 340B providers are larger and more likely to be teaching hospitals. We also found that 340B hospitals are more likely to treat cancer patients that are young, disabled, receive Part D LIS, and are duals compared to other providers.

MS. SUZUKI: Data shows that 340B hospitals have higher drug spending, but they also differ from other non-340B hospitals, and those differences may explain some or all of the difference in spending.

Our task was to determine if the 340B discounts increased Medicare's spending for cancer drugs without actually knowing the discount amounts.

To do this, we first examined what happens to cancer drug spending when a hospital newly gains 340B

status.

For this analysis, we compared spending patterns of hospitals that gained 340B status between 2013 and 2017 with those that either remained 340B in both years or were never 340B.

The main conclusion here is that we found no consistent pattern among new 340B hospitals relative to others, so this suggests that 340B discounts may not have had any effect on them.

There are a few caveats. The sample size is relatively small, and depending on the timing of the status change, the time period we examined may not fully capture the effects of the status change.

The second question we asked is what happens to cancer drug spending when more patients are treated at 340B hospitals.

Results from our regression analysis suggest modest effects for some cancer types, which I'll come back to in a minute.

The model we used looked at average Part B and D cancer drugs spending at the MSA level. This approach allows us to address potential patient selection by 340B

status. We also adjusted for the effects of provider consolidation.

We ran separate regression for the five cancer types, and the key variables are 340B market share, defined as the share of patients treated by 340B entities, and HOPD market share, defined as the share of patients treated by any hospital, meaning either 340B and non-340B.

Including both of these market share variables allows us to separate the changes in cancer drug spending attributable to expansion of 340B market share from the effect of overall increase in hospital market share.

Other variables include general trends in oncology drug spending, patient demographics, and other systematic differences across MSAs.

This table summarizes the main findings from the regression analysis.

The effects of 340B market share was statistically significant for two out of five cancer types, prostate and lung cancer. The estimated effects were about $300 per patient month. In 2013, that translates to a difference of about 28 percent for prostate cancer and 11 percent for lung cancer.

The effect of HOPD market share, on the other hand, was not statistically significant in any of the cancer types. The implication here is that the increase in hospital market share did not affect spending for the specific cancer types we examined.

We did find that effects of general trend in oncology drug spending, which reflects both increase in the prices of existing products and new product launches, to be statistically significant in all cancer types. Being younger also had large and statistically significant effects on spending for most cancer types.

Reasons for high spending at 340B hospitals appear to be specific to the type of cancer.

When we took a closer look at spending for lung cancer patients, we found that average Part B drug spending was higher at 340B hospitals than at other settings, and that difference was partly due to the greater use of the new immune-oncology products at 340B hospitals.

For prostate cancer, we found that prices at 340B hospitals were higher for both Part B and Part D drugs, suggesting differences in the mix of drugs used. We also found that patients treated at 340B hospitals used more

Part D medications than patients in other settings.

But as we noted earlier, we are unable to attribute these findings specifically to incentives created by 340B discounts because we lack access to the discount data and the magnitude of discounts are not necessarily proportionate to the prices, as shown by the OIG study.

Here are the key takeaways:

We found evidence of higher drug spending at 340B hospitals for some cancer types, but other effects, like the general trend in oncology drug spending, tended to be larger.

We also found that effects on cancer drug spending are likely to be idiosyncratic and not generalizable to other cancer types or conditions.

Overall effects on beneficiary cost sharing for cancer drugs is likely to be small, if any, depending on the type of cancer and the patient's supplemental coverage.

For discussion today, we will address the questions you have on our presentation as well as any questions or comments on the revised content on from November.

We look to you for guidance on finalizing this

report.

DR. CROSSON: Okay. Thank you, Nancy, Kim, and Shinobu.

Let's open for clarifying questions. Brian.

DR. DeBUSK: First of all, great report, love the analytics. The regressions were impressive.

Could you speak to or help me understand the other sources of discounts, for example, a Medicaid discount? It seems like we're using the price of the drug in the regression, not necessarily the margin. Are there other sources of discounts that could be generating margins that would create competing incentives here?

MS. SUZUKI: So, I mean, to the extent that on the Part D side plan formularies are driven in part by rebate and tiers, that may have some impact on which drugs are filled by beneficiaries.

DR. DeBUSK: Are there in general other sources of discounts, I guess, that could compete -- that could create competing interests? Let me reframe the question.

MS. NEUMAN: Are you speaking specifically with regard to 340B hospital or all providers?

DR. DeBUSK: All providers in general.

MS. NEUMAN: All providers in general. So, you know, providers have the potential to purchase drugs sometimes with discounts and rebates, and they're paid based on average sales price. So we know that some providers get bigger discounts than others. So we would expect in the physician office, for example, from there to be variation in purchase prices across providers, so some providers might have more or less margins than others.

I would say in general we would not -- not being able to see the data, the 340B ceiling prices, that's the caveat. But, in general, I would say that we would not expect other providers to generally have discounts of the size that 340B providers --

DR. DeBUSK: Okay. So if you qualify for 340B, it's safe to assume the discounts you receive are overwhelming to any other potential source of discounts, say a group purchasing organization or some other discount you may get?

MS. NEUMAN: In general, we think that's --

DR. DeBUSK: Okay. Good. Thank you.

DR. CROSSON: Jaewon and Kathy.

DR. RYU: Hi. Thanks for the analysis. I know

that you had mentioned that the analysis was really based on the pre-2018 change, and I think that's because we don't have a full experience since the change. But given that the effect is fairly nominal, it sounds like there's some evidence but it's not huge, if I can kind of summarize it, and then in '18 with the ASP-22.5, is it a fair assumption to sort of, if we had to guess, it seems like that should remove any differential that could be there? Is that fair? Is that too far of a leap?

MS. NEUMAN: So for brand drugs, there's the basic rebate, which is generally 23 percent. So you can think of the payment cut as kind of washing away the basic rebate, but there is still an inflation rebate component to the ceiling price. And for some products, that is quite large, and for others it may not have it at all. And so I would say there's probably variability across products in the extent to which they have substantial margins.

DR. RYU: So after the 2018 change, to the extent there's an inflationary driver of some of this dynamic, that would still be in place.

MS. NEUMAN: Right.

DR. RYU: Okay.

MS. NEUMAN: And then I would just note one other thing. It was on the slide, but we didn't talk about it. Currently, passthrough drugs are paid ASP+6 percent even under current law, so they're still subject to the same dynamic that existed prior to 2018.

DR. RYU: And that's just for the, whatever, two years that they have passthrough status.

MS. NEUMAN: Two to three years, yes.

DR. RYU: Thank you.

DR. CROSSON: Kathy.

MS. BUTO: Let's see. I've got a couple of questions. One of them is, since the old drugs, I think, get bigger discounts, especially because of the inflation-related rebate, do we know anything about the mix of older versus newer drugs in 340B hospitals? Any sense of that?

MS. SUZUKI: So, in general, this is just eyeballing by 340B versus non-340B hospitals.

The drugs that are used for specific cancer types are generally similar, and looking at the spending, ranked by spending, they're not terribly different. So we find that the choice of drugs used in those two settings are not very different for a given cancer.

MS. BUTO: Okay. So the newness and the extent of the rebates related to inflation don't seem to be a major factor is what I hear you saying.

Then the other two questions I had were -- and this may have been in the paper, and I just missed it. How much do we know about how the 340B drug, I guess, payment to cost differential has contributed to hospital margins? Do we have any sense of that? I have a feeling you've dealt with that, but I cannot remember.

DR. JAFFERY: Maybe an extra percent increase in the margins or 2 percent, maybe, and then in 2018, though, remember then they took that 22.5 percent away.

MS. BUTO: Right.

DR. JAFFERY: And they distributed it across all the different outpatient services.

MS. BUTO: Services, yeah.

DR. JAFFERY: So what that actually did is, in 2018, we saw a little bit of a reversal. So that if you were a non-340B, you did better in 2018 because they took some money away from the 340B and distributed it to you and everybody else.

MS. BUTO: Okay.

DR. JAFFERY: So we see the 340Bs doing better initially, and then in 2018, we see like probably a 1 percent bump-up for for-profits and other people that weren't getting the 340B because they redistributed some of the 340B money.

MS. BUTO: Okay. And is that discount still in effect? I know it’s being challenged in court.

DR. JAFFERY: Yeah. The discount is still in effect, but they're litigating over whether you can actually take that discount and redistribute it across everybody.

MS. BUTO: Okay. So they're not questioning whether the 22 percent or so can be taken away. It's whether or not it can be redistributed to other services.

DR. JAFFERY: That's my understanding.

DR. ZABINSKI: [Speaking off microphone.]

MS. BUTO: They don't like it.

And then the last question I had was -- and, again, I'm pretty sure you've dealt with this, but I could not find it -- the extent to which we have seen a major shift in oncology care from the physician office to OPDs as a result of 340B. Do you have that, a sense of that?

Because that then leads to the issue of higher cost to the program, potentially.

MS. NEUMAN: So I have some data that's specific to lung cancer that I can provide for you now. We could put something broader in the paper.

For lung cancer, what we see is that about roughly 40 percent of patients were treated in hospitals in 2009, and by 2017, that was about 60-ish percent. And roughly, two-thirds of that 60 was 340B. So that gives a little bit of a sense.

MS. BUTO: And then the dilemma I have is I know to the program, which is still paying ASP+6 for many of these drugs, the cost of the drug is not measurably different from the physician's office, but it's the other services that go along with that, that would increase cost to the program. So I think just a sense of what that change has been is helpful as we think about it.

Thank you.

DR. CROSSON: Jim?

DR. MATHEWS: Yeah. Kathy, if I could just jump in here, and, Kim, if you can give me a gut check on this. We have observed the shift in setting that Kim just

described, but I do not think we have specifically attributed that effect to the 340B program per se. That over the years, we've observed general trends in the migration of services -- cardiology, to some extent oncology, orthopedics from the office setting to OPDs. But we've attributed this more towards the payment differential and not specifically 340B. Is all of this reasonably correct? Yeah, okay. Thanks.

MS. BUTO: You reminded me of something else. Were you surprised to see that there were DSH hospitals that were not 340B hospitals? That surprised me.

MS. NEUMAN: Criteria that you have to meet, you have to be nonprofit, and there's certain criteria about your share of low-income patients and so forth.

MS. BUTO: Great. Thank you.

DR. CROSSON: Amol?

DR. NAVATHE: I have a couple of simple, quick comments, and then I can go on to the question.

One thing is, on page 17 of the writeup in the hospital consolidation piece, I think you're missing a "not." It says "while individual hospitals under financial strain may consolidate this hypothesis does account." I

think you want "does not." Just a mundane point.

The other mundane point was I think the Desai et al. reference is missing from the bibliography.

And then the real question I had was on Slide 10, if it's possible to go to that slide. Just to understand exactly what's happening here, I was curious. Do you guys have a sense of what are the characteristics of the hospitals that are gaining, newly gaining 340B status? In part, the reason I ask this question is because I think it will help us in interpretation. You outlined just now a couple of the criteria around low income and DSH payments and such to get 340B status, but in some sense, this comparison would be most helpful if interpreted as the obtaining of the 340B status was not anticipated and/or not deliberate on the part of the hospital. But I wonder what you guys think about that assumption that would actually help us understand what the differences are. Otherwise, it may be actually quite hard to interpret this analysis in terms of obtaining the 340B status and what it really means.

DR. PAUL GINSBURG: While they're thinking about it, wouldn't you think that all hospitals would like to

obtain 340B status? I don't know that there would be a simultaneity problem.

DR. NAVATHE: Well, I think the issue is that if we're looking at hospitals that gain 340B status and then say effectively pre/post for them, what changes, if they're anticipating or if they're doing other things to gain 340B status, then they may change their behavior much in advance, and the actual pre/post wouldn't really be that helpful.

DR. CROSSON: It seems to me it's been a few years now, but when we were talking about formulating our own 340B policy, I think our analysis suggested that at least some of these hospitals were obtaining 340B status through horizontal consolidation. Is that not the case?

DR. NAVATHE: Yeah. That's part of my worry here is that they're deliberately also doing this. So, in that case, why not, quote/unquote, "ramp up" your spending while you know you're going to get that status because you're doing other activities? And that would confound this analysis.

DR. CROSSON: Before we go on, does someone want to answer?

MS. SUZUKI: So just a couple of things. So the newly 340B hospitals were on average smaller than the 340B hospitals. They were also older hospitals -- older patients. I'm sorry. And I don't know that we have a lot of information about whether the demographics differed for these hospitals, but we can definitely take a look and get back to you on other differences.

DR. NAVATHE: I think what might also be helpful, if I may, is to see if there was any -- to Jay's point, any other sort of consolidation activity that preceded getting this status or if we can understand how they gained the 340B status, and in particular, if we could look at the criteria for 340B status and look in the pre-period to understand, effectively, how close were they or how not close were they, I think it would give us a little bit of information around who this population of hospitals are and to what extent this is sort of like a windfall, "Oh, look, we hit 340B status," and then this analysis is more helpful, or we deliberately tried to get 340B status through some activities and this analysis would be a little bit more -- we might want to interpret it a little bit more cautiously.

DR. CROSSON: Pat, are you on this point?

MS. WANG: I can't comment on the analytical pieces of it, but I do wonder about changes in the environment that might have qualified more hospitals for 340B status, including the Medicaid expansions that came about as a result of the ACA, because as I recall, Medicaid in patient share is a criteria for determining 340B status.

I think there may be different things going on in the environment in addition or, you know --

DR. NAVATHE: That's great. That would be tremendously helpful for us to describe, then. That piece itself would potentially truly exogenous or close to exogenous and would help us interpret these results more strongly.

Thanks, Pat.

DR. CROSSON: Great.

Paul?

DR. PAUL GINSBURG: Yes. You mentioned that 340B hospitals are much more likely to be teaching hospitals than nonteaching hospitals, and I would imagine for cancer or maybe many treatments, a teaching hospital would have a different treatment pattern. So I was wondering if in your

regression that you could hold teaching constant or some other tabular thing just so cross tab with teaching, nonteaching.

MS. SUZUKI: So in our regression model at the MSA level, we did control for teaching status in the MSA.

DR. PAUL GINSBURG: Oh, good.

DR. CROSSON: Larry?

DR. CASALINO: This is my question, but just to follow up to what was just said, control for teaching status and patient case mix, correct as much as you could. In the regression, you can control for teaching status and some measures of patient health.

MS. SUZUKI: So we did try running a couple of versions, and demographics was one of them. It's hard to control for the severity of the specific cancer, but by selecting individual cancers and running separate regressions, we try to control for the condition of the patient.

DR CASALINO: Yeah. Cancer is particularly difficult for that reason, I think.

My question is, to my knowledge, every study of provider behavior, although this is mostly about

physicians, shows that when they have strong incentive, financial incentive to do something, they do more of it. So these results are a little surprising because they're not that strong.

I wonder if there's another step that could be done. So hospitals don't order drug treatments. Physicians do; in this case, oncologists. And you could hypothesize that oncologists who are employed by a hospital might -- if there is going to be a response to this 340B incentive, could I hypothesize that oncologists that are employed by a hospital might behave differently than oncologists who were treating patients in the hospital but not employed by the hospital? And, you know, if there's going to be an effect, you would expect to see more of an effect with the oncologists who are employed. Would it be possible for you to -- it's not that easy to tell who's employed by a hospital, necessarily, but I wonder if it would be possible for you to try to look at that to see if it's also different if you looked just at hospitals where the oncologists are employed.

MS. SUZUKI: We'll look into this, but we're not sure whether that's something that we could do on a short

term. But we'll take a look.

DR. PAUL GINSBURG: Larry, these are all outpatients, and wouldn't you think that the office-based physicians would be doing this in their office rather than a hospital and outpatient --

DR. CASALINO: Yeah. That's a good question. I'm not sure. Sometimes yes, but for particularly sick patients or for certain treatments, they might be using the hospital as the physician's workshop and still be independent physicians treating in that hospital outpatient. I don't actually know for sure.

DR. PAUL GINSBURG: That would be a very difficult case-mix adjustment, then.

DR. CASALINO: Yeah, it would. Yeah.

DR. CROSSON: Okay. Bruce and then Pat.

MR. PYENSON: Thank you very much.

I'm wondering if you could describe the cash flow process for 340B. My understanding is that there's a retrospective settlement process. So the actual discount comes in the form of refund later, later on in the process, at least for Part D drugs.

I didn't see it in the document. I think it

would be useful to have that.

MS. SUZUKI: We could definitely add information on the cash flow for Part D drugs. This is through contracted pharmacies, that sort of thing.

MR. PYENSON: Yeah. And sort of the timing of that and the entities involved in that.

MS. SUZUKI: We'll try to provide a little more information.

MR. PYENSON: Oh, thanks.

Another question I had was I think I saw that dedicated cancer centers were not included in the study, and the question of why or what your thinking was about that?

MS. NEUMAN: They are in the data in the MSA analysis, cancer hospitals.

MR. PYENSON: So it seemed like a PPS, only PPS hospitals were included?

MS. NEUMAN: I think, technically, they fall under the category of hospitals paid under the OPPS. So they are in there.

MR. PYENSON: Ah, okay. Got it. Thank you.

DR. CROSSON: Pat?

MS. WANG: I just want to make sure that I understand the responses to the question that Kathy was asking about hospital acquisition of physician practices and Jim's comments. There are a lot of reasons for that to have happened in the environment, both from the physician side as well as the hospital side, but did you comment on and do we know whether we can see that there was more such activity by 340B hospitals versus non-340B hospitals?

MS. RAY: Our study does not look at that.

MS. NEUMAN: Are you interested in how the patients are shifting across sites or more the sort of acquisitions piece of things?

MS. WANG: I guess it's more the acquisitions piece. It goes to the concern that Kathy raised as a potential concern with expense of a physician's office converting to an HOPD, for example, and whether or not there are incentives, there are greater incentives in addition to everything going on in the market for 340B hospitals, either to welcome a physician practice that is wishing to be acquired or to actually seek them out and whether 340B status is a factor in that.

MS. SUZUKI: So I think, in general, it seems

like there were expansions, like purchase of physician practices by both 340B and non-340B entities during this period. I think our study was addressing a narrow question, but in looking at the data, we did find both expansions and not necessarily that 340B dominated the answer.

DR. CROSSON: Okay. Seeing no further questions, we'll move on to the discussion period. If you look on the slide up there, the request from the staff is to provide any further guidance for the formulation of this report, which is due in March. We had some already in the discussion period in the prior presentation last month -- or was it November? I can't remember. November. Any further input?

Larry?

DR. CASALINO: Yeah, just to be clear, so, I mean, we've had some discussion, I think, and Kathy was trying to get at this, about whether 340B increases hospital employment of oncologists, and I think it's generally thought that it does. Is it out of scope to just note, in the report, that 340B can increase costs to Medicare in more than one way. One way would be what

you've studied, and I think what Kathy was getting at, and Pat, is another way would be if it's increased employment of oncologists but then, you know, with facility fees again, that could be rather an actually large increase in cost to Medicare.

But I don't know. I don't think you have the data for that, so it would be just a note that this could be the case, and I don't know if that's even in scope. But it is, just looked at from above, in scope or not, it is probably an important phenomenon.

DR. MATTHEWS: Yeah, we could probably raise that as a possibility, but we do not have the data to be able to definitively say one way or the other.

DR. CROSSON: Jon.

DR. PERLIN: Thanks for a really interesting report. This may be more 1-1/2 than Round 2 discussion, because it's someone methodologic. I wonder if one of the markets of evolution of hospitals using 340B is really service mix, in the sense that you've identified that 340B associates with certain particular services. That may be a marker or a tracer along those lines.

The comments are sort of two-fold, is that I

think the thread of questions here were really, what is the relationship between 340B as an instigator of consolidation. Is there a way to expand access to 340B and does that motivate consolidation? That's, I think, the question that was on the table. The discussion on consolidation in the chapter is somewhat dissociated from the question of the impact on 340B, and I encourage tying those together.

I also offer, you know, a sort of general commentary, which is that I was thinking about this conundrum. We used a fairly small market area for the providers, the CBSAs, and, you know, the smaller the market area obviously the more concentrated you'll find the providers to be. When you get down to a single hospital it's 100 percent concentrated, as an example.

And yesterday we had a discussion about some of the challenges of consolidation, but we also had a discussion about the utility of certain integrations. And as we think about not just one aspect of the Medicare program but the quality, if you imagine a perfectly non-consolidated four-hospital town, that each has one quarter of whatever type of complex patient -- cardiovascular,

oncology -- you might say, okay, well, from a market standpoint it's distributed, but from a quality standpoint I would tell you that, you know, it's hard to undo volume outcomes relationship. Would you really expect the care to be good if you had a number of sub-adequate programs as opposed to actually a concentrated program?

And I wonder, when we think about our discussions of consolidation, we need not only be thinking about consolidation at the hospital level but really talking about some of the high-impact services. And as we think about some of the high-impact services, I think we need to think about the dichotomy between, you know, concentration from a market standpoint but also utility of concentration from a quality and effectiveness program.

If you had four cardiovascular programs, do you really want four programs that do a handful of heart transplants every year? Do you really want four programs that do, you know, advanced oncology? Probably not. You probably want, you know, facilities that have some lower level and a center of true excellence that consolidates expertise.

So I think we're losing that thread of, and so

those are my two comments on, one, purposefully connecting the discussion of consolidation with the question of 340. It stands a little bit on its own. And second, really asking us to contemplate, you know, the concept of volume outcomes relationship in terms of sophisticated services. And I guess a corollary to that is that I wonder if we don't have to ask ourselves in the next round of contemplation about how that operates at a service-line level as opposed to just facility level. Thanks.

DR. CROSSON: Thank you, Jon. Warner.

MR. THOMAS: Just a couple of comments on the 340B and then on the consolidation. So in the chapter, it says overall, we found modest evidence of, you know, kind of associated higher drug spending. But when you just listen to the discussion and the kind of back and forth, I'm not sure, you know, if that's necessarily true. I mean, is it really -- it sounds like it's somewhat inconclusive.

And I guess the other question I would have is, and I think going back to Larry's comment on the severity of the patient, it really comes to the stage of the cancer. I mean, we really don't have insight, that I'm aware of,

looking at the rating of what stage of cancer which significantly drives the type of treatment that a patient would get and, in many cases, the materiality of the drug costs. And then you did indicate there's a much higher propensity of LIS, you know, recipients for many of these hospitals, normally, although I'm not say that's the case here, but normally, they're also caught at a later stage of cancer treatment, just because screening is not at -- and I don't know if you have that information or not. Do you have good insight into the stage of cancer, which I think would provide some insight on the cost side as well.

So, I mean, that may be -- if we don't, we may at least want to make that reference that we don't know that, and that certainly has a major impact. I do think there is literature. I look to some of our physician colleagues here and researchers that normally, in LIS populations, you do catch cancer at a later stage, which does typically drive a higher cost structure in treating patients. So I'm not saying we can make that conclusion, but we may want to say that that is something that could be happening here as well.

I don't know if any of our physician colleagues

want to comment or have any thoughts on that at all.

MR. PYENSON: I'm not a physician.

DR. CROSSON: Hold on. Thank you for that. Jim -- let's take Jim and then Bruce.

DR. MATTHEWS: So just to address this specific question, one of the critiques of the prior studies that have been done looking at the relationship between spending for Part D cancer drugs at 340B hospitals versus other hospitals, is that they have not sufficiently controlled for patient characteristics, including progression of the disease.

MR. THOMAS: Right.

DR. MATTHEWS: We have attempted, in this analysis, to do that by stratifying our analysis by cancer types. So in that sense, I personally believe it's an advance beyond some of the other studies that have been done.

However, we do not have the very granular level on stage of cancer in the data that we are looking at. We do allude, in the chapter, to, you know, the potential for unmeasured patient characteristics influencing even the small differences in spending that we have observed in this

study. And to your point, one of the characteristics that may influence these differences is -- and again, correct me if I'm wrong -- the patients treated at 340B hospitals tend to be somewhat younger and may be candidates for more aggressive interventions, you know, wherever the progression of their disease is.

MR. THOMAS: Yeah, and I think obviously breaking it down by type of cancer helps tremendously, because that's, you know, a very different situation, but also stage within those types of cancers has a big differential as well. So I just wanted to make a comment.

DR. CASALINO: There is a database that can be used to look at that. And so the SEER-Medicare data does give you the stage of cancer.

MR. THOMAS: Yeah.

DR. CASALINO: And I think people who want to criticize the work will probably ask, you know, about why didn't you use SEER-Medicare data. It may be that the sample size wouldn't have been big enough for you. So that's one question.

And just to comment on what Jim just said, I do think it's very likely that the sickest patients, either

initially or when they get really sick, are more likely to be treated at academic medical centers, and it really is hard to adjust for that, even if you have stage, frankly. Although stage would, as Warner is saying, I think, make a -- it would make -- it would be a more -- it would be more immune to criticism, I think, if it could be done, including that.

MR. THOMAS: So one's going to --

DR. CROSSON: Hold on. One second. Warner, before you go on, did you want to -- Bruce, did you want to make a comment on this?

MR. PYENSON: Well, just about the costs of, for example, in lung cancer, early stage, is typically not treated with chemotherapy today. It's just surgery. Late-stage patients die very quickly, where most patients are identified. But there's huge shifts in therapy occurring today with the immuno-oncology that's probably not too much reflected in any of the data here. So it's become very different than it used to be, over time.

MR. THOMAS: Okay.

DR. CROSSON: You are getting very close to an honorary MD degree.

[Laughter.]

DR. CROSSON: And I think that was --

MR. PYENSON: I take it all back.

[Laughter.]

MS. SUZUKI: So I just wanted to respond to some of the comments about severity. So it's true that our hospital-level descriptive analysis is not adjusted for some of the differences in hospitals' patient characteristics that we talked about, but for the MSA analysis, the way to think about it is it's an average across all patients in the MSA. And what we were trying to measure is controlling for, you know, sort of different characteristics in the MSA. If the market share for 340B increased, does that increase the average spending in that MSA?

So I don't think we're as concerned about this selection issue that you were highlighting. I think our measure is purely, is the share of 340B driving any spending increase for cancer drug spending.

MR. THOMAS: In total. In total for that area.

MS. SUZUKI: Right, and it's a per-month estimate, but yes. So on average it seems like the share

does affect spending for two of the five cancer types.

MR. THOMAS: Okay.

DR. CROSSON: Warner, are you proceeding?

MR. THOMAS: Yeah. Just one other comment, and obviously today's presentation was a lot more around the 340B conversation. Obviously, the chapter also covers consolidation, and I just think going to Jonathan's point, I mean, there has been information added around other -- I was just looking for the area -- other consolidation that has occurred.

I do think, especially in, you know, insurers being in the physician world and that sort of thing, I'm not sure we capture the materiality of it. You know, it mentions that United Healthcare and Optum, you know, employs physicians, but they -- at least in their most recent counts they employed 47,000 physicians, the largest employer of physicians in the country, and I'm not sure we capture that materiality, which I think would be important.

So, because it kind of seems like it's just kind of a trend that's just beginning, and actually I think it's maturing pretty significantly. So I think we could probably beef up references to those components in the

chapter as well.

DR. CROSSON: thank you. David.

DR. GRABOWSKI: I was just going to make a brief comment, kind of piggybacking on Jon's, about connecting some more of the dots here. I felt like -- and this is more to the provider consolidation part of the chapter than the 340B -- I felt like the chapter was very good at sort of getting at the direct effects on Medicare payment, but I also feel like -- and we've been going through this exercise at this meeting and the last meeting with the payment updates -- there's also indirect effects here. And we live in a world where Medicare pays in a multi-payer environment, and so as costs are rising, how do we think about Medicare margins and non-Medicare margins?

And I just want to, maybe in the chapter, think about that interplay. There's obviously direct effects on Medicare payments but then there's indirect effects in a world where kind of a rising tide might float all boats. Thanks.

DR. CROSSON: Thank you, David. Paul?

DR. PAUL GINSBURG: Yeah, I was going to -- the issue came up about the effect on physician recruitment

that 340B stimulates. And, you know, when I saw the request for the study my initial reaction was, hey, you asking the wrong question. Isn't the effect of 340B on making it more profitable for hospitals to employ more oncologists, say, the really important thing? I know we haven't done a study, but I really think that it's important to mention that there's this possibility, if only sketching at the logical case, as to why that might be. And particularly if there's any other literature on that specific question we could add that in, because otherwise it just seems strange answering the specific question on volume of drugs in a vacuum.

DR. CROSSON: Thank you, Paul. Kathy.

MS. BUTO: Paul was making very much the point I was going to make, which is I assume underneath the question that we were asked was a question of is there an impact on higher costs to the Medicare program? And it focused on drugs, but I think we know that there are higher costs to the Medicare program associated with what is sort of a payment distortion that's drawing certain -- stimulating certain behavior, which I agree with Jon that some of it is actually very healthy, and I think we'd want

more ability to create centers of excellence for oncology care.

On the other hand, I think this is beyond that because of the attendant costs that go with it in the outpatient department. So it's hard to pick out a real increase in drug costs, even as you've done it, but I think the costs are really much broader to the program. And so at least to mention that I think would be important as we complete this chapter.

DR. CROSSON: Okay. Thank you. These are very good comments, and Kim and Nancy and Shinobu, we look forward to seeing your final report. Thank you so much.

We will proceed on to the second session of the day.

[Pause.]

DR. CROSSON: Okay. Our final presentation for today is going to be part of our continuing work on improvement of the accountable care organization model, and we're going to be focusing today on the issue of beneficiary assignment. So David, Luis, and Jeff are here, and, David, you're going to begin, I guess.

MR. GLASS: Yeah, thanks, Jay. Good morning.

Today we're going to talk about two issues concerned with beneficiary assignment to ACOs. I will provide a brief background, and then Luis will present two concerns about assignment which lead to your discussion.

As you know, ACOs are collections of providers willing to take accountability for the spending and quality of care for an assigned patient population.

Actual spending is compared to a benchmark. If spending is under the benchmark, the difference or savings is shared between Medicare and the ACO. If spending is over the benchmark. there are two cases. If the ACO model is one-sided, then the difference between spending and the benchmark or loss is absorbed by the program. If the ACO model is shared risk, also known as "two-sided risk," the ACO may have to pay CMS for some of the difference.

Today we are going to concentrate on the Medicare Shared Savings Program, or MSSP, which is by far the largest ACO program in Medicare and the only one set up in statute. The others are demonstrations under CMMI.

In 2019, there were 518 ACOs in MSSP, which was 30 fewer than in 2018, but the number of beneficiaries was at a new high of 10.9 million.

New rules went into effect in 2019. Two new tracks replaced the old track 1, 1+, 2 and 3.

There's something called "BASIC," which has five different levels that range from one-sided the first year to two-sided by the fifth year.

ACOs have to move up the scale in BASIC each year, so the idea is to move faster and with more certainty to two-sided risk.

However, in 2019 most were still in the one-sided model, and that's still true in 2020. About two-thirds are in one-sided.

As I just mentioned, ACO performance is computed relative to the benchmark that CMS sets for the ACO; therefore, how the benchmark is set is very important to the individual ACOs. However, to understand if an ACO model as a whole, such as MSSP, is saving money for Medicare, a different metric is needed.

To understand if an ACO model as a whole is saving money for Medicare, you have to look at the counterfactual -- that is, what spending would have been in the absence of the ACO model.

Relative to a counterfactual, we found slower

spending growth for beneficiaries assigned to an ACO in 2013, about 1 or 2 percent through 2016. That estimate does not include shared savings payments. If they had been included, savings would have been less.

We also found that beneficiaries who were continuously assigned to an ACO had lower spending than those who were newly assigned to the ACO or lost assignment to an ACO. And we also found that a health event such as a hospitalization could lead to a switch in a beneficiary's ACO assignment and to higher spending.

So over all ACO models, studies tend to estimate 1 to 2 percent savings, or about 1 percent after shared savings payments, and results depend on the program and the specific evaluation. So we included results from the PGP, Pioneer, and NextGen demonstrations, as well as other evaluations of MSSP in your mailing material. The point is savings are relatively small, and if shared savings payments are unwarranted, they could shift an ACO program from small savings to program losses.

Luis will now explain two of our concerns about current rules in the MSSP and their potential for unwarranted shared savings.

MR. SERNA: This morning we will address two concerns we have with current MSSP assignment rules, and we will provide potential options for addressing those concerns. I will now go over the first of these concerns: identifying ACOs through taxpayer identification numbers, TINs, to create benchmarks and assign beneficiaries.

It is important to understand that this discussion strictly addresses how ACOs are defined for purposes of calculating the beneficiaries assigned to ACOs to create benchmarks.

Before discussing our concerns with TIN level assignment, it is important to understand how ACOs are defined. First, let's review some terminology for identifying providers.

Each clinician has one national provider identified, or NPI. An NPI can bill under one or more taxpayer identify numbers, or TINs. A TIN can range from a solo practitioner to hundreds of clinicians within an integrated delivery system.

MSSP identifies participants in an ACO as a collection of one or more TINs which are used to construct benchmarks and determine beneficiary assignment.

Beneficiaries are assigned to ACOs based on a TIN under which their claims are billed. However, TINs were not designed for that purpose. A concern of inaccurate benchmarks arises when a clinician shifts which TIN she bills under or if the clinician starts to bill under multiple TINs.

When this occurs, the changes in how NPIs bill through TINs are not reflected in ACOs' benchmarks. In MSSP, TINs are used to calculate an ACO's benchmark and performance spending. Benchmarks represent the spending for beneficiaries who would have historically been assigned to the ACO's current list of TINs in the base years. Assignment is obtained by having the plurality of primary care visits to the ACO's TINs.

An ACO's shared savings is determined by measuring its performance year spending against its benchmark. Performance year spending is calculated via the beneficiaries who are assigned to the ACO's current list of TINs in the performance year. Changes that an ACO makes to its list of TINs takes effect in the subsequent year, when CMS annually recalculates an ACO's benchmark based on its updated list of TINs. CMS does not recalculate benchmarks

based on changes in the NPI's billing under the TINs.

However, the use of TINs to identify an ACO's clinicians weakens the utility of historical assignment and benchmarks, potentially creating unwarranted shared savings.

When individual clinicians leave or join a TIN, the beneficiaries historically assigned to that TIN do not change, and the ACO's benchmark is also unchanged.

The figure in this slide illustrates how changes in clinicians who make up a TIN could lead to unwarranted shared savings.

In the benchmark year, the TIN is comprised of Clinician A and Clinician B. If Clinician A's beneficiaries are high cost and Clinician A is removed from beneficiary assignment for the performance year, these high-cost beneficiaries remain in the ACO's benchmark.

Further, if the ACO adds Clinician C, who has historically low spending, to its TIN, the ACO's benchmark would not reflect the low cost of this provider's beneficiaries, but performance year spending would. The mismatch between the benchmark and performance year clinicians raises potential concerns about the accuracy of

shared savings.

One alternative to TIN-level benchmarks is to identify ACO clinicians based on combinations of TIN and NPI. This method is used in the NextGeneration ACO demonstration. This method solves the problem of benchmarks not changing when clinicians are removed from TINs.

However, identifying ACO clinicians through TIN and NPI combinations have some similar concerns to using TIN-level benchmarks. Benchmarks are not adjusted for NPIs added to TINs. Moreover, NPIs may selectively bill to TINs outside the ACO without a corresponding change to benchmarks. One ACO interviewed in a 2019 RAND study created a separate TIN for clinicians that disproportionately saw high-cost patients.

Rather than basing historical benchmarks off of TIN or a combination of TIN and NPI, NPI-level benchmarks would most accurately capture the ACO's historical spending.

Any changes in an ACO's performance year clinicians would correspond with changes in the clinicians used for historical benchmarks.

One potential issue to using NPI-level benchmarks is that historical benchmarks may be more likely to capture the historical claims of clinicians who joined an ACO after having moved from a different market that was outside the ACO's service area. Consequently, the claims outside of the ACO's service area would have to be removed from benchmarks.

Use of NPI-level benchmarks would also mean that clinicians would only be able to participate in one ACO. Consequently, clinicians with a wide range of TIN billing arrangements may be less likely to participate in an ACO. Under any of these arrangements, clinicians would still see and bill for any Medicare fee-for-service beneficiary. This change would just affect which claims were counted for ACO performance spending.

It's important to understand that redefining ACOs on the basis of clinicians' NPI would not require any changes to the structure of the ACO, its clinicians, or the specialists clinicians may prefer for beneficiaries. Here we illustrate an example of the current definition of an MSSP ACO, which is a collection of TIN 1 and TIN 2.

NPI A only bills under TIN 1. NPI B historically

only billed under TIN 2. However, NPI B subsequently begins billing under TIN 3, which is outside the ACO. If MSSP ACOs were redefined on the basis of NPIs, the ACO and its affiliated clinicians would have the exact same structure and billing arrangements. The only difference is that rather than the ACO being defined as a collection of TINs, the ACO is now defined as a collection of clinician NPIs.

To summarize the options for defining ACOs: For the option of defining ACOs as a collection of TINs, inaccuracies in the benchmark occur when a clinician is removed from a TIN, added to a TIN, or selectively bills to a TIN outside the ACO.

This potentially leads to unwarranted shared savings if an ACO removes high-cost clinicians or adds low-cost clinicians to a TIN.

For the option of defining ACOs as a collection of TIN and NPI combinations, inaccuracies in the benchmark also occur when a clinician is added to a TIN or selectively bills to a different TIN. This potentially leads to unwarranted shared savings if an ACO adds low-cost clinicians to a TIN or selectively removes high-cost

beneficiaries through use of an additional TIN.

The option of defining ACOs as a collection of NPIs largely mitigates the potential benchmark inaccuracies listed above, but historical claims from outside the ACO's service area would have to be excluded, and physicians would only be in one ACO.

The last concern with MSSP assignment we will discuss today is retrospective beneficiary assignment. Under the latest MSSP rules, ACOs can annually choose retrospective or prospective assignment. In retrospective assignment, beneficiaries are assigned based on primary care visits during the performance year. In prospective assignment, beneficiaries are assigned during the prior year. In our October 2018 comment letter, we highlighted concerns with allowing annual choice of retrospective or prospective assignment and the negative incentives it could introduce. Next, we summarize the advantages and disadvantages of prospective and retrospective assignment.

The main advantage of retrospective assignment is that the ACO is never responsible for the spending of beneficiaries its clinicians did not see during the performance year. However, it opens the door to potential

favorable selection.

In contrast, prospective assignment mitigates the potential for favorable selection and provides more certainty.

In prospective assignment, ACOs are never responsible for beneficiaries their clinicians have not previously seen, creating more certainty in assignment at the beginning of the year.

Under prospective assignment, ACOs are also more accountable for decedents, and prospective assignment mitigates unwarranted shared savings if ACOs target low-spending patients at the end of the year (such as through wellness visits).

In our June 2019 report, we found that retrospective assignment may exacerbate spending differences from assignment changes. These assignment changes often corresponded with changes in health care use.

Newly assigned beneficiaries (or joiners) and beneficiaries who lost assignment (or leavers) had higher average spending relative to beneficiaries who remained assigned to the ACO (or stayers). This is concerning because it may incent ACOs toward patient selection.

This brings us to the question of whether spending differences between ACO stayers, leavers, and joiners are alleviated under prospective assignment.

To answer this question, we simulated MSSP prospective assignment by using the prospective list of assigned beneficiaries CMS sends to all MSSP ACOs prior to the start of the performance year. We compared the 2017 spending of the ACOs that used retrospective assignments with the spending for those ACOs under a simulated prospective assignment.

We found that prospective assignment reduced the differences in spending between assignment stayers, leavers, and joiners. This increased parity under prospective assignment reduces the potential of rewarding ACOs for patient selection. The increased parity occurs because spending is determined a year after assignment and is, therefore, less tied to changes in health status during the year.

The average spending for stayers increased by about $900. This is partially because low-spending beneficiaries who were only assigned through an annual wellness visit had almost no spending under retrospective

assignment but now have some spending in the year following the wellness visit. Also, decedents with a prior E&M visit during the year are more likely to be assigned prospectively rather than retrospectively.

Under prospective assignment, the average spending for leavers and joiners decreased by more than $1,000, respectively. This is because sharp changes in health care use caused spending that was larger during the year of assignment compared with the following year. Keep in mind benchmarks would be calculated on a prospective basis as well, so we do not anticipate the difference between spending and benchmarks would change appreciably.

Overall, prospective assignment reduces potential rewards from patient selection.

That brings us to our questions for your discussion.

Should prospective assignment be mandatory for MSSP? For some time, we have been discussing the potential improvements that prospective assignment would have on MSSP. If the Commission is comfortable, we could come back with a recommendation in the spring.

Should MSSP use NPI instead of TINs to identify

clinicians in ACOs? Is there additional information the Commission would like on this topic?

Are there other policy ideas related to ACO assignment that the Commission would like to discuss?

We look forward to the discussion on these points, and now we turn it back to Jay.

DR. PAUL GINSBURG: It's Paul now.

MR. SERNA: Who's not here.

DR. PAUL GINSBURG: We're open for clarifying questions. Brian, Jonathan, Larry. I'll come back for more.

DR. GRABOWSKI: And David.

DR. PAUL GINSBURG: And David.

Anyone else?

[No response.]

DR. PAUL GINSBURG: Okay. Go ahead, Brian.

DR. DeBUSK: First of all, thank you for an excellent chapter. It was a really, really great read.

If we could go to Chart 13, please. When you talk about the physicians for the assignment, basically a physician has to be assigned to a single ACO now. I mean, obviously, with this new method, you can't go backward.

I had two questions. First of all, we already wrestle with specialists' participation in ACOs. The question always comes up: What about the specialists?

When I think of primary care, it's not an issue, but could you speak to specialist engagement and what this could do and what percentage of physicians in ACOs are specialists now and how many could be affected? So that's my first question is sort of this disproportionate impact of specialists versus primary care physicians under this new proposed rule.

Then the other question is, considering the subject that we just took up, could you speak to any effect this could have on consolidation? Could this inadvertently force physicians to choose sides, and would that have a consolidating effect?

MR. GLASS: Well, I think at one point, we looked at the percentage, percentages of specialists and primary care physicians, and they were about the same in ACOs as they are out in the rest of the world -- the rest of the United States.

And a specialist could still be in an ACO, but it could only be a participant in one ACO. He can still

perform surgery, say, on any patient that wanted to show up there, regardless of the patient's assignment.

DR. DeBUSK: Well, for example, an orthopedic surgeon in a given town, though, let's say there are two ACO models within this MSA.

MR. GLASS: Right.

DR. DeBUSK: You'd basically have to choose one or the other for your ACO participation.

MR. GLASS: That's right.

DR. DeBUSK: But not necessarily for your privileges. I understand that.

MR. GLASS: Correct. And that surgeon -- I mean, patients would probably not be assigned through that surgeon, anyway, because they're assigned nonprimary care visits.

So the specialist participation in an ACO may not contribute a tremendous amount to the assignment of the patients to the ACO. Whether the surgeon gets shared savings from an ACO, another question. That's up to the ACO to decide how to split things up. So not being in the ACO may not make much material difference to the surgeon, anyway.

DR. STENSLAND: This is just for assignment. If you're a surgeon and we have two ACOs, you could say for ACO 1, I'm in this ACO as its list of providers, and I will have my patients assigned to that ACO if they never see a primary care doctor during the year and they only see me. That's not a big deal.

In the ACO No. 2, you could still be a preferred provider, and in certain models, you could agree to be paid by even that ACO. There are some models where the ACO gets the money, and then they pay you. And you can create your own compensation arrangements with that ACO.

So working with two different ACOs is okay. Having financial arrangements with two different ACOs is okay. It is only assignment goes through the one ACO, and for you, you're probably not going to have that many patients that never saw a primary care doctor.

DR. DeBUSK: SO you could do an affiliation agreement with only one ACO, but you could still participate in financial arrangements through multiple ACOs just by being on the provider list.

DR. STENSLAND: Yeah.

DR. DeBUSK: Got it. Thank you.

DR. PAUL GINSBURG: Yeah. Actually, a follow-up. Of the physicians who were assigned to -- where beneficiaries are -- that lead to beneficiary assignments to an ACO, such as primary care and specialists where there is no primary care physician and they're perceived, what percentage of those are specialist?

MR. SERNA: So it's roughly about 10 percent of beneficiaries are assigned through specialists who do not have a primary care visit with a PCP.

DR. PAUL GINSBURG: Okay.

DR. SAFRAN: And on that point, do you know of that 10 percent, how much are medical versus surgical specialists?

MR. SERNA: I do not, but not all specialists are eligible for beneficiary assignment. I believe there's a set of about six or seven types of specialists -- nephrologists, endocrinologists, hematologists, and cardiologists.

DR. SAFRAN: So to the point that, Jeff, you were just making, I think that a patient who only saw a surgeon in the year wouldn't get assigned at all; is that correct?

DR. STENSLAND: That's a good point.

DR. PAUL GINSBURG: Good.

Jonathan?

DR. JAFFERY: Yeah. Thank you.

So this is a really fun chapter, which I think solidifies my position as a geek pretty solidly.

[Laughter.]

DR. JAFFERY: Honestly, so now we have stayers, leavers, joiners, and switchers. That's what we've got. That's what we're working with.

I think just to build on the conversation that was just happening here, first of all, one clarifying point, because, Brian, you talked about affiliation agreements, and there actually is this category in some newer models, as Jeff was saying, about preferred providers. You can be a participant, which would be if you were in a category where your patients could be attributed to the ACO as a participant. Those patients would go to one ACO, but you could be a preferred provider for multiple ones.

Some of the questions were getting at what I'm thinking about in terms of how many people are attributed, what percentage, by specialist. Do we have information

about how many people, how many providers are in multiple ACOs? Is there any breakdown by primary care and specialist after that?

MR. SERNA: We could definitely look into that. We've only looked at it for PCPs, and, of course, most PCPs are only assigned to one ACO. Actually, about 5 percent of PCPs were assigned to multiple ACOs. Yeah.

DR. CROSSON: Larry?

DR. CASALINO: For some reason, I realize there's a limited number of combinations, but I'm finding it still difficult to work through.

One of the problems with TIN-level assignment is, as you said, that strategic TINs could be set up, for example, to really game the system. With NPI-level assignment, I think in the example you showed, the particular physician who was in the ACO, if they move -- could you show that slide again? I'm not sure which one it is, the first one you showed. Yeah.

So if NPI B moves to TIN 3, that could be strategic, as you guys mentioned, for gaming the system, but it also could be -- and this probably would be more common, I would think -- the physician could actually

switch to a different medical group that has a different TIN and happens not to be part of the ACO, right? I mean, that would be not an unusual event, I wouldn't think.

So, in that case, when I read this, I thought, "Oh, yeah. NPI assignment is the way to go, but I just want to see if I understand correctly. If a physician switches, an NPI switches to a medical group that's not part of the ACO, with NPI-level assignment, the patients would still be assigned to the ACO, that NPI's patients. Is that correct?

MR. GLASS: No. Because the NPI would probably no longer be a participant in the ACO. If his medical group switched out of the ACO completely or he switched to a medical group that was not in the ACO, then his NPI would not be a participant in that ACO. So it wouldn't be this picture. It would be NPI B moving out of the ACO box.

DR. CASALINO: But how would you know that the NPI had moved out of the ACO?

MR. GLASS: Because the ACO sends to CMS each year a list of participants, and at the end, if you were to use NPI-level participation, the ACO would send CMS a list of NPIs that who are participants in the ACO.

DR. CASALINO: And if the NPI switches medical groups to outside the ACO in February or something like that, are these lists updated?

MR. GLASS: Yeah. The lists are, I believe, updated quarterly?

MR. SERNA: Yeah. So the lists are updated quarterly, but the changes wouldn't take into effect until the subsequent performance year.

DR. CASALINO: Okay.

MR. SERNA: So, in this case, if the change was made in February, those patients for that physician would still be assignable to that ACO until the next year.

DR. CASALINO: Okay. So it could be a disadvantage. I'm not trying to make an argument here, but I'm just still trying to understand.

NPIs are probably more likely to move to a different medical group than medical groups are to move outside an ACO, I think, in a year.

MR. GLASS: Well, that's a question.

DR. CASALINO: Yeah. Okay.

MR. GLASS: Also, as you say, one could strategically move NPIs or TINs in and out.

DR. CASALINO: Yeah.

DR. JAFFERY: On this point. So that this issue of somebody leaves in February, if they were assigned by an NPI-TIN, you'd still have the same issue, right? I mean, they're still part of the part.

MR. SERNA: Yes. It's the same issue.

DR. JAFFERY: Okay.

DR. CASALINO: It's a little different TIN assignment if TINs are less likely --

DR. CROSSON: Mic, Larry?

DR. CASALINO: Oh, sorry.

DR. JAFFERY: But if a lot of the current models have moved to NPI-TIN combinations, and in that situation, I think you'd have the same.

DR. CROSSON: Okay. Dana?

DR. SAFRAN: Yeah. Thanks.

I originally didn't have a question on this topic, but I'll just raise one. Have you thought about the impact on this issue of physicians switching out or in this picture, an ACO deciding to strategically move an NPI to a TIN that's not part of their list, if the list was based on TIN, not on NPI? That would then deny that physician their

APM participation bonus, which is a significant 5 perce2nt, right?

So I'm just curious whether you've considered that piece of things in terms of how this dynamic could work.

MR. SERNA: Yeah. So for purposes of being part of the APM, CMS could collect the same information. So, administratively, things don't have to change drastically. So they could still collect a set of TINs and just require that all the NPIs under that TIN are participants, as they do now, but the assignment of benchmarks would be calculated at the NPI level. So everything would remain the same, and the physician still is part of the ACO.

DR. SAFRAN: Okay, okay.

MR. SERNA: In this instance, we would just have to make sure that the physician is only part of one ACO for purposes of measuring assignment.

DR. SAFRAN: I see. Okay.

So my original question, which I'll turn to now, had to so with prospective versus retrospective. There's actually two questions here.

One is, in the work at Blue Cross Mass, we use

what we called "concurrent attribution," and I'm curious. Is that something that you looked at? Because I haven't seen it talked about.

MR. SERNA: So retrospective assignment is essentially a concurrent assignment. The ACOs are sent lists that are updated quarterly, and then there's the final list at the end of the performance year that is actual assigned beneficiaries for which the performance spending will be calculated.

DR. SAFRAN: Okay. So I had a hunch there was just a nomenclature thing going on there, because oftentimes people talk about retrospective as if it doesn't make sense. You're supposed to manage a population. How can you manage a population if you don't know who's in your population? But that's not actually how it works. You are getting lists all throughout the year, and it's only retrospective in the sense that it gets settled at the end of the year in terms of over the year who manifests as actually being your patient.

MR. SERNA: Yeah, that's correct.

DR. SAFRAN: I think that should be made clearer.

And "retrospective" is just a very misleading

word when it comes to like an accountable model. Probably, 80 percent of the people in this room, maybe even around this table, think that that means you don't know who your population is until December 31st. So I would just suggest that we clarify the language.

That's probably around two comments.

A question. As you thought about this issue of movers and switches and all of that, I guess what I read in what you're saying is a kind wanting to neutralize the effect that you see in the data, which we've seen for a long time. Typically, a health event precipitates somebody changing providers, whether it's an ACO or not, and so the one they go to is picking up a case where something is wrong and some care is needed.

So I guess I'm just curious about the thinking behind that and this interest in sort of neutralizing because it does strike me that we would want those who are accepting the case to feel accountable for that case, that cases now come to them and the patient has a health problem that needs to be managed.

So I just want to understand the thinking better in the work that you sort of summarize on Slide 17, but

that was a big part of that segment of the chapter.

Thanks.

MR. GLASS: Yeah. I mean, part of the idea is that we want to remove the possibility for gaming the thing, basically. In other words, you don't want to set up a system where it's really good for the ACO to do a wellness visit at the end of the year when they know the person has no claims for that year and ensure that person's assignment to the ACO. It's the susceptibility to selection that makes us want to kind of even out those numbers.

DR. CROSSON: David, on this point?

DR. GRABOWSKI: Yeah. What does the set of beneficiary characteristics on spending look like year to year? I think that would tell me whether there's selection or not, not the statistics -- I'm sorry -- on Slide 17 on sort of the stayers, the leavers, and the joiners. I think this is where Dana was going. I don't know that those are very informative. I think it's been relatively balanced year to year.

I realize this is more Round 2 than Round 1, but what is the sort of pool of --

MR. GLASS: Oh, you're saying what's the balance between joiners and leavers --

DR. GRABOWSKI: No. Overall spending in the group look like year to year, I think that's pretty balanced, whether you use prospective or retrospective. I don't think selection has been a big sort of issue here.

MR. GLASS: Well, we don't know that it has been in the past, but we'd like to not sent up incentives for it in the future. And I think we gave an example in your mailing materials if one ACO were to appear at that. Perhaps there was some strategic things going on.

DR. GRABOWSKI: I guess, though, on this idea of stayers, leavers, and joiners, I don't know what that tells us. I would want us to sort of pull back from that. I think there's better metrics. I don't think this tells a selection. I think we'd want to look at kind of what does the overall population look like. These could be very misleading.

DR. STENSLAND: One alternative --

DR. CROSSON: Wait. Hold on. Sorry. Are you answering?

DR. STENSLAND: I was going to ask David back a

question, but one alternative is if you go back to what we showed before was that individuals who are assigned via a wellness visit tended to have very low costs in that year of assignment. In fact, the wellness visit was a good indicator of how much cost you had earlier in the year, but it wasn't such a good indicator of how much cost you're going to have in the future. So we could show that, that this would clearly be a profitable strategy, if you could look at your HRR-adjusted costs are low when you're assigned by a wellness visit.

DR. GRABOWSKI: I would want to check overall to look for selection here. I'm less concerned about these issues around retrospective or prospective. I would want to see are there sort of broader kind of selection issues and are there ways to kind of test for that, and as David just said, to date we haven't seen that.

Now, I think under the new sets of incentives, we'll probably see more of it.

DR. STENSLAND: You probably will.

But, yeah, I think this is definitely not saying, "Oh, let's look at our old results, and we're concerned that it was selection that was causing them." I don't

think that's what we're saying.

We're saying are there some vulnerabilities in the current model where people can start directing their resources towards selection rather than better patient management and increase their shared savings, and how could they do that?

DR. CROSSON: Okay. I saw a bunch of hands. Who wanted to join on this point? Bruce and Jonathan.

And then anybody else wanted to get in the queue? Pat. Okay.

Yeah, I have you, Larry.

Okay. Bruce and then Jonathan on this point.

MR. PYENSON: Yeah, just on the selection issue. There is an episode that happened a couple of years ago when CMS decided to remove site of service 31 from the attribution, from the claims used for attribution. That was a nursing home site of service. And that led to some pretty dramatic shifts of people in and out of ACOs. Now that was an example of inadvertent selection and change and fluctuation. But I think there's no question that there's a huge interest by ACOs in evaluating potential additions or subtractions from their attribution, based on the

potential profitability of those individual physicians and physician groups.

So this is very much in the visibility of the ACO industry, so I think it's definitely a good thing to look at. The vulnerability has been recognized broadly in the industry.

DR. CROSSON: Thank you, Bruce. Jonathan.

DR. JAFFERY: Yeah, thanks. So focusing, I think, the response to Dana's questions about this in terms of ways that ACOs might game getting expensive people out, but then, you know, thinking about this notion of, you know, should ACOs be accountable for patients even if they do have higher health needs and new health conditions, the onset of new health conditions.

I guess I've been thinking of it from the other angle which is if you take in patients that have suddenly got a new health condition and yet your benchmark is based on people who didn't have that, a predominance of people, so that -- I guess can you comment on it from that angle? To me that's just as an important angle.

MR. SERNA: Yeah. So I think that's why we included the joiners in this analysis, because I think

that's what you're taking about is you don't want an ACO's shared savings to be determined by the balance of its leavers and joiners, right? I mean, overall you don't see selection, but it may just so happen that the mix of clinicians within an ACO means that they get more expensive patients relative to patients that leave the ACO, right? So I think this speaks to that being more balance and shared savings being more accurate.

DR. CROSSON: Okay. Larry?

DR. CASALINO: Yeah. Going back again to the question of one of the problems with retrospective assignment being that the strategic use of wellness visit, which I think to the extent we continue with retrospective assignment I think we can anticipate seeing more strategic use, as, yeah, you'll get to seem like a dumb ACO if you're not doing that.

So, you know, if we step back for a second and just think about assignment on the basis of a single claim or a single E&M visit or service in a year, if you actually think about it, it's not all that plausible that just because you have a visit with some provider that that provider is really responsible for you. Now I know there

was this debate early on, and I think it's kind of been mostly forgotten as far as I know.

But do you have any information or any thoughts on what if it took two visits or two E&M services in a year to be assigned? I guess it might be hard. You'd get a lot of ties and I guess that could be a problem. But two would be a lot more credible than one, in terms of assignment, and might, just to a considerable extent, solve the wellness visit gaming. Thoughts about that? Has anyone actually looked at, to your knowledge, or have you guys looked at what difference it would make it required two rather than one to assign, two or more?

MR. SERNA: So I think part of the issue is that even for wellness visits, roughly about 40 percent of wellness visits there's another E&M service alongside the wellness visit. So would that count as two or would that count as one? And that kind of gets into what exactly is one encounter versus two encounters.

DR. CROSSON: Another variation of that would be, in retrospective assignment, excluding the situation where the only visit during the year was a wellness visit. Similar idea.

David.

DR. NAVATHE: For what it's worth, just on this point, there are definitely commercial attribution algorithms that use the two visit -- two separate visits as a form of attribution.

DR. SAFRAN: I'll just mention the downside of that is you start to have smaller percentage of people attributed.

DR. CROSSON: David.

DR. GRABOWSKI: Great. I wanted to ask you about an example you provided in the text of the report on page 15 about an expensive procedure like a knee replacement. And take me to what happens. So that -- you give the example, there's this anticipated need for this expensive procedure, and they lose assignment. What happens to their baseline spend? Is there any sort of -- that's excluded, that's not attributed. What happens? Does risk adjustment at all address this currently or not?

DR. STENSLAND: So I didn't have a lot of costs last year, and you know that, so I have a low risk score. And you're my physician and I'm coming to you and thinking, you know, my hip is bothering me. And what you could do is

say, "Oh well, I think you really need to see a more compassionate physician, Jon Perlin, my friend, who absolutely--"

DR. PERLIN: Don't do that.

DR. STENSLAND: He is in an integrated medical system. They have orthopedic surgeons there. Then you'll have your primary care and your orthopedic surgery all at the same place. It will be more coordinated. Your medical records will be shared back and forth.

Then me, who this year, you know, or next year, even under prospective, you know is going to have an expensive year because you're having a hip replacement, and you know you're going to have an expensive risk-adjusted year because your HCC is from the prior year when you really didn't have too many diagnoses. And that person is no longer going to be on -- you're not going to be responsible for their spending anymore. It's going to be this integrated delivery system that's going to be responsible for their spending.

DR. GRABOWSKI: And one other question I wanted to ask about was just this issue around TIN splitting. Maybe put up Slide 12. I was trying to think through the

incentives here, and if I -- would I find it easier to kind of exclude physicians based on their NPIs, and maybe this is a variation of Larry's question from earlier. But if I was going through and trying to find the high-cost docs, at the NPI level, versus the TIN level, with regional benchmarks, isn't the NPI approach easier to sort of pick out the kind of problem children in that?

DR. STENSLAND: Yeah, so I think that's what I was trying to allude to earlier. So CMS could still have the requirement where they collect TINs, and all NPIs under those TINs have to be assigned to the ACO, I mean, as they do now. It's just the actual measurement of assignment and benchmarks is a collection of NPIs rather than the collection of TINs. So if that was a concern it would be addressed in that way.

DR. GRABOWSKI: Got it. And just as a final question, you have a term in the report, like -- and I think you used it even, Luis, during the presentation, "benchmark accuracy." And I think folks are going to react to that, because benchmarks can be accurate or inaccurate. And so just cleaning that up, that, you know, I think unwarranted shared savings was another way you framed that.

But just being careful about that, because these whole benchmarks are not counterfactuals and that's going to cause people to react. So just as a comment.

DR. CROSSON: Larry, do you have a comment on David's comment?

DR. CASALINO: [Off microphone.]

DR. STENSLAND: I was just going to try to clear up. I don't know if this was clear, but the main point is to match the people that are in your benchmark to the people that are in your performance year. And so the concern is when it's TIN-based you have -- your TINs are going to measure your base period. And you have, say, one doctor who has a lot of people that are non-compliant or cognitively impaired, and they just look expensive relative to their HCC, and they're in your baseline. You could say, well, let's have that person bill under another TIN, and the problem is they start billing it under another TIN, their high-cost patients are still in your baseline. So you get them to create your benchmark but you don't have them for your performance year. And you get this mismatch of having expensive people in your benchmark and being able to get them out of there before they hit your performance

year, and that's kind of the problem that we're trying to avoid.

DR. CROSSON: Yeah.

DR. CASALINO: Is there any evidence that -- I'm just throwing this off as -- I don't know, maybe it's a question -- is there any evidence that if physicians behave in the way that was just postulated, that you would tell a patient not to be your patient anymore, to improve your ACO? Certainly physicians respond to financial incentive, but I think it's important to distinguish things that an organization can do and things that an individual physician is likely to do. So wellness visits, you know, I doubt that the ACOs that are doing that are kind of leaving it up to the individual physicians. They are probably putting, systematically, you know, inviting patients in for wellness visits, right. And the physicians, of course, wouldn't object to that, in all likelihood.

Similarly, setting up a TIN just to dump all your high-cost, you know, NPIs into -- if done at the organizational level -- that's quite different from an individual physician making decisions that may or may not be in a patient's best interest and may not be in the

physician's best interest. They have a patient they like and they're going to dump the patient to save the ACO money.

So in terms of a question, is there any evidence that physicians care very much, really, about this ACO stuff, right? First of all, it's very hard to understand, even for us, at least for me, and secondly, you know, I don't know what kind of evidence there is on the sum of money that an individual physician can get if their ACO does well, and the extent to which they understand how that works. I think the sum is really very small, very, very small in most cases, and the number of physicians who understand it, even in a rudimentary way, probably is probably small. They may know, yeah, we should try to keep costs down, but that's quite different than strategically trying to select patients.

So do you have any evidence on this kind of thing at all?

MR. GLASS: I don't think there is any evidence, and as we've said, we're looking at vulnerabilities, not data on has this happened or not.

DR. CASALINO: I mean, my concern is --

MR. GLASS: And also, I would point out that when we've done physician focus groups, some physicians aren't even aware if they're in an ACO.

DR. CASALINO: Yeah. So my concern isn't to defend physicians. I'm just saying there was a comment from a Commissioner earlier, at the table here, we don't want to let the tail wag the dog. So I think we have to be a little careful to think of hypothetical situations. We know that the gaming is happening with wellness visits. You guys have evidence for that. But we don't necessarily know, and it may not even be that plausible, that physicians would act in the way that was just postulated here.

So I wouldn't want to make policy necessarily based on hypotheticals that, from all the kind of reasoning one can put to bear and evidence, if there is any, don't seem likely to be very prevalent.

DR. CROSSON: Okay. What I've got is, I think, Amol and Dana coming in on this point. Dana, are you the unnamed Commissioner involved here? Okay. So why don't we -- and then, Pat, I saw your hand, but you're on the list. Did you also want to come in on this point? You're up next

anyway.

Okay, Dana, Amol, and then we'll go to Pat.

DR. SAFRAN: Yeah, just a quick question, and that is, Jeff, in the scenario that you were describing about, you know, at the beginning of the year if I know you're likely to need a hip replacement I might, you know, suggest the compassionate doctor across the street. That made me wonder about, you know, back on the use of the term "concurrent," part of what we did was not only have concurrent attribution but concurrent risk adjustment. And something in what you said made me think that that's not happening. And if that's not happening, that is a key tool to avoiding the scenario that you're talking about. So I just wanted to flag that.

DR. CROSSON: Amol.

DR. NAVATHE: On the sub-point of on that point, so I think the reason that they freeze the ACC's priors is because otherwise it gives them an incentive to up-code, basically, a la MA. So that's my understanding of why they don't do their current coding risk adjustment piece.

DR. SAFRAN: Yeah, but the incentive -- you get bad incentives -- the incentives are worse the other way.

DR. NAVATHE: Yeah. I'm explaining my understanding of the rationale, not defending it per se. But I think there's a trade-off there, if there's one incentive in one direction and one incentive in the other direction. Brian, did you want to comment?

DR. DeBUSK: Well, just on that point, I still think full risk coding is inevitable. I mean we can fight it, we can push it back, but it's sort of like democracy. You know, it's the worst form of government, except the other forms that have been tried from time to time. So it's inevitable. I'm just sitting here waiting for it.

DR. JAFFERY: Very quick, I think one thing that hasn't come up about any wellness visits is that I think a lot of ACOs use them as a strategy for coding, getting people in, and less, though, about attribution.

DR. NAVATHE: Fair. So the point I was going to make is I think, if I read the literature right, and David, I know some of your colleagues have done some work on this too, and there's some passionate debates that have been had around selection and ACOs, the sense I get is to Larry's point. There is not a lot of evidence, if any at all, around sort of physician-level behavior changes that may be

pernicious in some way, but that there is evidence now -- there may be some debate around it but there is some evidence around ACO-level, you know, a la what you're describing here a little bit, in terms of which physicians are in and which physicians are out, TIN creation, and the like.

And, in fact, I think the other thing that might be interesting here is to talk to ACO operators, because I think in a couple other venues that I have heard this topic discussed there have been ACO operators who have described strategies that they've used to try to succeed under the program, and I think some of them do have elements of thinking about strategically how we would use TINs or NPIs or manage higher -- you know, physicians who have higher intensity panels or something like that.

And so I was wondering if we've considered doing any kind of discussions with the ACO groups or the ACO trade organization to try to get some sense of how much of a problem this is to the stability of the program, as a way to complement some of the analytic exercise, recognizing that the analytic exercise has some obvious intrinsic limitations.

MR. GLASS: We certainly have spoken to both individual ACOs and the ACO organization, but, you know, I don't think they're -- and there are also studies, I think the RAND study, where ACOs did say they were engaged in some of these things. But normally they wouldn't say, "Yeah, we're doing this," you know. That wouldn't be likely.

DR. NAVATHE: Yeah. I think --

MR. GLASS: But yes, we do talk to people.

DR. NAVATHE: -- it would have to be -- I agree, it would have to be sort of delicately handled. But I think that -- I guess I may have misinterpreted something that you guys said. It sounded like you were saying there was no evidence of any of this broad types of selection, and so I thought that that was -- that there may be some evidence and, hence, there's some greater depth here.

DR. STENSLAND: I think to Larry's direct point, I don't think we have specific examples about individual physicians trying to dump expensive patients. And I think that's a good point. We have enough other examples that we can use. But we do hear, and there are some cases in the literature, of being strategic with your TINs and how

you're billing people in or out of the ACO. So that addresses kind of both of your --

DR. CASALINO: [Off microphone.]

DR. CROSSON: Okay. Pat.

MS. WANG: At the risk of sounding a little cynical, to Larry's point, I think that even in the absence of, you know, like a chapter-and-verse detailed sort of report on different kinds of behaviors, can comment about ACOs because the incentives are a little less direct. But sometimes the organization is the physician, and I can tell you that in the capitated world this happens, and it's something that you have to be very -- I'm just telling you it happens, when physicians are at financial risk. And maybe it's true of larger organizations, but all I'm saying is hopefully we hope that it's around the margin.

DR. CASALINO: When you say "capitated world," do you mean a lot of risk for the individual physician?

MS. WANG: Yeah. Yeah.

DR. CASALINO: Well, that's the difference --

MS. WANG: So, yeah. So the financial stakes are much higher.

DR. CASALINO: Yeah, I think we know from the

'90s that if there's high financial stakes for individual physicians they would do something like Jeff had hypothesized. But that's not the way it is in ACOs.

MS. WANG: I don't know about that, Larry. I mean, there are physician ACOs that earn substantial bonuses, and it's real money to them. So, you know, I'm just --

DR. CASALINO: Well, that's where it would be nice to have some evidence that, you know, how many physicians are at all likely to get more than like $1,000 a year from their share of shared savings? I would suspect the number is very low. That's quite different from the kind of capitation in the '90s was put on individual physicians. We know that then there were extreme behaviors from physicians, I agree. But I would argue that this is a very different situation.

MS. WANG: It may be. It may be.

What I wanted to ask was, you know, I was a little bit confused because these are two important recommendations that you've made here. I wanted to ask you about the degree to which they do or do not overlap and have interdependencies. And of the two, TIN versus NPI, or

prospective/retrospective, whether you have an opinion about which is more important to ensure, or tighten up the integrity of the program? Because I think that's what you're trying to do.

But is there a relationship between the two? If you fix the TIN/NPI issue, which I think we all kind of see potential. Even though we may or may not think that it actually is being exercised, you see the potential. If you fix that, would the prospective/retrospective be as much of concern as these two completely freestanding issues?

DR. STENSLAND: I think of them kind of as freestanding. I think of the TIN/NPI issue mostly about moving physicians in or out of your ACO in a way that is advantageous, you know, to keep your benchmark high and your performance spend low by moving these guys in and out. And I think on the retrospective/prospective, that's more about moving the patients in or out. If I have the retrospective or call it "concurrent" assignment, I have more ability to control a favorable selection of the patient movement.

DR. CROSSON: Brian.

DR. DeBUSK: Just on that one point, it may be

interesting to look at specifically low-revenue ACOs that are physician-led who have implemented a two-TIN or multi-TIN strategy, because that might be an interesting subgroup to see if the behavior like Pat's describing is there. And it should be really easy because you could pick their TINs. It's all claims-based.

DR. CROSSON: We are still on questions. Go ahead.

MR. PYENSON: A couple of questions. If risk adjusters were perfect --

[Laughter.]

MR. PYENSON: -- then perhaps many of these issues would be resolved. And I'm wondering if you could address that, maybe some case examples, because I suspect people looking at this might be confused about why risk adjustment doesn't work. Of course, the benchmark, you know, we talk about sick patients, or I'll use the term "high-cost or "low-cost patients," and, of course, risk adjustment will take account of some of that. But just the variability is one question, if you could -- it is a question, if you could come up with illustrations on that.

But the other question I have is, you know,

thinking about risk adjustment and, you know, Carol Carter had created a risk adjustment or a system for thinking across sites of service, and I'm wondering if a risk adjuster or an adjustment for leavers or stayers or switchers would fix some of the problems even with prospective attribution or if that's just too far. And maybe attribution itself is flawed and can't really be fixed.

You know, I'll make a comment on that in the second round, but I'm wondering what your thoughts are on -- you know, you've identified some pretty big issues on here, and is it fixable, in your opinion?

MR. SERNA: So I'll take the second half of that. I don't think you can do an adjustment for stayers, leavers, or joiners because on the non-ACO side you don't have a collection of comparable entities, right? So then you're essentially only adjusting on the ACO side, so you're basically giving them higher risk scores than you would for the non-ACO population. So I don't think that that would work.

On the question of why risk adjustment doesn't handle this, obviously given the example that Jeff gave, it

does handle it better prospectively because you have a year delay and the claims used for risk scores. It'll never completely adjust because it's what the beneficiary's characteristics spending would be on average, right? So you have adjustments to the model such as the condition account from the 21st Century Cures Act that should also help beneficiaries who have more conditions, have more accurate scores, so that may be better reflected. But it's never going to be perfect because it is linear.

DR. CROSSON: Karen.

DR. DeSALVO: I just wonder if you could say something about whether you think any of these solutions -- retrospective, prospective, TINs, NPIs -- helps with the additional challenge of a beneficiary being in multiple alternative payment models.

MR. GLASS: I don't think we sorted through that question, though if it's prospective, at least you can say at the beginning of the year this person's in an ACO and, therefore, can't be assigned -- can't be counted for, you know, all the other ones that they've dreamt up.

DR. CROSSON: Okay. So what we want to do now is to provide -- sorry.

[Comment off microphone, laughter.]

DR. CROSSON: We want to try to provide guidance to the staff so they can come back to us in the spring with some recommendations that we could vote on. And so what I basically would hope we could do here as we go through the discussion period is have people express support or lack of support for, you know, one or the other of the two choices in these two categories of assignment that we're dealing with, so we get a sense of whether we're sort of tending in one direction or the other or not, and that would then, if we're not, mitigate perhaps some different approach. So, Jonathan, I think you're going to start off.

DR. JAFFERY: Sure. Thanks, Jay.

There's a lot to unpack in this conversation, and I'm left feeling -- this may sound a little Pollyanna-ish, but I feel a little sad for ACO operators who get up in the morning and think about how do we switch people from TIN to TIN as opposed to how do I build this piece of the care model that is actually trying to achieve the intended goals. And I'm going to continue to believe that most people are in the latter bucket, but maybe I would run of those dumb ACOs.

So, first of all, I really appreciate the evolution of this conversation around the prospective versus retrospective assignment, and I think, you know, as -- I feel a little more comfortable, a little more like I have a little bit better understanding of the perspective and how this may help decrease the gaming opportunities as we have each conversation.

That said, I think Round 1 brought out a number of questions that are still -- that still may require us to have a little bit more clarification on how this might impact different scenarios. And I think, you know, Pat's comment about do these two things intersect or overlap in any way I think is an important one, and I think -- I don't know. The TIN/NPI or the NPI conversation is sort of a new one, and so I think thinking through that a little bit would be helpful.

That said, I think this NPI recommendation -- I'm not -- you know, I liked the evolution from TIN to TIN/NPI, and I think this one has some merit. And I don't see -- I'm not seeing necessarily a significant amount of downside to doing this, as long as you do address the things that you bring up in the chapter which are how do we exclude

people who, you know, have a large -- basically who move or things of that nature.

So I think, you know, getting to this other question about what other ways to deal with beneficiary assignment or attribution, you know, Bruce brought up -- started to allude to and it sounds like you've got some comments that you'll make about how are we thinking about this the right way. And I think there are a couple things to think about. Maybe some of them are more granular, like the specialist attribution. Is that something that we should even have? And how much is that impacting attribution in ACOs?

I also think about, you know, we've been talking about bringing people for annual wellness visits or bringing people in for multiple visits, the attribution and the pros and cons there. You know, a lot of the model we've moved to is to try to be accountable for a population of patients without necessarily having to always rely on seeing them face to face continuously. And so there are a group of patients that we may take some accountability for, or we may ask our providers, our primary care providers, to take accountability to make sure that they're getting their

preventive care needs and things like that and available for interaction for relatively straightforward or minor things where maybe the physician and the patient have a relationship that goes back many, many years, where we are doing this more and more through non-face-to-face means.

Are we still accountable for them? We are. And sometimes, you know, things happen out of the blue, where people who have been healthy for a long time, and we can even do things where sometimes if somebody's got a relatively straightforward -- you know, somebody's got hypertension that has been longstanding and easy to control, do we necessarily need to bring them in every year just to make sure that they're okay?

So I think that, you know, when we think about the capitated world, one of the benefits to that for the organization is to say, well, we're actually going to be accountable for a group of patients that may not need a ton of care, and that may balance out the patients who need more care. And so I think as we move towards -- as some of these models move towards some of that global kind of budgeting or capitation, we're going to have to think more about what attribution models make sense.

I guess the other thing I want to take maybe a step back for a second and think about -- oh, one other thing about the attribution in addition to the specialist. There's also the APP attribution, and because in the past the APPs have not been able to discern between primary care and specialty care, that has played a role as well for trying to -- how do we include people or not include people are participants.

I want to take a little step back, though, because I think that these conversations are really focused on how do we stabilize the program at a pretty granular level. But I was really struck when I was looking at the appendix in the reading and thinking about how we have had -- we're about nine years into ACO models now, right, if we exclude PGP? So we're about nine years into it. And there were two things that struck me when I was looking at that.

So, first of all, you know, you brought this up in the presentation. We've got a 1 to 2 percent savings if we're using counterfactuals, and we sometimes refer to that as small savings or modest savings. And I can't get a sense of if we as a society or as a Commission think that's a good thing. Is that a success or is it not? Because

sometimes it comes off as, well, this is too small and it's not enough or we're not going quickly enough.

On the other hand, I don't know of any other program that we talk about where we're doing anything, and Medicare Advantage we've talked about as adding costs to traditional fee-for-service. So I guess I just want to put that out there, that that's not clear to me always that if we think this is a success and what we think is a realistic goal, even the short term.

The other thing is just to think about how many different models we've had in nine years and how difficult this is to operate under this lack of stability and this uncertainty. And now we've got, you know, a third of the population, we've got over 10 million people. We may be seeing some instability. As you mentioned, the number of ACOs has grown until 2019, and it decreased. It was modest, but that was the first time it went down. And these models keep turning over.

And so we look at NextGen as an example, so it's not the MSSP model, but that's a demonstration model. It's a small group of organizations that there seems to be some success there, and rather than sort of building on that in

a way that I think would help organizations that are involved in those models, take things to the next level, move things toward some sort of more global payments, we're now moving to an entirely different model, direct contracting, which is described as the next step for NextGens. But, you know, to date, there is so much uncertainty there. You know, our colleagues, other Commissioners, who either run NextGens or have -- I think Warner's in the MSSP ENHANCED, so they're not here right now to comment. But having talked to them and others, there's a lot of uncertainty about whether or not we can go into this next model. And I will tell you that it's very, very challenging to try and implement long-term innovation when you're spending every couple years trying to figure out what the next program is and trying to explain that to your senior leadership and trying to model things out.

So while I applaud you for digging into these issues, and I think we need to continue to think through them, I guess I'd like to see us try and find -- strike a different balance between how much we get into the granular aspects of existing models or changing models and how much we're going to -- how do we stabilize this? Because after

a decade, it feels like it's starting to have the potential for unraveling a little bit. Thanks.

DR. CROSSON: Okay. We're going to go on to the discussion period. Let me see. I think we're going to start with Bruce, who already volunteered he has something to say, and then Dana, Brian, and David.

MR. PYENSON: Well, thank you very much for your work, and I think it's really among the most important things that we've done and you've done.

In thinking about the ACO movement, I think historically it has often been seen as capitation lite and a way to create something that was like capitation but without the beneficiaries or, in the case of commercial insurance, the members knowing about it and without as much rigor on the part of the provider systems. So the attribution methodologies were a way to define, if you will, a natural assignment of capitation and to create virtual budgets and virtual gains and losses based on the virtual budget. And I think what you've identified in your work are some flaws in that that probably were not foreseen by most of the people involved in thinking about how those programs would work and the risk selection issues and the

vulnerabilities of that.

So we're at a point today where perhaps the question is: Does capitation lite or attribution methods, do they really work? Or are there too many challenges with them that make it mean we have to get to something more direct? I think that's perhaps not as much of a challenge as we might think.

Part of the appeal of attribution has been a belief by providers that bringing special focus on particular patients identified in advance would bring advantages and better outcomes and lower cost. And I think there's been a series of tests of that hypothesis, most recently the work that was done on hotspotting or the Camden approach. But there's been a whole series of other tests of that that have shown that that hypothesis probably isn't right or broadly isn't right.

But I think that's actually good news for the test at hand, which is, to pick up on what Jonathan said, perhaps a direct relationship between the physician and the patient isn't as important as many people think, that what really counts is what the system brings to the individuals. So if that's the right answer, then I think that's good

news for what we're trying to do because it means that having ACOs accountable for a fixed population, regardless of where they get their cost, probably isn't as crazy an idea as some might think.

So I think where we're heading here with this information is a different model of ACO which looks a lot more like Medicare Advantage perhaps or capitation, where a provider system is responsible for the patient that's assigned to them no matter what. Some of those patients are going to be seen personally, and others are just going to be there. And I think what -- I'm interpreting the results here as a step towards a perhaps better model and one that's simpler and one that's better connected to the evidence of what works and what doesn't work.

So I think the work you've done has really been fantastic and paved the way for the next steps for accountable care. So thank you very much.

DR. CROSSON: So, Bruce, let me just thank you for pointing out to the Commission and also to our guests that we currently have two levels of work going on here with respect to ACOs. One is, I think, well represented by what you've said, and I think that's a longer-term piece of

work; and one that, as we mentioned, we're going to be coming back to in the spring, which would include, I think, some more comprehensive changes to -- and I'll call it the "ACO program," but I think as you suggest it's broader than that. It's how to get a payment system that rewards the successful management, cost, and quality of a population.

Another level of work which I think the presentation today gets to is, given all that, you know, how do we repair the flaws in the engine of the car that we're currently driving, not to stretch the car metaphor beyond where it should be, but, you know, we have to give attention to both levels of engagement at the same time. So I think it would be helpful, you know, again, to try to provide to the staff some suggestions about which of these four choices people might think they are supportive of.

Dana.

DR. SAFRAN: Thank you.

I'll start with the NPI issue and say that I'm very supportive of moving in a direction that uses NPI tied to ACOs. I personally don't see the value of including the TIN in the mix, and from this conversation, I see a multitude of mischief that could happen when that occurs.

Given the way that attribution works, which thank you, team, for clarifying that really is -- I think you said 90 percent primary care physicians, 10 percent specialists but only in six medical specialties. I do think that simplifies what otherwise could be a kind of mind-bending expertise for surgical specialists who might practice in different settings that are associated with different ACOs.

So I do support that idea of using NPI and having NPI tied to just one ACO for physicians for whom there can be attribution, if that makes sense.

On the attribution model, I have to say that I still have a lot of concerns about "prospective." One got added to my list by Jonathan's comments about just stabilizing the program, so that I'll add that to my list of reasons.

My main reason is that, as I think my earlier question probably indicated, we do know that part of health care works, and I don't think we're trying to change this, is when patients have a significant health care need, they may move to a different system. I know that it's true that currently -- that in MA, the way that works is you are the

plan, and you are accountable, regardless of where care happens.

ACOs are meant to be different. ACOs are not plans. They're delivery systems, and so I think I'll paint the picture of my concern. And it relates to the conversation we had yesterday about transforming hospital payment in a way that is going to become clear in a second.

So patient is part of right now ACO A, and there is ACO B that has expertise in, let's say, the particular health condition that emerges in April of that calendar year. Under a model where the patient remains ACO A's accountability, no matter what, the hospital in ACO B's contract is riding their fee-for-service horse when they are taking care of that patient. They have no accountability for managing the cost of that case, and ACO A has really very little ability to influence that hospital, other than starting to try to dramatically shift the referrals they make in general for their population to hospitals that are more cooperative, but given this being the Medicare program and patients being able to go where they like, I think that's part of our problem.

On the other hand, if what manifests is that ACO

B's hospital and physicians are really the best place for this patient to get care for what's going on with them this year, then I really do think that a model that says this is where the patient is getting care this year and this is who is accountable is a very good model.

I think the other thing that we came across in this conversation that I think is important to add is that not only is it concurrent attribution, it's concurrent risk adjustment. If the risk adjustment model is tied to last year, you get a multitude of concerns.

I guess the last thing I'll say is that the worries about December wellness visits and so forth, I think, are really quite small compared to, I think, the significant worries that we should have about patients with significant health needs and where they get their care and who's accountable for making sure that care is good quality, getting the best possible outcomes and managing the overall cost of the episode.

So thanks.

DR. CROSSON: Thank you, Dana.

Brian?

DR. DeBUSK: First of all, thanks again for a

great chapter. I really, really like the technical work that you guys do. I really enjoy seeing us in this more and more too in making ACOs successful. So thanks you.

Specifically on the NPI approach, with the delineation between an NPI used for assignment versus a participating NPI like we discussed in the clarifying round, I definitely think NPI is the way to go. I mean I think philosophically, technically, for a lot of reasons.

Also, on the prospective attribution, that makes a lot of sense. I think, again, your technical work there, you've built a good case using the leavers and switchers and stayers analysis. So I think you're definitely moving in the right direction there, so, again, two excellent technical fixes.

I want to mention sort of the next round of technical fixes. I mean, Dana just mentioned it. I think Amol mentioned it earlier. This risk adjustment thing, if I had to pick two sort of elephants in the room, risk adjustment and beneficiary engagement, at some point, I think we're going to have to take those up. I feel like we're sort of avoiding two difficult subjects, and I don't blame anyone for avoiding them. But I also feel like

they're inevitable.

To speak on beneficiary engagement for minute, we talk about 10 million people in ACOs. I'll bet 9.9 million of them don't know they're in ACOs, and I think that's fair. Yeah. I think that's a good example of the challenge. You've got to have some mechanism to engage your beneficiary. So many of them are protected from cost sharing. So I don't know that you can use that lever. I don't know if it's Part B premium. I don't know what's left, but I think we are going to have to at least visit that subject.

The last thing I want to touch on -- and I'll try to be really brief -- anytime we provide, either intentionally or unintentionally, an opportunity, let's say an arbitrage for physicians or for providers, they adopt those remarkably quickly. I mean weeks, months, certainly not years, to make adjustments to the practices.

So let's look at this program. We're nine years in. They've got this tremendous degree of freedom around managing the patients that are assigned to them right now. They also have this tremendous degree of freedom around managing the providers that get attributed to them or

associated with them. So you've got these two huge degrees of freedom.

Jeff, I think that's what you described it as, as sort of two independent degrees of freedom.

If you look at what we're going to publish in March, we pay 91 cents on the dollar to a hospital and contribute 8 percent toward their fixed cost. You back into that. That means 86 percent of their costs are fixed. That's just to make the math tie.

So I'm thinking you've got these two tremendous degrees of freedom in this program that's nine years old, and they get to shed 86 percent of their costs and then get 48 percent of that cost back in shared savings through the 50 percent shared savings. And I don't mean to be -- I love ACOs, and I want to see them successful, but I'm asking myself, shouldn't we do some soul-searching? I mean, you would think we'd be having meetings talking about how we have to pare these savings back, and how do we slow this program down?

We've had these very tepid results in a program that has some pretty well-documented vulnerabilities. In a system to shed 86 percent of the cost and get 48 back, I

mean, that's a 38 percent margin swing in a 5 or 6 percent margin industry.

Jaewon ought to have a van driving around town picking up patients for the ACO. I don't mean to be pejorative.

But let me plant a bug here, one last thing. I've gone way too long. If the world isn't working the way we think it should if we've got this idea -- Bruce touched on this with this new start of going "hotspotting." Either the idea of care coordination and the idea that we can actually cooperate, communicate more in all this and reduce cost, either that idea doesn't really pan out or at least doesn't work nearly as well as we thought it would or our underlying assumptions are wrong, and I still keep coming back to everything we've done in the ACO space is built on top of fee-for-service. And is it time to either question care coordination, which I still believe in, or is it time to question the assumptions that we're going into this experiment with? Because or both of those are wrong, unless Bruce wants to disagree with me. One or both of those are wrong, and I would just encourage us to look at, explore things like global budgets and some form of

capitation and really changing the way hospitals and physicians are paid.

Thanks.

DR. CROSSON: Thank you, Brian.

Marge, on this point?

MS. MARJORIE GINSBURG: Yes.

DR. CROSSON: And Dana as well.

MS. MARJORIE GINSBURG: I felt we were told last year that CMS was going to be notifying all ACO enrollees that they were in an ACO. They were going to be sending letters out. We heard that, I think, at our last July meeting. Did I dream this?

MS. TABOR: The ACOs are now required to submit letters.

MS. MARJORIE GINSBURG: The ACOs?

MS. TABOR: Yes.

MS. MARJORIE GINSBURG: Are they doing it?

MS. TABOR: They are. It's probably too early to say what the results are because it's too new, but I'm tracking it, so one more report. But, yeah, there is a requirement now that ACOs have to both send a letter, notifying beneficiaries that they're in an ACO, and then

also I believe posters or banners or some kind of notification within some buildings.

DR. JAFFERY: That was the original. That used to be the case that ACOs had to do that. So we did that for years. We didn't have to anymore, and now they have to again. So it's not a new thing, and so it's maybe early to see what happens here. But it didn't seem to impact beneficiaries' ability to know that --

MS. MARJORIE GINSBURG: [Speaking off microphone.]

DR. JAFFERY: There was a very small subset that would respond usually by writing a letter back. Yeah, usually without a lot of understanding of what it means.

DR. CROSSON: Dana?

DR. SAFRAN: Yeah. On this point too. I was going to pick up Bruce's point but decided not to, but now I feel like I need to.

The New England Journal article this week about the hotspotting is a very important piece of research. It should not undermine our confidence in decades of research that show definitively that clinical relationships matter, that clinical relationships influence patient behavior.

This is a study of extreme population in terms of poverty and social need, and it should not surprise us that care coordination isn't on their Maslow's hierarchy of needs, the thing that's going to make the difference. They need housing. They need food, and that article should both accelerate our attention to social determinants of health and the important bringing together of social care and medical care. But it really should not for the broad population, including Medicare beneficiaries, undercut our confidence in the evidence that coordinating care for people who have complex medical needs is critical and that the clinical relationships matter immensely, because adherence to clinical advice is on the pathway from what happens in the clinical encounter to whether you get good results. And we know that patients adhere to those whom they trust and those they feel know them. So I just wanted to punctuate that.

DR. DeSALVO: Amen.

DR. CROSSON: Thank you. Dana.

Okay. So Jonathan, and, Brian, you want to comment on that. David is in the bullpen here.

DR. JAFFERY: Yeah. First of all, Dana, thank

you for saying that. I couldn't have said that better. That was amen, indeed.

I think maybe connecting that and also to Brian's similar comments about beneficiary engagement, I'm not sure I always understand what people are saying when they're talking about the beneficiary engagement gap, and I think, in some ways, the need here is to try and find that balance between what is an ACO team doing to building the structure to provide support, ideally to provide support for building that team-based model of care, so that primary care in particular has other resources to deal with folks with behavioral health in the clinic and whatnot, and then ultimately, more and more, try to move upstream to how do we get involved in social determinants of health. That's one of my reasons for wanting more stability in the program, so that you're not reinventing the wheel every three years and not dealing with those things.

But I think the other thing is that's the role maybe of the ACO structure more. The individual physicians and other providers are still the ones that have that relationship with the patients, and to me, that's the beneficiary engagement part. People tend to stick with

their primary care doctors, and I take my job with the ACO as supporting that team.

DR. DeBUSK: Just to clarify that other comment, I also believe in care coordination, and that's interesting. I knew sort of who the care coordinators would be, who would speak up when I made that comment.

Here's my point. We've had nine years for this ship to come in, and I still believe in the idea. The question is, especially for the people who believe in care coordination, are we building these models on top of the wrong chassis? Because that's the only other answer. Either it doesn't work, because it's had nine years to work, or we're building it on the wrong chassis.

Thanks.

DR. CROSSON: Okay. David and then John.

DR. GRABOWSKI: Great. Thanks.

So I'm pleased that we're continuing to focus on ACOs. I'm a little bit worried that we're losing the forest for the trees to some extent. I guess I'm less concerned with assignment issues and more concerned with that uncertainty that Jonathan expressed.

I agree selection is a problem, but I think it's

a problem if the Jonathans of the world leave the program. I'd like to see us focus on incentives to participate, to save and select, and to kind of think about the big policy issues and focus. I just don't see assignment as being a huge first-order issue.

So let me say a couple of words about the two points in the chapter and then make some broader comments.

Regarding prospective versus retrospective, my view on that is t here's tradeoffs with both. I'm fairly indifferent. I actually think prospective just delays a lot of these incentives by a year, and ultimately, we get to the same sorts of behavior. You could convince me, and I'd be receptive to kind of going to prospective, but I don't think that's going to solve our problems here. So I'm not convinced that that's a huge area of focus for us.

On the TINs versus the NPIs, I'm glad, Bruce, that you raised risk adjustment. I think that's a huge issue. I think this could be solved by risk adjustment, that we should as a Commission be kind of making recommendations and investing in better risk adjustment. The ACO CAHPS is an example of one survey that we might leverage. So there are other ways to do this better, and

could we be pushing on that front?

I don't know. Once again, I don't have strong thoughts on the TINs versus the NPIs, but I just don't know. I'd rather see us focus on risk adjustment than kind of the leveling there.

The final remark is I do believe -- and Jonathan talked about the kind of enrollment decline in this year. I do think the program is starting to unravel. ACOs can leave the program or jettison TINs to get under the regional benchmark. I think the real problem is kind of this regional benchmark coupled with this shift, as you mentioned during your presentation, slowly towards downside risk. I think we want to really revisit and focus as a Commission on how we're setting the benchmarks and thinking about the structure of risk in the program. I'd like to see us go after the high-level issue and not focus necessarily on assignment.

Thanks.

DR. CROSSON: Jon?

DR. PERLIN: Let me associate with David's comments and just as a bit of a segue into the difference between sort of looking at the population overall and then

this issue of care-spotting, care coordination.

You say okay, the ACOs, that the results have been modest. Maybe that's true on average, but folks who work with me in my office know my favorite Lincoln quote is "A man with is hair on fire and his feet in ice water is, on average, comfortable."

[Laughter.]

DR. PERLIN: And the extremes are very, very different.

There may be some patients who are intense utilizers. One of the things I would have liked to have seen and I hope we'll take up as an adjunct to this is to really push CMMI to offer some models that look at those extreme utilizers, the extreme risk, because it may be that the average is belying a couple different populations, a population once held that we've had some conversation about that really doesn't need much, and good for them; the population in the middle who will be somewhat represented by that 1 percent, and a population that will be extreme utilizers and if not managed -- and this is the way I thought about it in VA -- deprive the number of beneficiaries that can be served or the depth of service to

any particular beneficiary.

If one can identify the risk adjustment, it has a couple of implications. First, that you begin to build the ACO around the beneficiary as opposed to around the providers, that maps differently, and under perhaps the aegis of CMMI, that some of the social determinant issues that are so confounding might be addressed.

Let me just cap that with this, that the most powerful prescription I ever wrote at the VA, in fact, the most powerful prescription I ever wrote in my life, was for a window air conditioner for a gentleman with end-stage COPD who was in and out of the emergency room every two weeks. Were he not a veteran, he would have been using Medicare resources, and in Richmond and summer, the inside of his double wide would get to be about 120 degrees. After that $1,200 intervention, his utilization was about twice per year and without the sort of extreme situations. So I just think we need to think both about the distribution of risk and how we apply certain tools, perhaps pushing the boundaries through CMMI and then what are the implications for defining the population for care in an accountable care arrangement around beneficiaries and

their risks, perhaps.

Thanks.

DR. CROSSON: Thank, Jon. Amol and then Kathy.

DR. NAVATHE: So I definitely agree with the broader points that Brian and David and others have made about the focus on sort of bigger picture and our role in sort of helping advance that thinking. I think, you know, Brian sort of alluded to it without really saying it, in some sense, that maybe the real destination here is to try to get away from fee-for-service and to a capitation-based model or something that's more population based in terms of payment.

And so one lens to view this in, I think, is, you know, are these kinds of technical and/or structural details, are we moving toward a system, or moving toward the direction of a true population-based payment type of model? And it seems to me, in that sense, the prospective and the NPI, these are all positive shifts for us to be recommending, because I think most of the capitated type models do function largely that way.

Another sub-point, just to make the bullet point on the prospective versus retrospective, I totally agree

with David and Dana and others that there's tradeoffs between the two, but I think there is also an important sort of behavioral, psychological benefit to prospective attribution for physicians and ACOs and ACO operators around, you know, feeling like they know who they're responsible for, and that could be actually huge in terms of its eventual impact.

I think, to come back to the 30,000-foot view, I think an important question that we have to ask ourselves is, you know, if we are trying to move this shift towards population-based payment, and again, Brian alluded to this, is, you know, are we doing enough? Are we dialing it up enough? But I think another question that comes up over and over again is, you know, what are the capabilities needed to be able to really succeed in those models. And I think most of us would probably feel like turning on a two-sided model for the entire nation in a mandatory fashion would probably not be the right way to go, because we just probably don't have the right capability.

And I think that's the direction, in some sense, that we need to think about, is if we're going to move away from the system that is inherently flawed, that is

inherently not driving the right types of incentives, and, frankly, not delivering for our beneficiaries, then what are the steps that we need to make, from a structural perspective, to actually bridge this gap so we can get the delivery system to a place where it can handle a population-based type payment model that probably most of us feel is the destination that we're really searching for.

DR. CROSSON: Thank you. Kathy.

MS. BUTO: So when I -- I actually don't have a strong opinion on these issues, but I was inclined to support the recommendations to move toward an NPI versus a TIN, and prospective versus retrospective, until I listened to the conversation.

So Dana, actually, I thought, was pretty persuasive that there is some real value in having the accountability follow the patient, which makes me a little more indifferent to which way we go on the assignment issue.

I think the NPI still makes more sense, but I really liked David and Jonathan's comments about the larger issues. And I realized that ACOs were originally developed with the notion that we should try to make coordination of

care as painless as possible for the beneficiary.

And I wonder if we've reached a point now where we ought to be willing to step beyond that, to look at a level of ACO which involves enrollment, not attribution, and where there still could be shared savings, but begins to move more in the direction of partial capitation for some aspects of care. And I would just say I think we're ready to look a little beyond where we are for those ACOs that are ready to take a bolder step.

And Brian, I know your issue with fee-for-service chassis, but frankly, you know, I don't see us cutting loose from fee-for-service until we either have premium support or some other basis on which to value the care. Right now it is the data that tells us what care is costing for Medicare beneficiaries. Until we have another way to value that, I don't know how quickly we can break that, you know, move away from that chassis issue, say.

But, you know, I think I'm open to that. I think we all are. It's just what exactly do you have in mind, and I think that probably needs to really be discussed among the group.

But I just want to say that I think where we're

stuck on ACOs is just that it was always going to be an incremental savings program with the hope of improving quality. But maybe it's time to look at, all right, time to evolve beyond that. And beneficiaries are probably ready for it too, at least for that choice. They can still choose the less-risky choice.

But those are my comments.

DR. CROSSON: Thank you, Kathy. Jonathan and then Larry.

DR. JAFFERY: Yeah, I just want to add onto what Kathy just said, and I really appreciate that perspective of how do we evolve this.

I won't speak to the enrollment piece, but just to give people a sense, because I recognize that not everybody is as close to some of the models as I am. And so in NextGen there is the opportunity for organizations to move towards more population-based payments. What I hear, in talking to a lot of colleagues who are in the same situation, is that they do, in fact, want to go in that direction or have started to. And, you know, one of the issues is that NextGen is a demonstration through CMMI, and this is the last year, the final year to start it.

And so direct contracting is designed to be the next step, but I think my concern is that rather than just taking NextGen and extending it and trying to evolve it to get towards some of those goals, which CMMI could do, it's sort of being replaced, maybe not whole cloth but enough that it's very difficult, because you're stuck switching into a whole other space in order to get to that capitulation or population-based payment.

And so maybe there's something that we could start to recommend towards CMMI that, rather than do that here's a way we can involve the model in what you have already created that has actually, for a relatively small number of high-performing organizations, a fair bit of -- I would say a significant bit of engagement.

DR. CROSSON: Larry.

DR. CASALINO: Yeah. I think that, you know, the issues of assignment and the NPI versus TIN issues are vitally important in the program, and I have to say I still feel like I'm ping-ponging back and forth as I hear people speak. I don't actually have a fixed position. I'm not going to comment on those now, but people are trying to kind of set up for the spring work we're going to do, and

I'll just make a couple of quick comments about that, I think.

You know, I've been a big supporter of ACOs from the beginning, and I think that they have been successful, very much so, in the sense of changing the culture and what's kind of taken for granted, culture in health care, which is important. It changed it in the sense that, you know, there is a sense that we have to change more towards systematically improving quality, reducing costs. That's kind of taken for granted. Now it's hard to remember, maybe even though it wasn't, 10 years ago, but I think if we look at the program now, 9 years is a pretty long time. And in the Medicare ACO programs, at least, you know, we don't have a tremendous amount of savings to show for it, and we don't know that much about the quality.

Part of the problem may be that so many of the ACOs have hospitals at the center of them, and, you know, the hospitals obviously really have a foot in two canoes and probably are a barrier, not a facilitator in many cases to not all but to ACO success.

But I think the other problem is the amounts of money at risk are so small, maybe not so small for an

independent physician group that, you know, has 5,000 beneficiaries and is doing it, but for a hospital-based system or, you know, a large medical group system, very little money involved. And I think those are two of the reasons we're not seeing much change.

The real point I want to make is that, you know, we do have examples that worked, for whatever reasons, or are working. So I think more could be learned from what Blue Cross Blue Shield's Alternative Quality Contract has done, and it would be very instructive, I think, to try to understand the reasons why that worked, how well it's working, the reasons why it works as well as it does, and to what extent could Medicare do that or not do that. There are some advantages that, you know, commercial MA has that and Medicare doesn't have. But explicitly trying to learn from that.

And then a lot of people in the room, probably the majority, are too young to probably know much, if anything, about this, or even know that it existed, but, you know, more than a quarter of a century ago, in California and some other places, these were mostly medical groups and IPAs. The hospitals were not part of this.

They were extremely successful at taking large amounts of risk. And one of the problems with the program now, I think, is that the amounts of risk that are being taken are really fairly trivial, in my opinion.

It's kind of incongruous to me to -- so I kind of grew up on the California experience, which was give us more risk, give us more risk, give us more risk. That's the way we're making money. That's the way HealthCare Partners made money, this $4.4 billion group when it was bought a few years ago. So part of me still lives in that "give us more risk" world, and to have very large organizations, much larger than these medical groups, who are saying, "Oh my God, you know, we can't afford to take 1 percent downside risk," you know, I think as long as we don't have more risk we're never going to get very far.

So it's obviously true that we can't make the whole U.S. health care system not take lots of risk. It's not organized for that. But I wonder if it's worth thinking about, at least, trying to -- there are still people alive and there are some publications to try to learn, how did that -- in addition to learning from Dana's program, how did that happen in those days? How were these

groups successful? How were the programs set up? And are there any lessons from that at all, if we want to even think about a larger set of suggestions for the ACO program, instead of or in addition to making important technical fixes in the program as it is now.

DR. CROSSON: Thank you, Larry. I mean, my memory of this, because, as you know, I was around during that time as well, is that a lot of the success was in the Los Angeles basin, where there's a concentrated population, and many hospitals are not that very far apart. And so not entirely but to a large degree, some of the success enjoyed by the large medical groups there, in taking capitation, was due to the ability to move patients from one hospital to the other. And essentially, it's kind of the opposite situation that we've been describing here where, in fact, we have hospital-led ACOs who have a different payment incentive. In that situation, the hospitals are very strongly incented to play along, in an appropriate manner, with the directives that came from the physicians.

DR. CASALINO: In the L.A. area.

DR. CROSSON: In the L.A. area. And the question has always been, you know, how replicable is that model to

situations with less population density, less hospitals, and the like.

DR. JAFFERY: Yeah. I guess one more thing to think about as we carry this conversation on, and I said this a little bit, but, you know, again, it goes back to what exactly is success here? You know, we keep hearing people say that we haven't got much savings, and I'm not sure what the goal is. So where -- if 1 or 2 percent isn't success here, then what is? Is it 5 percent? Is it 10 percent? I mean, I think that would be good to understand.

And I think the other thing is, you know, we talk in other spheres about, you know, trying to keep payments to efficient providers, and we don't really have a parallel situation here. You know, I think theoretically we want quality to continue to improve. Theoretically, I don't think we're talking about total cost of care going down to zero. And so what is -- is there some point where we get to a total cost of care for an average beneficiary in a geography that is the right amount and we're trying to keep costs from not going up higher than inflation, or are we always talking about trying to keep it going down? And it doesn't matter what we get to, that doesn't seem like a

sustainable approach.

So those may be some other things that we want to grapple with, so we actually understand if and when we get to success.

DR. CROSSON: David.

DR. GRABOWSKI: Just quickly on this idea of whether 1 or 2 percent is small or modest and whether we should celebrate that. I often after we get so few victories in health care policy, generally, Medicare policy specifically on this Commission, that we should celebrate any sort of savings we get with no corresponding decline in quality. So I think at times we can be very dismissive, and I think we should actually frame it as a real positive here, and I think you guys did that nicely during the presentation. There's no doubt we want to continue to innovative, but let's not lose sight of the fact that we've generated savings here.

DR. CROSSON: Okay. In summary, I think we had a very strong consensus here around the fact that we are generally in support of ACOs and ACO-like developments, moving towards prospectively taking responsibility for cost and quality of a population, without question. We have

been from the beginning. And that there are a host of large issues, program design issues, for example, with respect to ACOs or beyond ACOs, that we need to tackle. And again, I think this is consonant with where the Commission has been.

And so I think it was appropriate for people to reinforce that message, both to us and to anyone who is listening to us. And as I said, we're going to do that again in the spring.

Having said that, with respect to the issues on the table here -- and I'm going to test this, but I think that with the recognition that some Commissioners have remained silent on these choices, I get the general sense that moving to the NPI is something that -- I'm getting mostly bobble-head consensus here -- is something that we should do.

With respect to prospective versus retrospective assignment, I think -- my sense is that Dana moved the ball here on us, very effectively. And you said, Dana, in your comment, you know, there are some Commissioners around here who think retrospective assignment means you don't have anything until the year is over. I thought that, to be perfectly honest. And what you were describing as

concurrent, incorporated in my mind the notion that, well, in fact, yeah. I mean, there are mechanisms in place here for ACOs with retrospective assignment to have no immediate knowledge but relatively useful knowledge about who they were accountable for.

I think that's made this choice for the Commission rather difficult, because I think we have a consensus that yes, it's a good idea, it's a rational idea for an entity that's accountable for a population to know what that population is. Less clarity about whether that needs to be day one or whether that knowledge three months later is adequate to fulfill that same need.

And so I have not heard a consensus here. I've not heard a consensus here, that I can articulate, that says we should clearly favor prospective in the current way that it's organized, prospective versus retrospective, without complicating it. There's another issue, I think, that we have addressed directly with CMS, which is whether it makes sense for a particular ACO to change models from year to year, which is a secondary question, which I have some trouble understanding the rationale for.

But having said that, I want to test this with

you, because we do need to give direction to the staff. Do people feel strongly in favor of prospective assignment or retrospective assignment, or us remaining essentially agnostic on it at this point in time?

DR. SAFRAN: Jay, can I clarify a point?

DR. CROSSON: Yeah, I think Bruce put up his hand first.

DR. SAFRAN: I was just going to make one clarifying point, because I want folks to understand that with concurrent or retrospective, however we're going to label it, a provider who's in an ACO still on January 1st gets a list of the patients who are attributed to them, and then they get periodic -- in our case it was monthly; it sounds like CMS has been doing quarterly -- updates to whether that is shifting over time. So --

DR. CROSSON: But that's different from the payment mechanism.

DR. SAFRAN: Yes, it is. I just am saying that because you said, you know, in three months, and I wanted folks to understand like on January 1st --

DR. CROSSON: All right. I'm sorry.

DR. SAFRAN: On January 1st, you know who your

patients are, and then you periodically get updates if that's evolving.

DR. CROSSON: That's helpful. But the payment mechanism as opposed to the clarity around who you're responsible for is the different element. Right? Then help me because maybe I'm confusing myself as well as the Commission. What's the essential difference between the two approaches in your mind?

DR. SAFRAN: I don't know how the payment works in prospective, so I can only comment on the concurrent, which is that you're paid over the course of the year for the population that is attributed to you, and then at the end of the year, there's a settle-up on, you know, any difference between who you've been paid for and who actually manifests as your population.

DR. CROSSON: Okay. So we're throwing a curve ball in here.

PARTICIPANT: Can I ask Dana a question about that?

DR. CROSSON: Can anybody help? Kathy?

MS. BUTO: So if the primary care physician is in one ACO and the beneficiary in your example has a condition

that's best treated at another -- a hospital that's associated with another ACO, you know, medical expenses are in both ACOs, if you will. I liked your example of the expensive care is still accountable under the second ACO. It doesn't disappear and the first ACO has very little leverage. But how are the costs attributed to the two ACOs? Is it where the preponderance --

DR. SAFRAN: Right.

MS. BUTO: -- of cost is? Is that ACO responsible? Or how does that work?

DR. SAFRAN: We may be getting out of the level detail that I know, that I can remember clearly enough, and I should, you know, connect staff with the appropriate colleagues of mine from Blue Cross to describe this. My recollection of it is that the costs get assigned at the end of the year and, you know, settled up as to where care actually manifests. But, of course, over the -- like so the hospital that provided the care will get paid their fee-for-service rates, but who's accountable for that expense is the piece that I'm saying is moving. I hope that clarifies things.

DR. CROSSON: So Larry and then Amol.

DR. CASALINO: I thought I understood all this very well, and I thought that the staff did a great job of explaining things. But it seems pretty clear right now that -- it seems pretty clear to me that I don't have the understanding that I thought I had of either the AQC or what the Medicare ACO programs do. And I'm pretty sure that's true of some other Commissioners as well, which is a surprise.

I don't think we're going to resolve it with this kind of discussion now, so I would ask for the next time -- I thought the staff did a great job, but it seems like we really need a kind of step-by-step-by step, and maybe for the AQC as well, if Dana's willing to provide that, step by step how the retrospective versus concurrent, if they're different, versus prospective attribution works not only in the current year, but then what happens -- if you start with year one, you know, what happens? You know, how does the benchmark get set? And how does that carry forward into future years? That's another kind of complication of this. I think we need it just kind of spoon-fed to us so we can have, frankly, a better informed discussion.

DR. CROSSON: Amol and then Bruce.

DR. NAVATHE: So I agree. I was going to try to answer your questions, Jay, but I think actually I'll just hold off for the sake of time.

One point I will make that I think is important for us to recognize is when -- you know, in a retrospective model vis-a-vis a prospective model, when you have somebody, a beneficiary, on your list initially to start out the year, but at the end of the year they end up not on your list, or vice versa -- right? There could be somebody who wasn't on your list who ends up on your list. The disproportionate reason that happens is because of spending and utilization. And so it's particularly damaging in some sense to an ACO when those shifts happen. The majority of patients who stay continuously attributed, there's going to be a big chunk of them that don't have a lot of utilization. The people who shift around, they have a lot of utilization. That's why it's particularly challenging, and at least from sort of a behavioral and management perspective can be particularly challenging.

So I think it's worth just noting that, yes, you can get most of it right on day 1 and day 30 and day 90, but the shifts that happen are happening for particularly

important people that tend to have an outsized impact on your performance in the program.

DR. CROSSON: Right, okay. I mean, I think what -- and maybe that's to repeat again, but I think what shifted for me was the notion that one of the primary reasons that I heard articulated for prospective assignment was the rational argument that, of course, you want to know who it is you're accountable for. And I think that argument -- for me, that argument was weakened as a consequence of this discussion, which left -- now I'm talking just for myself, but I'm also trying to get a sense of where we are as a Commission, and I think where we are is we need more information about this. We need to understand the mechanics here and the trade-offs in more detail before we come to a conclusion.

DR. PAUL GINSBURG: Yeah, I was just going to say I think, you know, that in your previous model, knowing those who you're responsible for, it's going to make the most difference for the low utilizers. And I think what Amol is talking about is the critical thing in ACOs' success or failure, it's going to be how they deal and how the high utilizers are attributed. So in a sense, that

advantage of prospectivity may not be what it's cracked up to be. But, you know, I think what I'm concerned about is just differences between the data that determines the benchmark and the data that -- you know, the time period for the benchmark and the time period for the shared savings.

DR. CROSSON: So just to be clear, what I was hearing you say, if I'm right, was an argument for retrospective assignment?

DR. PAUL GINSBURG: No.

DR. NAVATHE: No. I was saying that the certainty of knowing that you're managing a certain population has benefits, because when you start out -- they start out on your list for the year, the benchmark is set based on that population. At the end of the year, the reconciliation's based on that same population.

DR. CROSSON: Right.

DR. NAVATHE: So you know with certainty, effectively. In the retrospective model, while it does have advantages -- there's definitely trade-offs, but while it does have advantages that you're attributed based on who actually saw you, at the end of the year the benchmark is

effectively set for the population who you saw during the year. Right? That's the advantage. The downside is that there can be shifts compared to who you thought you were taking care of, and those shifts happen disproportionately for people who spend a lot. And so when you reconcile your list of here's who I thought I was for, who I was responsible for, and who did CMS reconcile me against as being responsible for, there's going to be a margin -- there's going to be a group of patients who you didn't know and a group of patients who you thought you were responsible for who are no longer on your list. That group of patients, they have a lot of spending. And that's why it's particularly challenging for ACOs.

DR. CROSSON: Okay. Bruce and then Jonathan. Then I think we're going to have to stop.

MR. PYENSON: Yeah, just I agree with Amol on a practical issue. Currently, ACOs get quarterly data feeds with a lag. So the complexity of the lags on that also add a lot. You know, CMS claims after three months to be 95 percent complete or more. But if you're getting quarterly feeds, there's an awful lot of lag by the time you get those, probably six weeks after the quarter completes, so

it's not a concurrent image.

There are, of course, alternatives. I think one of the Blues does monthly attribution, which sounds very much like fee-for-service. But I just wanted to add --

DR. CROSSON: But what you're describing with respect to the lag and the accuracy of that could be very different from what Dana experienced in Massachusetts in a much smaller environment.

MR. PYENSON: I suspect CMS was faster than Blue Cross Blue Shield of Massachusetts on processing.

DR. CROSSON: Okay.

MR. PYENSON: But I could be wrong.

DR. CROSSON: Well, I think we're going to have to let you guys work that out after the meeting.

[Laughter.]

DR. CROSSON: Jonathan.

DR. JAFFERY: Now I'll be very brief, and I know we're a little over time. To me, putting the conversation together, I think we can come up with some things where there are trade-offs and pros and cons to each of the retrospective, but I like calling it "concurrent," versus prospective. And my understanding of the policy

recommendation here is not so much whether we're deciding which is better for the ACO in some ways because at this point people can choose in some of these models, and what you're trying to say is let's make these all mandatory prospective, but, rather, is there gaming that occurs in one versus the other?

And so I think that's a little bit different than saying, well, what are the trade-offs? Because if there aren't -- if we're not concerned -- if the gaming question is off the table and there are trade-offs, then, you know, we should be able to leave it up to ACOs to decide which one they -- so that to me would be the question to resolve.

DR. CROSSON: And there could be ways to mitigate the potential for gaming. Okay. So, again, in summary, thanks for the work, emphasizing the importance of this and our future work. We're going to head towards NPI, come back with a recommendation there, and we need to do more work on the prospective versus retrospective, as well as alternatives, I think, you know, clarifying what's the problem we're trying to solve and whether there are alternatives that could be added to, for example, the retrospective assignment.

Okay. David, Luis, Jeff, thanks very much.

We now have time for a public discussion period. If we have anyone in our audience who wishes to make a public comment, please come up to the microphone. I'll make a comment in a minute. This is an opportunity to address the Commission on issues that we have discussed this morning. We'd ask you to identify yourself by name and any organization that you are affiliated with, and please keep your comments to two minutes. When this light comes back on, that two minutes will have expired.

MS. TESTONI: Good morning. My name is Maureen Testoni. I am president and CEO of 340B Health. We're a trade association that represents over 1,400 hospitals that participate in the 340B program.

340B is vital for the safety net providers and for the patients that they serve, and I wanted to comment that we appreciate MedPAC's very thoughtful analysis that was presented today on 340B and on Medicare spending and beneficiary costs. We're really pleased to see how MedPAC really engaged and did a rigorous analysis of this issue. As was noted, this was the first of its kind that I've seen, and we spend a lot of time looking for that kind of

thing. And it was just a much more rigorous analysis than we've seen in the past by GAO or others.

We note that some of the findings about there being some differences for two of the five cancers that were looked at, and much of the differences can be explained by beneficiary characteristics and facility characteristics, are similar to research that 340B Health has done as well, even though we use completely different approaches in terms of looking at this issue.

So I wanted to thank the Commission for doing that, and I also wanted to thank the staff. We've been working with MedPAC staff for a number of years, and we really appreciate how open they always are to meeting with all the stakeholders, looking at all of our research and data, and being open to different points of view.

Thank you.

DR. CROSSON: Thank you.

MR. ZAMAN: Good morning. My name is Shahid Zaman, and I'm with America's Essential Hospitals. I wanted to provide the association's perspective on the 340B discussion as well, and I echo Maureen's comments as well. We really appreciate the thorough look at the link between

the 340B program and any potential behavior with regard to the use of Part B drugs.

So we represent 300 hospitals, nearly all of which are 340B hospitals. Essential hospitals disproportionately care for low-income patients, so about 75 percent of our patients are on Medicare or Medicaid or uninsured, and they face many social risk factors such as homelessness or food insecurity.

This commitment to mission means that the average essential hospital provides about $70 million in uncompensated care costs, about 10 times the national average, and operates on narrow all-payer margins. So the average essential hospital operates on about a 1 to 1.5 percent margin.

Given these challenges, 340B is a lifeline for our hospitals and their patients and helps our hospitals provide many comprehensive services to their patients.

So, again, we appreciate the research and would echo the point about 340B not being the underlying driver of high drug prices. Instead, it has been for our hospitals a key buffer for hospitals and patients from runaway prices. 340B discounts make up less than 2 percent

of annual drug sales, so it's inconceivable that such a small program could drive up increases.

The one undisputed factor driving up spending on drugs in both Medicare and in the larger health care system is rising list prices, which are set by manufacturers and not by hospitals.

As was alluded to in the discussion, 340B hospitals, there are distinctions in the characteristics of 340B hospitals versus non-340B hospitals, and the Commission did allude to this in terms of patient characteristics and being academic medical centers that are important to take into account.

And just one quick point on the question that was asked about the 340B litigation. We are a party to that litigation, and I think a question was asked about whether it was about the -- or the legal issue was the redistribution or just whether CMS had the authority to make the cut. So the issue that the district court ruled on in favor of us was simply on whether CMS had authority to reduce payments for 340B hospitals.

Thank you.

DR. CROSSON: Seeing no further discussants, we

are adjourned until the March meeting. Thanks very much.

[Whereupon, at 11:44 a.m., the meeting was adjourned.]