MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Thursday, March 5, 2020
9:33 a.m.

COMMISSIONERS PRESENT:

FRANCIS J. CROSSON, MD, Chair
PAUL GINSBURG, PhD, Vice Chair
KATHY BUTO, MPA
BRIAN DeBUSK, PhD
MARJORIE E. GINSBURG, BSN, MPH
DAVID GRABOWSKI, PhD
JONATHAN B. JAFFERY, MD, MS, MMM
AMOL S. NAVATHE, MD, PhD
BRUCE PYENSON, FSA, MAAA
JAEWON RYU, MD, JD
DANA GELB SAFRAN, ScD
WARNER THOMAS, MBA
SUSAN THOMPSON, MS, RN
PAT WANG, JD

B&B Reporters
29999 W. Barrier Reef Blvd.
Lewes, DE 19958
302-947-9541

AGENDA PAGE

P R O C E E D I N G S

[9:33 a.m.]

DR. CROSSON: Okay. I think we should get started now.

Let me welcome our guests to the March MedPAC meeting. This morning we're going to be taking up two issues which are part of our continuing work on accountable care organizations. The first one will be addressing MSSP vulnerabilities. We've got David, Luis, and Jeff here. Who's going to begin? David.

* MR. GLASS: Yes, good morning. Today we are going to talk about addressing vulnerabilities in the Medicare Shared Savings Program.

I will provide a brief background on ACOs. Then Luis will present our concerns with patient selection and one method of addressing some of those concerns that is using NPI-level benchmarks. We will then present the Chairman's draft recommendation on requiring NPI-level benchmarks, which will lead to your discussion.

During the discussions in January, you asked for more information on several topics. You expressed interest in knowing more about the mechanics of assignment when done

prospectively compared with retrospectively and on the results of the alternative quality contract. So we have provided that information in your reading material and can take any questions later during the discussion. Larry also asked about the size of shared savings payments per primary care physician, and we will present our findings on that. The recommendation and other topics will be included in a June chapter.

So, for review, 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 spending above the benchmark 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 spending above the benchmark.

Today we are going to concentrate on the Medicare Shared Savings Program 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 2020, there are 517 ACOs in MSSP, one fewer than in July 2019, but the number of beneficiaries is at a high of 11.2 million

New rules for the MSSP went into effect in 2019.

There are two new tracks, basic and enhanced, and they replaced the old tracks. The idea is to move ACOs faster and with more certainty to two-sided risk.

We're not yet there. In 2020 two-thirds of the MSSP ACOs are still in one-sided risk models.

MSSP benchmarks are a blend of spending for beneficiaries who would have been assigned to the ACO in the baseline years -- that is, the three years prior to an ACO's agreement period -- and fee-for-service spending in the ACO's region, which includes spending on beneficiaries in ACOs.

To understand if an ACO model as a whole is saving money for Medicare, a counterfactual is necessary; that is, what spending would have been in the absence of the ACO model.

Over all ACO models -- PGP, Pioneer, MSSP, and NextGen -- studies relative to a comparison group of

beneficiaries not assigned to an ACO estimate 1 to 2 percent savings, or about 1 percent after shared savings payments. Results depend on the program and the evaluation.

Relative to a counterfactual, for the MSSP, we found slower spending growth for beneficiaries assigned to an ACO in 2013, by about 1 or 2 percent through 2016. That estimate does not include any shared savings payments, which would have decreased estimated savings.

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 that a health event such as a hospitalization could lead to a switch in a beneficiary's ACO assignment and correspond with higher spending.

The point is savings are relatively small but still more than most care coordination models, and those savings need to be protected. If shared savings payments are unwarranted, they could put Medicare savings at risk and shift the MSSP from small savings to program losses.

Luis will now explain our concerns with patient selection because it has the potential to create

unwarranted shared savings and put program savings at risk in the future.

MR. SERNA: The modest savings achieved in MSSP thus far could be vulnerable if ACOs can engage in patient selection that is not reflected in their benchmarks and leads to unwarranted shared savings payments. This could result from having low-cost patients enter the ACO without changing the benchmark or having high-cost patients exit the ACO without changing the benchmark. We have not seen evidence of pervasive selection thus far, but we are concerned about the incentives as ACO experience matures.

Patient selection in MSSP can lead to unwarranted shared savings payments.

Selection is problematic because it can inaccurately improve an ACO's performance year spending relative to its baseline years.

Selection can occur by adding clinicians that disproportionately have low-cost patients or by removing clinicians that disproportionately have high-cost patients.

Selection can also occur via beneficiary assignment to ACO clinicians by keeping low-cost patients and losing high-cost patients.

As previously stated, we do not believe selection in MSSP has been occurring on a widespread basis, but under current rules, Medicare is vulnerable to such manipulation.

We first consider the selection of low-cost beneficiaries in ACOs via annual wellness visits, or AWVs.

In our June 2019 report, we found that ACOs had higher rates of wellness visits in 2016. In addition, ACOs were more likely to perform the visits at the end of the year.

Patients who received wellness visits toward the end of the year had disproportionately lower spending than patients who received the visits toward the beginning of the year.

Building on that work, we examined beneficiaries who were continuously assigned to the same ACO from 2014 to 2016. Beneficiaries who received an initial wellness visit were relatively healthier before they had received the visit.

Cumulatively, this evidence suggests that AWVs could help retain low-cost patients in MSSP ACOs -- beyond what was expected in ACOs' benchmarks

While the selection effects of wellness visits

has the potential to be offset by lower spending growth and improved care, the evidence to date suggests this has not yet occurred.

Among beneficiaries continuously assigned to an ACO, we found that having an initial wellness visit in 2015 was not associated with slower spending growth through 2016. In fact, average spending growth during ACO assignment was actually $174 higher for beneficiaries that received the wellness visit in 2015. Wellness visits were not associated with lower spending growth during ACO assignment even when examining different lengths of time before and after the visit or restricting the analysis to physician-only ACOs.

In addition, researchers at Harvard University found that wellness visits had no overall effect on Medicare spending, screening rates, emergency departments visits, or hospitalizations.

Furthermore, beneficiaries in MedPAC focus groups over the last few years have generally reported that wellness visits were not useful for their own care needs.

Thus far, the evidence we have suggests that wellness visits have not demonstrated Medicare savings or

care improvement thus far, increasing the likelihood that use of AWVs in MSSP has had a greater effect on patient selection than in generating savings for the program.

In our January meeting, the question arose of whether clinicians in an ACO had sufficient monetary incentive to take any actions to select against high-cost beneficiaries.

We found that in 2017, 50 ACOs received shared savings of over $50,000 per primary care physician in the ACO, increasing the incentives for patient selection among these ACOs.

Comparing beneficiaries that exited MSSP ACOs in 2017, beneficiaries who exited MSSP ACOs with the highest shared savings per PCP had unusually high relative spending.

Overall, the correlation between shared savings and favorable patient selection is problematic, even if the selection is not intentional.

In the next section, we will discuss selection via the removal and addition of clinicians.

We provide one way of addressing the vulnerabilities of patient selection -- the use of NPI-

based benchmarks. I will go over how patient selection may be exacerbated through an ACO's Taxpayer Identification Number -- TIN -- to create benchmarks. It's important to understand that this discussion strictly addresses how the claims of ACO clinicians are used for beneficiary assignment to compute benchmarks and performance year spending.

Before discussing our concerns with TIN-level assignment, it's important to understand how ACOs are defined. First, let's review some terminology for identifying providers.

Each clinician has a unique National Provider Identifier, or NPI. An NPI can bill under one or more 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 the TINs under which their claims are billed. However, TINs were not designed for that purpose.

A concern of inaccurate benchmarks arises when a

clinician shifts the TIN she bills under or 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 year spending. Assignment is obtained by having the plurality of primary care visits to the ACO's TINs.

Benchmarks are the spending for beneficiaries who would have been assigned to the ACO's current list of TINs in the base years.

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 NPIs billing under the TINs.

What this means is changes in how NPIs bill through TINs are not reflected in the benchmark

calculation.

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. We have seen anomalies where this has occurred. For example, one ACO with high shared savings that we discussed in your mailing materials reduced its primary care physicians by 42 percent the year its benchmarks were rebased. The drop in ACO participants coincided with a drop in average risk scores by 19 percent. However, the benchmarks of the ACO did not decline. The ACOs collected over $35 million in shared savings over the next three years and dropped out of MSSP when its benchmarks would have been rebased again.

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. This mismatch between the benchmark and performance year clinicians raises potential concerns about the accuracy of baseline spending used for benchmarks.

Rather than using TIN-level benchmarks to identify ACO clinicians, the Next Generation ACO demonstration uses combinations of TIN and NPI.

Unlike TIN-level benchmarks, benchmark changes do appropriately occur when clinicians are removed from TINs. However, identifying ACO clinicians through TIN and NPI combinations have some concerns. Benchmarks do not change when NPIs outside the ACO are added to TINs.

Additionally, benchmarks increase when NPIs with low-cost patients are removed from benchmarks but remain in the ACO as a new TIN and NPI combination. Because they are a new TIN and NPI combination, they cannot be in the

benchmark.

Moreover, benchmarks do not change when NPIs selectively bill expensive patients using a TIN outside the ACO. One ACO interviewed in a 2018 RAND study created a separate TIN for clinicians that disproportionately saw high-cost patients.

As we discussed in January, rather than basing historical benchmarks on TIN or a combination of TIN and NPI, NPI-based 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. If an NPI bills under a TIN participating in an ACO, CMS could use all primary care visits from that NPI, regardless of what TIN they are billed under, to assign beneficiaries to that ACO.

Using NPIs to compute benchmarks and performance year spending would reduce selection from removing high-cost clinicians from ACO TINs, adding low-cost clinicians to ACO TINs, and billing high-cost beneficiaries outside of ACO TINs.

It is important to understand that redefining the

ACOs on the basis of clinicians' NPIs would not require any changes to the structure of the ACO, its clinicians, or the specialists clinicians recommend 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. Currently, both the ACO and the ACO's beneficiary assignment are defined on the basis of TINs.

NPI A historically only billed under TIN 1. NPI B historically only billed under TIN 2. As long as NPI A and NPI B continue to bill under one of the ACO's TINs in the performance year, no mismatch of clinicians' claims occurs between the benchmark and performance year.

If beneficiary assignment for MSSP ACOs were redefined on the basis of all the ACOs' NPIs, the ACO and its affiliated clinicians would have the exact same structure and billing arrangements.

In this example, NPI B subsequently begins billing under TIN 3, which is outside the ACO, creating a mismatch in clinicians' claims between the benchmark and performance year.

Under the NPI option, the only difference is that rather than the ACO's assignment being computed based on a

collection of TINs, the ACO's assignment is now computed based on a collection of clinician NPIs.

All claims billed by the ACO's clinicians are now used for both benchmark and performance year assignment.

In summary, ACO savings have been modest.

Unwarranted shared savings payments to ACOs could result in costs that exceed MSSP savings.

To avoid putting MSSP at risk of being a net cost to Medicare, CMS needs to reduce vulnerabilities that can result from patient selection, even if the selection is not intentional.

To help limit vulnerabilities, both MSSP baseline and performance year spending could be computed using the performance year NPIs rather than TINs.

The integrity of using historical benchmarks requires reliably matching the ACO's performance year clinicians with the ACO's historical primary care visits. Calculating benchmarks based on a collection of NPIs is the only method available for ensuring that performance year clinicians are captured in benchmarks. Allowing ACOs to benefit from changing NPI participation in TINs creates the potential for patient selection and unwarranted shared

savings.

That brings us to the Chairman's draft recommendation, which reads: The Secretary should use the same set of National Provider Identifiers to compute both performance year and baseline spending for accountable care organizations in the Medicare Shared Savings Program.

This recommendation may result in a small reduction in Medicare spending from lower shared savings payments relative to current policy, but the magnitude of spending reduction is unclear. Specifically, the degree of unwarranted shared savings that would be averted may be small in early years but could be somewhat larger in future years as MSSP participation matures.

The recommendation would not have any effect on beneficiary access to care.

The impact on providers would likely be small; some providers may receive smaller shared savings.

That brings us to our questions for your discussion.

Are there any clarifying questions about the material informing the draft recommendation?

Are there questions about the information on

assignment to ACOs included in your mailing material?

Are there other policy ideas that the Commission has for future analyses?

We anticipate the recommendation would be included in a chapter in the June report.

We look forward to the discussion on these points, and now I turn it back to Jay.

DR. PAUL GINSBURG: I want to open it for clarifying question now. Jonathan and then Brian and Dana.

DR. JAFFERY: Yeah. Thanks. Thanks for a great chapter. I'm excited about this discussion.

I have a few questions. The first one has to do with some of the stuff that was in the reading about the prospective versus retrospective assignment. I'm curious how that impacts waiver use, and the reason I bring that up is thinking about the SNF three-day waiver. We have prospective assignment in Next Gen, and there's sometimes issues about who is on the list. So then we're wary or unable to utilize the waiver if it turns out that somebody is not going to be on the list finally and worried that the beneficiary might end up with a big bill. Can you comment on that at all to start with? How might that work? Have

you thought about how waivers might be impacted?

MR. GLASS: Well, in the past, our position has always been that prospective makes it a lot easier for granting waivers if you know whether the person showing up in the hospital is an ACO-assigned beneficiary or not.

DR. JAFFERY: So that's sort of my question.

MR. GLASS: Right.

DR. JAFFERY: In retrospective, has that been an issue?

MR. GLASS: I'm not sure how that works.

MR. SERNA: It hasn't been an issue thus far because you're required to have two-sided risk in order to be eligible for the waiver, and under previous rules, you had to be under prospective assignment if you had two-sided risk, so tracked through ACOs when prospective assignment. Now that things are changing, that's changed a little bit.

DR. JAFFERY: Okay. Shifting gears to talk about some questions about the annual wellness visits. Two questions on those. One, do you know how many of the AWVs are associated with an additional billable visit and, thus, a charge to the beneficiaries?

MR. SERNA: Yeah. So it's roughly between 40 and

45 percent.

DR. JAFFERY: Okay. And then have you looked at and noticed or do you know about any association with the annual wellness visits and specialty referral patterns?

MR. SERNA: We haven't looked at that.

DR. JAFFERY: Okay. Finally, shifting to the --

DR. NAVATHE: Jonathan, can you just clarify why you're asking that question?

DR. JAFFERY: Yeah. So one of the things I'm thinking about that could be happening is if you bring somebody in, some potential issue is identified. They're referred to a specialist, and one of the phenomena that happens when you go down to see a specialist potentially downstream, utilization and testing, and as a specialist, there's a sense sometimes that somebody is being sent to me for something, and there actually tends to be sometimes -- I think people feel pressure, in one sense, to do testing maybe that they wouldn't do if it's a borderline referral, or just bias towards your practice pattern, which is to test for things in your area that maybe aren't totally necessary, but you get put in a different category once you're actually seeing the specialist, and so thinking

about how that would create some downstream utilization that maybe is avoidable and why you might see people, who then get the annual wellness visit, look less healthy in subsequent years. But you're not seeing that pattern necessarily.

So thinking about the PCP incentives, two questions about that. First, to pick those PCPs that were in ACOs, they had greater than 50,000 savings. How did you end up defining PCP?

The reason I'm asking that is some of the larger group practices, like our own, try to include all of their practitioners and could include a fair number of, for example, pediatricians. Clearly don't have a lot of ACO beneficiaries attributed through them or take care of them, but it might change the number of PCPs.

MR. GLASS: CMS puts out a file, with the ACO number and the number of PCPs in it. We took the number of PCPs they had in the file.

DR. JAFFERY: Okay. Interesting.

MR. GLASS: We didn't go into great detail on how they came up with that number.

DR. JAFFERY: All right. Finally, there was

something in the reading that talked about not knowing how ACOs distributed shared savings, but that is publicly available. Every ACO has to publish a website that actually describes how they do that. I don't know if you start to look at that maybe for this subset of ACOs to see if they distributed a lot to their providers or not.

MR. GLASS: We looked at a couple on the websites of several of the ACOs. The one I remember is they gave all the money to the -- they took some off the top for ACO administration and data, that sort of stuff, and then what was left, they gave to the PCPs. But we did not do an exhaustive check on how they all did it.

DR. JAFFERY: Understanding that maybe the accuracy of those might be limited, it might be worth it.

I did a little bit of a random sampling too, and it does look like it's all over the board. Some give it all back. Some don't give any and talk about it all being back to either administrative costs or reinvestment. It might be worth looking at.

Thank you.

DR. CROSSON: Brian?

DR. DeBUSK: First of all, congratulations on a

great chapter. It was a really, really good read.

I'm going to keep all this to Round 1. I have my own separate Round 2 thought.

But a quick question -- or two questions. First of all, you built the argument around the NPI-10 vulnerability. I thought you really built a great case. You built an argument, and it led to this recommendation.

On the average wellness visits, I thought you built an equally sound argument. I felt like I was being led up to a prospective attribution recommendation too, and I even re-read the chapter because I thought maybe I missed a paragraph or two.

But for my first question, did the idea of a prospective assignment recommendation die?

And now for something completely different, Appendix A -- and then I'll be done, I promise. Appendix A, I have my own thoughts on it, but I want your thoughts on -- when I look at the most successful ACOs here and I look at this list in terms of payments for PCP and I look at the top ten, eight of the top ten are in Florida. What's going on there?

[Laughter.]

DR. DeBUSK: I have my own thoughts, but I want to hear what you think.

DR. MATHEWS: Well, David, let me take the first question.

Brian, recall that at our January meeting, we did present two policy options for the Commission's consideration, prospective versus retrospective as well as TIN/NPI. And the Commission had expressed the need for additional information about how prospective and retrospective worked, and my takeaway was that the Commission collectively was not yet ready to advance to a recommendation.

In contrast, there was a strong consensus on TIN versus NPI, and that's why we, in coordination with Jay, have presented that here. We could come back to prospective, retrospective at a future point if the Commission is now settled.

DR. DeBUSK: Could that be a Round 2 discussion today, or is that out of this analytic cycle?

DR. CROSSON: Yeah. I mean, I think you can bring up anything you want.

Just as Jim said, as I remember the January

discussion, towards the end of discussion, we got into some complexity about what prospective and retrospective really meant, and in the field, there were examples of - and I think, Dana, you brought this up. There were examples that kind of were in the middle of that, and I think at that point, many of us had the sense that we weren't ready to kind of move right on and all get behind prospective, although I have to say I think there was a plurality in favor of that.

But, as Jim said, I think to do the topic justice and to proceed in the way that we normally do so that we have everything on the table and everybody understands everything, we need to do some more work.

So I think if you have points of view about that, it's perfectly fine to bring those up, but I don't think we're ready to nor will we be ready in April to bring it forward as a recommendation.

DR. DeBUSK: Florida.

MR. GLASS: Florida.

So, in past work, we've shown that there's a good correlation, I guess you'd say, between the service use in an area where service use is defined as kind of

standardized spending, and the success of ACOs relative to their benchmarks. So it's not too shocking to see that, and a lot of these seem to be concentrated in areas that have traditionally high service use.

DR. DeBUSK: So Florida is the only state with high benchmarks?

MR. GLASS: It's not a question of the high benchmarks.

DR. DeBUSK: It's 80 percent.

MR. GLASS: It's a question of service use.

The distinction is benchmarks include the pricing effects. San Francisco can have a high benchmark, but it's a very expensive area. The service use actually is fairly low relative to other parts of the country, but if you look at service use, then Florida and certain parts of Texas are really quite high. Louisiana could be quite high. So this isn't too shocking to see this.

DR. CROSSON: Okay. Dana?

DR. SAFRAN: Thanks.

A few questions. I'll start with the second part of the chapter where you're talking about the TINs and NPIs. The first question related to that, can you explain

what would happen when somebody, a provider, clinician actually changes their affiliation from one ACO to another? That happened frequently in my commercial world. People would get recruited away from one system to another. So how does that work in this scenario?

MR. SERNA: So if they move into an ACO, their historical claims would be excluded, right, because they weren't part of any of the ACOs performing to your TINs.

If they move outside of the practice, which is not affiliated with the ACO, then they would no longer be in the ACO's performance here. So they would not be in the performance here or the benchmarks.

DR. SAFRAN: Right. So would that ACO's benchmark get reset?

MR. SERNA: So CMS annually recalculates benchmarks as is for the new sets of TINs. So it would get reset at the beginning of the next performance year.

MR. GLASS: Are you asking about under our proposal?

DR. SAFRAN: Yeah, under your proposal.

MR. SERNA: Yeah. It's under our proposal.

DR. STENSLAND: It would get reset.

DR. SAFRAN: For that performance year or in the future?

MR. SERNA: In the subsequent performance year. I mean, it's kind of impossible to make changes as they're happening, as is now.

DR. SAFRAN: Yeah.

MR. SERNA: Right.

DR. SAFRAN: So I guess I'm not entirely clear how it solves the problem that you're trying to solve. It just takes it down one unit of measurement, but you still do have the issue of providers, whether you're talking about a group of providers or an individual provider who during their course of a measurement year will change where they're practicing, and therefore, the entity has been baselined with them in and now is getting measured with them out.

MR. GLASS: You do it during the performance year. It would be in the next performance year.

DR. SAFRAN: People move in the middle of the year all the time.

MR. GLASS: Right. But, I mean, that's okay. So, yeah, you couldn't be able to catch that immediate

effect.

So the person moves in -- I don't know -- September or something, but at the beginning of the year, they were associated with that ACO. I think their claims would continue to be assigned to that ACO for that performance year, even if in November or December --

DR. SAFRAN: Okay, okay.

DR. NAVATHE: In other words, it's sort of like an intention-to-treat kind of design where if you start out, then regardless of whether you move or not, you get attributed back. So that's why it does solve that change problem, I think.

DR. SAFRAN: Okay, I got that.

One other question, and then I have a question about the annual wellness visit.

I did not see in the chapter a recommendation that NPI should only be aligned to one ACO. Is that part of the proposal?

MR. GLASS: Yeah. I think that would be part of the text around the recommendation. Yeah.

DR. SAFRAN: Okay, okay. Good. Glad to hear it.

And then annual wellness visit, I guess my

question there was I get the inference that you think there's some gaming going on with respect to annual wellness visits, but what's the evidence base for that as opposed to knowing that somebody's in your population? What I saw a lot in the commercial world was we've got these quality measures we're accountable for. The year is waning. We better get these people in and make sure that we take care of these things, which I think is part of the intent of the program.

So I'm trying to understand what's behind the concern about having people in late in the year and whether we have evidence that some of the good quality that we want to see happening in the preventive screenings and so forth, that the visit is being used for that purpose, not just for documenting that we want this low utilizer to stay attributed to us.

MR. GLASS: Well, the intention for doing the annual wellness visit at the end of the year may be all -- just as you said, you want to keep your quality measures up, and you want to keep people attributed or assigned to your ACO, which is fine. But we're just saying the effect of it could be what we're seeing, that it keeps low, lower

than average spenders.

DR. CROSSON: Sue?

MS. THOMPSON: Well, I'm going to continue on this conversation about this thought process around annual wellness visits because that was one of the basic foundational building blocks of the work in ACOs in terms of aligning the beneficiary to the primary care. There were a lot of good things about that work.

If, indeed, the beneficiary is low cost, it's contributing to little contribution to the benchmark, and so I'm having a hard time understanding entirely this fear of if they're high cost, they're going to be avoided, and if they're low cost, they're going to be wanted. If you take that to the extreme, I get it, but as in Florida, I think the fact they've been successful has something to do with they've had an opportunity to reduce costs.

The shared savings only happens if you beat the benchmark. So there's got to be something there to beat.

Where is the sweet spot in that thinking? Because in the real world, we need both. We need some low cost and some high cost, and to think the data is so real time that we can make those kinds of fine movements in who

we have in and who we have out is really quite fascinating.

[Laughter.]

MS. THOMPSON: So I'm interested to know which ACOs you talked with because the gaming at this time and where we have data and where analytics are. Did you visit with any ACOs that are doing that sort of work? Give me a little bit more, because in theory, I agree with the recommendation, but in practicality, I want to hear more about who you visited with.

MR. SERNA: So it's important to understand that we're looking at MSSP, and we're looking at primarily retrospective assignment. So they will receive claims fees quarterly based on a three-month claim lag. So by the fall, they will know the beneficiaries that have not come in. They will know their claims history.

That's not to say that anything nefarious is happening. We're not saying that the annual wellness visit should not occur. What we're saying is that, inevitably, regardless of intention, what happens is towards the end of the year, there is a disproportionate number of wellness visits that occur, especially among ACOs relative to non-ACOs. Those beneficiaries tend to be low cost, often

because they're coming in for the wellness visit, and they haven't had a visit throughout the year. So they're pretty low users.

MS. THOMPSON: And there might be other reasons why they're coming in towards the late summer, early fall. It's flu shot time. It's October. Women are doing their annual visits. I mean, there are other variables feeding that third-quarter, fourth-quarter scheduling of wellness visits.

Talk to me more about which ACOs you interviewed. I think I just want to understand that a little better.

DR. STENSLAND: Maybe one clarification. It's not just that there's more wellness visits in the third and fourth quarter. It's that there's more wellness visits for people assigned to MSSPs in the third and fourth quarter than there is for people not assigned to MSSPs in the third and fourth quarter. So there's something unique about the MSSPs.

There's also, when we talk about the retrospective, prospective, it's important, I think, as he said, we don't expect this opportunity to really be there that much if you're in a Next Gen ACO and it's prospective

assignment because you're assigned to the person before you know they're spending. In this place, you know part of their spending before.

Now, people did not come up to us and say, "Oh, we're doing annual wellness visits became we want to game the system." No one said that to us.

[Laughter.]

DR. STENSLAND: But people did say, "Part of our strategy is annual wellness visits," and I think they often think that that is a positive thing. That might be a profitable and a positive thing in their mind.

But what it does do is it does give them an unfair advantage if you're bringing people in at the end of the year who haven't had any spending through the first half of the year. Maybe you're saying because we got to make sure they get the quality metrics or we want to keep them in our network or whatever it is. You're getting a disproportionate share of low-cost people assigned to you as opposed to your comparison group, which isn't doing this.

So there is an advantage for the ACO. Whatever the motivation is in the end it's an advantage to have the

low-cost people assigned to you, compared -- a disproportionate share of the low-cost people assigned to you relative to the comparison group.

DR. NAVATHE: Out of curiosity -- sorry, Sue, to jump in --

MS. THOMPSON: That's fine.

DR. NAVATHE: -- have we looked at this under other models where there is prospective assignment, so even like a CPC or CPC+ or a Next Gen? Because if we are -- hypothetically speaking, if we are seeing it as part of this quality effect that Dana is citing, then it should be happening under those models where they have a quality effect, quality benefit to go after. And if it's purely from this strategy around the benchmarks then we shouldn't see it in those areas, where there is prospective.

DR. STENSLAND: We haven't done it. That's a good idea. But however it turned out, it wouldn't make the problem go away.

DR. CROSSON: But it would feed into perhaps a later discussion going back to the issue of prospective versus retrospective assignment.

All right. On this point.

DR. GRABOWSKI: Quickly on this point. A third explanation could just be some regression towards the mean, right, that you haven't had this done and you're expecting it to go up late in the year. So I was getting a strong regression to the mean sort of vibe when I was reading this, but maybe others --

DR. STENSLAND: I think if it was regression --

DR. GRABOWSKI: [Off microphone.]

[Laughter.]

DR. STENSLAND: -- I think if it was regression to the mean we would see it for these other people that aren't being assigned to the MSSP. You know, you have this group of people that weren't preliminarily assigned to the MSSP and you would see, oh, they didn't have a wellness visit before and now they're going to have it toward the end of the year, and then you have this group that is assigned, and the fact that there is the difference between the two groups that depends on whether you're assigned to the MSSP or not, preliminarily.

So, you know, there's a bunch of people in town. We give you a list of these people that are preliminarily assigned to you and you know their claims history. And

then there are other people where you don't know their claims history, and their physicians probably don't either, and those other people aren't coming in as often to get their wellness visits at the end of the year, where the people that you had this list of these are the people and this is how much they've spent so far, they are coming in more often at the end of the year. And I'm saying it's not necessarily -- certainly there is financial incentive there to do it, but that's not necessarily the reason why they're doing it.

DR. NAVATHE: So Jeff, I think my point is that there's the quality incentive piece and there's the cost of care incentive, and the way we're looking at it right now we kind of can't disentangle the two, because in the non-ACO group there's not really a strong quality incentive to go after. So that regression to the mean effect that David is after doesn't apply in that group. You would have to look at a group that has the quality piece but doesn't have the financial piece to be able to capture that regression to the mean.

DR. RYU: It seems like there's a selection issue too, though, because the folks who have not yet been seen

during the year, they are going to be healthier because they haven't utilized because they haven't had an issue. So the healthier folks are going to be loaded towards the back end of the year versus the folks who have already utilized, they have utilized because they've had an issue, and so they will naturally be in the front half of the year. I don't know if that's regression to the mean. I don't get those same vibes, but --

[Laughter.]

DR. CROSSON: Okay. Enough regressive thinking. Jaewon.

DR. RYU: So I had a question around just logistically whether it's feasible, and maybe it's not. It kind of gets back to Amol's point and Dana's point, the intention to treat kind of mentality. I don't know if this is doable, but could it be done that if you have movement out of the ACO assignment of a high-cost beneficiary they would come out of the performance year -- I get that -- but couldn't you just recast the benchmark and they would just come out of your benchmark at that point too, as opposed to worrying about, you know, is it the TIN?

I mean, I agree with those recommendations, but

if you just had a system where it's almost like looking at a concurrent group of beneficiaries to measure benchmark and performance, and if someone wasn't in the performance because of any kind of migration, either at the provider or of the beneficiary, you would just go back and take them out of your benchmark.

DR. STENSLAND: That would change the program quite a bit, because then we would essentially be looking at a constant cohort of people, saying what's the cost of change for the constant cohort of people, as opposed to this group of people that you -- opposed to a constant cohort of clinicians, maybe a constant cohort of patients. And it would be more -- it would be a bit change. It would be a big change in the program.

MR. GLASS: I think that's, in fact, how they originally had the Pioneer set up, and they ran into the problem of what happens when beneficiaries die, as one of the issues. There was this whole thing about a decedent adjustment. No one could understand it. And they eventually -- remember this, right? Yeah. And eventually they came around to trying to do it this way. So they tried it.

DR. CROSSON: I mean, it seemed to me it would be a big change, because wouldn't it also affect one of the primary purposes and motivations for all of this, which is to be -- you're assigned people who are unhealthy. Your motivation is to try to improve their health, keep them healthy during the year. If, in fact, we have a system where they just drop out and you don't worry about them anymore, then philosophically that's a very different program.

DR. RYU: Well, they wouldn't drop out unless you -- if they drop out, they would drop out of both performance and benchmark. If they're in they would be in performance and benchmark, just to keep consistent.

DR. CROSSON: I understand that, but I think -- I still think it fundamentally changes the nature of the motivation of the direction of the program, although it solves the technical -- potentially solves the technical problem.

MS. THOMPSON: On that point, a practical application of that concept, I mean, these beneficiaries are attributed to ACOs via the relationship they have with the primary care physician, and for a primary care

physician to say you're too high cost and we're moving you -- I mean, just in theory I get the concept mathematically, but in practicality, it's very --

DR. RYU: Well, if you're that primary care doc I think you'd keep them in your ACO for both, is what I'm saying. So if they're in your benchmark then they'd still stay in, but if there's any kind of this migration, like what we're talking about, that would pull them out of your performance year, what I'm suggesting is, you know, couldn't you just go back and pull them out of your benchmark? Maybe not. I don't know.

DR. CROSSON: Well, so we are getting -- we are kind of leaking into the prospective versus retrospective piece, because I was hearing echoes in this of what Dana was talking about two months ago in terms of quarterly changes in the retrospective assignment. And I think all of this is -- this is a valid discussion, but I think this is part of the next piece we need to do, which is to come back to this and make sure we understand all of the different options.

MS. BUTO: And just one other thought. As I was listening to you, Jaewon, it just struck me that it creates

both some incentives for physicians who are not so, you know, I don't know --

DR. CROSSON: Professional.

MS. BUTO: -- professional, shall we say. But the other thing is it kind of tilts the ACO program away from accountability of the physician to sort of whatever happens to the patient, and it takes some of that accountability out of it. I think, to me, that's a bigger issue is changing who is responsible.

DR. CROSSON: And no implications that's that is what you were suggesting, but I think it's a good example of why this issue of assignment is so complicated and we need to spend more time on it.

Pat, on this point, or do you just want to be on the list?

MS. WANG: I don't -- it's just -- I don't know if it's on this point or not.

[Laughter.]

MS. WANG: I'm on the list.

DR. CROSSON: Okay. Go ahead then.

MS. WANG: I was just curious, on the NPI/TIN issue, it does seem like the work has been very iterative,

you know, the original approach then evolved into TIN/NPI and now based on the analysis and learning we're migrating to NPI. And it seems very logical to me. Is there any practical implication to this? Is it more difficult to implement? Is there a reason that the program didn't start this way? I'm just curious whether --

MR. GLASS: Oddly enough, we looked back at the 2011 final rule on this, and CMS explained that, well, this is the way it was done in the PGP demonstration, using TINs, and that's what they have been doing, and they thought it would be more administratively simple to do it that way. And that was kind of what the argument was. Yeah, I think there was some administrative --

DR. CROSSON: Okay. I've got David, Bruce, Warner, and Amol, and then I think we need to proceed to the discussion. So David.

DR. GRABOWSKI: Sure. I was just going to ask, picking up on this TIN versus NPI, do we need to think at all about the interaction with the historical benchmark versus introducing a regional benchmark? You talked about that in your presentation. I'm trying to think about, as we go down to the clinician level, we have this regional

benchmark. Does that sort of present incentives that you wouldn't get if you just had an historical benchmark?

MR. GLASS: Yeah. The implications of the regional benchmark are manifold, and we haven't gotten into that yet. For example, risk adjustment becomes more important if you're comparing the spending on these beneficiaries to the spending of beneficiaries in the region. And we just haven't gone through all of that yet.

DR. GRABOWSKI: But does it increase the incentives around selection, if I go to the NPI level versus staying at the TIN level? Is there any sort of issue there? Have you thought through that?

MR. SERNA: No, because the set of TINs for the ACO stay exactly the same. So the incentives, once you throw in a regional blend, wouldn't really change. I mean, what the regional blend obviously -- as you know, the incentive is to have that low cost, as low cost as possible. That way you can do status quo and still receive shared savings payments. But that doesn't really change under this scenario.

DR. CROSSON: Okay. Bruce.

MR. PYENSON: Terrific report. I've got three

topics I want to ask about. A question about the annual wellness visit, a question about risk adjustment perhaps in future models, and a question about sources of physician profiling data.

I think on the first one, the annual wellness visit, you've presented evidence or information that the annual wellness visit is of questionable value to controlling cost, and there's been some studies about that. I think this Commission -- correct me if I'm wrong -- we recommended that the annual wellness visit not be used by MA plans for risk adjustment because -- do you remember why?

MR. SERNA: So the recommendation was to not use health risk assessments in the risk adjustment model. And so how risk assessments are to be part of the wellness, it's an essential part. And so de facto wellness visits wouldn't be used in the risk adjustment model.

DR. MATHEWS: Luis, if I could just clarify, wasn't it, more specifically, that diagnoses collected solely from health risk assessments should not be used?

MR. SERNA: That's correct.

DR. CROSSON: That did not appear somewhere else.

MR. SERNA: Correct.

MR. PYENSON: So we -- maybe some people thought that MA plans were gaming the system, but certainly ACO wouldn't, perhaps. But are we -- did we challenge whether Medicare should even pay for annual wellness visits? That wasn't part of that?

MR. SERNA: No.

MR. PYENSON: Okay. Thanks. A question on risk adjustment. I think some of the newer models, maybe some of the older models, had risk adjustment as part of the benchmark calculation. And I think that -- how does that raise the issue of selecting physicians or NPIs? Because the unadjusted benchmark is what it is in terms of its dollars, but it strikes me that a risk-adjusted benchmark, the issue is whether the patient's risk score is higher or lower than the claims. So could you comment on how that issue might complicate some of the -- affect some of the discussion we're having here?

DR. STENSLAND: Well, I think the idea is you would want patients that have low costs relative to their risk score, and if you look at all these -- all your physicians in your practice, and you hire somebody smart,

say a guy like Bruce, and you say, "Tell us what the relative spending is of our various physicians, relative to how much they're contributing to our benchmark," and you're going to be able to say these guys' patients are spending more than you would expect relative to what they're contributing to the benchmark.

So if you got rid of those people you would get rid of more spending than you would get rid of benchmark, if that makes sense.

MR. PYENSON: Which models would that apply to?

DR. STENSLAND: I think it would apply to all the models.

MR. PYENSON: Okay. So a third question is you're probably familiar with the profiling, the provider profiling data that Medicare has made available through the qualified entity program, and that's comprehensive and identifiable. Do you see that data as being used to manipulate ACO panels or TINs, or could it be used for that?

DR. STENSLAND: I don't think we have a good handle on that. You might have a better idea on that. But I think in terms of the ACO themselves, they necessarily

wouldn't need that if they know their individual physicians, how the patient was attributed to those physicians, and what the spend of those patients are for each one of them attributed to each physician.

MR. PYENSON: Perhaps I was thinking of more of the consolidation of inviting other organizations to come into the ACO. Okay. Thank you.

DR. CROSSON: Okay. Warner.

MR. THOMAS: Two quick questions. One, I guess, how difficult do you think this change is to implement, just from an administrative perspective? Is it feasible? Do we know?

MR. SERNA: So we are not looking at changing the structure of the participants or anything about the program. It's strictly a calculation of how the NPIs are applied to benchmarks. So I think from our standpoint it's just a couple of lines of programming.

MR. THOMAS: Okay. And then two, I guess, you know, as I sit here and listen to this we talk about assignment. I mean, did you vet or think about just going down the road of assignment of primary care physicians for traditional Medicare patients, which would essentially

probably solve a lot of these issues, generally, and may solve other issues as well.

MR. SERNA: You mean having every beneficiary designate a certain primary care physician?

MR. THOMAS: That's what I mean.

MR. SERNA: Yeah, that's certainly a feasible idea, and in direct contracting they seem to be thinking that's going to happen a lot more. I guess we'll see how that turns out. They've tried it in Next Gen and there just hasn't been much take-up, I don't think. And where the beneficiaries have designated the provider it's kind of the same one that was --

MR. PYENSON: It's voluntary, though.

MR. GLASS: Yeah, it's voluntary. Right.

MR. PYENSON: And hasn't had much take-up at all.

MR. GLASS: Right.

MR. THOMAS: And I just bring it up because, I mean, it's -- and me and Pat speak about this, but it's pretty typical in Medicare Advantage, especially if there is risk orientation. So I know there's been a little bit of aversion to that, but I think as we move down this road of more global payments, more alternative payment

mechanisms, this idea of having a beneficiary identify with a physician who is their personal physician, I think becomes more and more important, and it would solve some of these issues that we're talking about.

MR. GLASS: And I think what has been brought up in our focus groups there hasn't been unanimous delight on the part of the beneficiaries on the idea of doing it, but it's certainly an idea that could be looked at.

DR. CROSSON: Amol.

DR. NAVANTHE: So I have a very nuts and bolts question, and I apologize because I think it is captured somewhere in the appendices of prior work, but I couldn't quickly track it down. So when we're looking at the assignment algorithm, there's the third step, which is the specialists assignment piece, and it's defined, as I was reading it, by primary care services provided by specialists. And then it goes on to describe that by regulation there's a specific set of specialists, medical specialists basically who primarily account for that.

My question is about the actual notion of differentiating the types of care provided by other services, by other billing codes. Are there particular

codes that we're looking at here? Or how is that actually being differentiated? Because standard E&M type visits could be primary care, they could be non-primary care, and I'm curious how that's actually teased out and whether it's teased out or purely based on specialty.

MR. GLASS: Yeah, there's a list of which E&M codes qualify to be counted for assignment. I don't know the list off --

DR. NAVANTHE: Do we have a sense of how primary care they are? Again, standard E&M codes could certainly be used for a cardiologist in the context of a cardiology visit, which is not really primary care.

DR. STENSLAND: I think it's just -- it's probably better just to call it an E&M code as opposed to a primary care.

DR. NAVANTHE: That's what I was hypothesizing, and that actually, at least in the way -- this is not your literature, but the way that it's written, I think it's a little bit misleading then, because the specialists who are included, many of whom are relatively high-cost specialties, then they actually have -- could have a pretty meaningful impact on assignment as a sort of third catch

bucket. So I'm curious, the winding way I was trying to get, the point I was trying to get to is: Do we have a sense of how much of that attribution is being driven via that third bucket of specialists? And, in particular, when we start to look at the questions we've been asking around high-cost patients and/or high-cost physicians, how many of them end up interacting with that third specialist assignment part?

MR. SERNA: So it's 10 percent of beneficiaries that are assigned to ACOs are assigned through that third step, through the specialist --

DR. NAVANTHE: Do we have a sense of are they higher cost or are they lower cost? Do we have a sense of those patients as well as the specialists?

MR. SERNA: We didn't specifically look --

DR. NAVANTHE: NPIs.

MR. SERNA: -- at that, but it didn't seem like there was a specific pattern. Obviously, some of them tended to be low use and others didn't. But it kind of varied.

DR. STENSLAND: And the key point is that there's balance, because those -- they'll be in your benchmark, and

they'll be in your performance year. As long as whether you're high-cost or low-cost is consistent in your benchmark and your performance year, we're okay. As long as there's not some sort of a shifting. If the hypothesis was, oh, your hematologists have high-cost patients, what you wouldn't want to see then is you're in your benchmark year, and then by the time your performance year comes around -- they still treat all their same patients. They don't say to no to any patients. They just start billing under a different TIN, and then they're not in your performance year. That's what we would get around with this recommendation.

MR. GLASS: The intent on the specialty assignment part was -- I'm going back -- that there were people who just see their cardiologist; they don't see their primary care physician. They have to see their cardiologist a couple times a year, so that's the only person they see. And they didn't want to leave those people out, and part of that was because you wanted to increase the number of people assigned to the ACO. You know, you wanted to get to your 5,000 minimum.

DR. NAVANTHE: Right. I guess in some sense I

can see this be a supporting point to the NPI-based rather than TIN-based methodology perhaps, but the types of selection, I guess I was thinking about, you know, if you have patients who attributed by the specialist and you just exclude the specialist in the performance year as an NPI, then you would potentially avoid having those high-cost patients in your performance year. And I think the NPI, the way we're doing sort of intention to treat, NPI would address that problem. But I just didn't have a sense of how important magnitude-wise this population was in terms of interacting with the selection effects.

DR. CROSSON: Okay. Somewhat increasingly characteristically, we used up almost the entire part of our assigned time for the questions. What we do have is a recommendation, and so I would like to have a discussion period, but I would ask you, since we've had a lot of good discussion in the question period that goes beyond questions, I'd sort of like to hear discussions on the recommendation, particularly people who think that they cannot support the recommendation when it comes forward next month. Marge.

MS. MARJORIE GINSBURG: This doesn't really

address your question, but I'm going to ask it anyway.

[Laughter.]

MS. MARJORIE GINSBURG: I've been struggling with the title, "Addressing MSSP vulnerabilities," and I particularly feel the word "vulnerabilities" just doesn't capture it or it suggests something that's not -- so I just wanted to make a suggestion for a different title: "Improving MSSP accuracy." And part of it is I wonder how much thought we give to what we title our things so that sort of the psychology of people looking at this and accepting it, saying, "Oh, this looks good," focusing on the positive, improving something may be more appealing. So enough said on that.

My second comment was just a concern. We're already seeing a very small improvement of 1 to 2 percent, and so I worry a little tongue in cheek that if we actually get more accurate, we're going to see the savings disappear entirely. So that's all.

DR. CROSSON: So on your first comment, I think it's a good point, and I personally favor more positive, and I would ask maybe we could reconsider the title in the direction you're describing. But just in general, in terms

of ACOs or MA or any other area that we try to take on, we often will have two things going on at once: one which is, you know, focused on making sure that the Medicare program is not overpaying and other sets of activities -- and we're going to talk about them particularly next month, but we have talked about them before -- to try to improve the program, whether it's ACOs or MA, to make it more successful, to make it better for beneficiaries. You know, so we might very well in this particular situation have the result that you're looking for, but in some of the other activities that we're engaged in, we would hope it to go in the other direction.

Yes, Brian.

DR. DeBUSK: On Marge's point, you started it; I wasn't going to say anything. But I agree with your second point, the observation that you made.

First of all, I support the Chairman's draft recommendation. I think it's wonderful. I'd love to see prospective assignment revisited well because I think you made the case for both really well in the chapter. But here is -- and I've done something like this before. You know, you look at the MSSP Shared Savings Program, and you

guys check my math as we go. Medicare pays 91 cents on the dollar and still contributes 8 percent to the fixed cost of the hospital. I think that's what we're going to publish in March. It was 8 percent, I think at least was the number in the reading material. So if I can avoid an admission or an ED visit, I'm going to shed 83 percent of my variable cost, so I'm going to incur 17 percent of my fixed cost, regardless -- that's what fixed cost is. You're going to give me back 48 percent in shared savings, which is going to give me a 31 percent margin. So I'm going to go from minus 9 percent margins, which 91 cents on the dollar is, to 31 cents. You're going to swing my margin 40 points. And you've done a great job of documenting these vulnerabilities that are in the system. Right? The ability to manipulate TINs and to manipulate -- I'm sorry, inaccuracies, Marge, seriously sorry -- inaccuracies that are in the system.

When I look at other areas -- and this is a philosophical question for next month's discussion, too. When I look at other areas, like when I look at hospitals buying physician practices and turning them into provider-based departments, when I look at MA plans figuring out how

to cross-walk enrollees, when I look at even we're going to take up the TDAPA issue in dialysis centers, I mean, these guys are reacting in months, maybe even weeks, when there's an inaccuracy presented in the system. This program's out there for nine years that appears to create a 40 percent -- 40-point swing in margin in a 5 percent industry. I can't figure out why we aren't having public meetings on how we slow this thing down and how it's just, you know, exploding the payments that we're making. What's wrong? Is the math -- does it not add up?

DR. STENSLAND: Different story. You actually have to find some unnecessary service use and agree on what it is and reduce it. It seems to be a hard thing to do, whether it's an ACO, whether it's a bundle that Amol looks at, whether it's MA plans.

[Off microphone]: Unless you live in Florida.

DR. STENSLAND: If you live in Florida and you have some extra to cut, it's a little easier. And especially if you're an entrepreneurial person, you may have been entrepreneurial on the upside, and maybe you're entrepreneurial on the downside.

DR. DeBUSK: I would be curious, and this is a

comment, not a rhetorical question, but I kept it out of Round 1 because I'm behaving. It would be interesting for you guys to look at the successful ACOs that are in Florida and try to gauge those providers and look at their MA footprint, because I have a working theory or hypothesis that because you see progressive MA, at least in parts of Florida, and progressive MA at least -- I'm not saying exhaustively -- in parts of California, I think that what you may be measuring is some spillover from progressive MA translating into successful ACOs as well.

DR. CROSSON: Okay. David, Jonathan, and Jaewon.

DR. GRABOWSKI: So I'm a little bit more neutral on the Chairman's recommendation. I wouldn't say I'm against it, but I sort of go back to the comment that Dana made in the first round about it seems like we're just trading one level of problem for another. And, ultimately, we're worried about risk selection here, but I think we're just kind of changing the level. And, you know, I like Marge's word, "inaccuracies." I was going to use "mismatches," but we're really worried about these mismatches. And I feel like we're trading mismatches over time and clinicians in the same TIN for mismatches in TINs

for the same clinicians. And I don't know that we're actually solving the problem. The problem here is risk selection. I would like to see us invest in better risk adjustment. I know we're going to have a session later today on a different application of risk adjustment, but I would like to see us improve the risk adjustment in ACOs, and I don't know that this kind of movement across levels -- - once again, I'm not against it. I just don't know that it solves the problem that we're going after here. Thanks.

DR. CROSSON: Thank you, David. And I see that point. And I don't want to put words in the staff's mouth, but I do think that they have the sense that, while that may be true, using the TINs seems to be more likely, and there may be some evidence that that manipulation exists; whereas, manipulation on the other side could become manifest in the future.

Now I got lost. Jonathan, Jaewon, and then Bruce. And then I think we have to finish.

DR. JAFFERY: Great, thanks. So I am supportive of this change. I think in terms of the Chairman's recommendation, I would like to see some wording that references what you have in the reading about adjusting for

regional movement. You were clear about how you'd do that, but it doesn't come out right there. And I think the fact that, like you said, administratively it would probably be a pretty simple fix as a positive.

I guess I wanted to just talk about a couple other pieces that I heard as a thread that I feel pretty strongly about, and I think -- Marge, I'm glad you brought up this notion of talking about vulnerabilities, because I hadn't thought of phrasing it in a more positive way. I think that's a great idea. But as I was looking at the title, what jumped out at me is that there are a whole bunch of vulnerabilities that we're not addressing that I think are a little bit more existential to the program overall. We've seen really an amazing increase in the number of CMS ACOs MSSPs over the years until now. We've actually seen a drop. And so it feels -- and I think I've mentioned this in previous meetings. It's starting to feel a little less stable and a little more threatened as a program overall. We're talking about modest savings and small savings, and I guess I'm still not sure what we're comparing that to when we don't have other programs that have released any savings. And what is the number that's

going to not be modest or small? As somebody who's trying to run this program, how do I know when that's going to be successful? Is it 4 percent? Is it 5 percent? And I don't know that we have an empiric number, but I guess sometimes I look at the 1 or 2 percent and think this is actually a win that we haven't had other places.

I'm looking at things around the new programs, the direct contracting and pathways to success that are all pushing us to risk more quickly, and I wonder if that's not nuanced enough. And maybe there are some parts of the country where going to risk quickly is an early win and is important and maybe places where there's lower benchmarks where maybe -- I'm not suggesting that we create benchmarks that just make it so that low baseline places automatically get savings, because that would not be in keeping with the goals of the program or the opportunities, but maybe going to risk in two years if your benchmark is in the lowest quartile to start with, your baseline spending is not realistic. I think we've seen experience in our region, Dana has described it with her group in the commercial world, that maybe it takes a little bit longer.

And then I think to channel a couple things that

Bruce and Warner said, do we think about some bolder type of recommendations? The annual wellness visits, what purpose are they serving exactly? I don't think that there's at present a lot of gaming going on in terms of the way that we've talked about, but a lot of places do use them not only for quality measurement but risk adjustment and straightaway revenue enhancement. If beneficiaries are getting a bill that they weren't expecting 40 or 45 percent of the time, and their focus group suggests they're not seeing any benefit, what's the big purpose of having them in the first place? And do we think about even eliminating them and still allowing for no co-pays for preventive care or what-not?

And then, finally, this notion of choosing primary care docs, I think this is a really important one that Warner brought up again. And maybe it's beyond assigning primary care docs. Maybe we get to the point where we think about do beneficiaries actually -- are they required to actually choose whether or not they participate in an ACO? We make them choose between MA and traditional fee-for-service. Once they choose traditional fee-for-service, they may or may not end up in an ACO. I'm not

sure the fact -- how did you put it, David? There hasn't been unanimous delight. I'm not sure that we wait for unanimous delight for anything. That's going to be a pretty high bar. And if people were actually choosing, I think it would force us to create programs that make sense to people. We probably need to not call them "accountable care organizations" and, even better, not call them "direct contracting entities." But it would be a lot more transparent if people were actually choosing what they wanted to be part of.

So not for today. I think that's a future discussion as we think about how do we really get rid of some of these vulnerabilities or the program overall.

DR. CROSSON: A lot of good points there. Okay. Jaewon and then Bruce, and then we have to end.

DR. RYU: So three points. One, I like the recommendation, so I think that makes a lot of sense. It does seem to get closer to -- and I'll use David's term -- being able to better match. So I think it feels comfortable without undermining or potentially putting at risk the progress that's been made in the program.

The second point around selection and getting to

even better matching, it just feels like if you look at this as high level simply as possible, at least to me, it feels like the more you can have whoever's in the measurement here, the performance year, should also be in the benchmark year, and whoever is not in the measurement year should not be in the benchmark year. Just at a very high level, it seems like that's the goal, to get the best matching possible. I don't know what the levers are, and I'm sure in the subsequent discussion, you know, when we get to prospective versus retrospective, it feels like that is the guiding principle, which, you know, led me down the path of, well, is it just concurrent beneficiary pools that you need to look at to get that perfect match. But I get that that introduces a whole host of other issues. So I think that's the discussion to be had for the next phase.

Then the other is just a quick comment on Brian's margin analysis. I think there is something to spillover effects from infrastructure that's been built to manage MA, and places or ACOs that are able to leverage that to help them do what they do on ACOs, because I'm not sure if it's a 40 percent lift for organizations or hospitals going from, you know, traditional fee-for-service payment into

the ACO world, because there's a whole lot of infrastructure and capability that needs to be built to figure out where is the unnecessary utilization and how do you manage that in a different environment and better. But to the extent places have done that because they've been managing MA populations, I do think there's some ability to cross-leverage those capabilities, and maybe that's, you know, why we're seeing that Florida seems to have a lot of these, in addition to the fact that they're starting from a point where they have a lot of utilization that can probably come out of the system. So I just wanted to make that comment.

DR. CROSSON: Thank you. Bruce -- Pat, on this point?

MS. WANG: No.

DR. CROSSON: Okay. Bruce.

MR. PYENSON: Yeah, I strongly support the Chairman's recommendation. I think it's a step in the right direction. It might be characterized as a Band-aid, but it's a really important one to stabilize the system.

I think the ability of ACOs in the current structure to optimize results without necessarily improving

care is a risk. It's a risk we've certainly seen in the Medicare Advantage program with optimizing risk scores and other characteristics. So I wouldn't be -- I don't think any of us should be surprised at that, as people are eager to see ACOs and should be eager to see the ACOs prosper. But I think the kind of risk that has been identified here is probably the tip of the iceberg. I see that sources of data such as the qualified entity data which is available to consultants is potentially being used to identify which individual practitioners, physicians, to invite into ACOs and which to disinvite. And given the ongoing consolidation of the market, I think that's a profiling tool that's out there and available. So I would recommend that we look at that and perhaps issue recommendations to CMS that controls that on its proper use or allowed uses.

I can say as a consultant in this business, I know I'm getting inquiries for exactly that sort of profiling. It's happening. I'm not saying all of the ACOs are doing that or most of them are doing it, but there's certainly interest in understanding that and using that data.

Finally, I echo Jonathan's comments about taking

a hard look at the annual wellness visit. Is it something we should recommend continue to be used? Does it have value? I think there's similar low-value items like shared decision-making visits that have no evidence, and I think it's part of our charge when we see things like that to ask those questions.

Finally, I do strongly support a prospective structure.

I'm going to say one more "finally" thing, which is that this picks up on Warner's recommendation on an idea on assigning primary patients, beneficiaries to primary care.

In the long run, it's not clear to me that attribution is a model that can work. Attribution has been used to create virtual capitation or virtual insurance, and it's just not clear to me that it can be used in a stable way. And I think that's something the Commission could usefully look at, whether we need to move away from attribution and more towards the model of people are assigned to primary care physicians or other physicians.

DR. CROSSON: Bruce, this is a point I happen to agree with, and it's come up a number of times. We started

at one point to move in the direction of attestation, which would preserve, because we have to at the moment, the right of beneficiaries to go wherever they want, but to put in the mind of beneficiaries at least that there is one physician or one group of physicians who are primarily responsible for them. I think maybe that thinking could be brought back again.

DR. DeBUSK: On that specific point, you could attach attestation to the Part B premium. You don't really have the cost-sharing labor because only 12 percent of our beneficiaries are exposed to cost sharing, but you could attach that to Part B premium and just basically do a buydown if you attest to a primary care physician. That would solve a lot of these issues.

DR. CROSSON: We walked up to this and then -- I can't remember -- a year or two ago kind of backed away from it. I think it is fertile ground.

Kathy?

MS. BUTO: On this same point?

DR. CROSSON: Yeah, all right.

MS. BUTO: Very briefly, I think it would also allow you to consider the issue of incentives for primary

care physicians and adding a larger payment to primary care physicians in the case of attestation for a range of things.

DR. CROSSON: Yeah.

MS. BUTO: So I think it opens some other doors.

DR. CROSSON: Multiple utility.

Okay. Pat, last, and then we do have to move on.

MS. WANG: Real quickly.

I support the draft recommendations, and just picking up on some of the other comments, I think that one of the areas that I'd be interested in us understanding better and pursuing is when I look at the list of these really successful ACOs in Appendix A, just eyeballing the names, it's consistent with the findings that the physician ACOs have generated more shared savings. So maybe there is a different equation or value proposition in understanding what makes a hospital-based ACO successful. To Jon's question, how do I know success when I hit it? It might be a different thing.

My personal view is that this is all good, the work in the ACOs, but that the effort to make sure that people have a real primary care physician is really not the

end of the story. I actually think that we need to move more towards system-ness, so that your primary care physician belongs to a system of care through which you move, and that includes specialists and acute care hospitals and vehicles to get to tertiary or quaternary care. This is only the start, I think, of the sort of observation or the narrative of what makes good care.

So I think it's very important. All of these things are very important, but a little bit more of a focus on maybe there is a different definition of success for a hospital-based ACO than for a purely physician-led ACO.

And the second comment, is there more that we can think about in the attribution model to encourage system-ness? Because that's really where I think the system needs to go.

DR. CROSSON: These are all good points.

I think I might expand. Having said we shouldn't be talking; I'm going to talk.

I really do believe that the fundamental incentives in physician-only ACOs and in hospital-led ACOs are substantially different, and as we've said in prior work -- and we're going to come back to this in April for

the June report -- the issue of how hospitals are paid and what their incentives are and the incentives inherent in our idea of ACOs are in conflict. Until we can move forward with models -- and there are some out there already -- where the hospitals have an incentive to improve the appropriateness of care services and not maximize care services, we're going to have a continued problem.

Having said that, wonderful work. Thank you. I think we have a direction for the April meeting, and we'll now move on to the next presentation.

[Pause.]

DR. CROSSON: Okay. I think, in some ways, similar to the end of the last discussion, there have been questions raised here at the Commission and more broadly about the role of specialists in alternative payment models and particularly in ACOs and to what degree specialists are or should be involved in the incentives and rewards and penalties of those sorts of payment models.

The Commission has not done a lot of work on that yet. There is the intention to do that, and again, I think we'll see this topic appear in the paper for April.

But Ariel is here to begin to lay the groundwork

for this work by describing the current situation with respect to the role of specialists.

Ariel?

* MR. WINTER: Good morning.

This is an informational session about the role of specialists in alternative payment models, or APMs and ACOs.

Before I begin, I want to thank several people who helped with this work: Kevin Hayes, Sam Bickel Barlow, Carolyn San Soucie, Rachel Barton, as well as Luis, David, and Jeff.

During previous meetings, several Commissioners have asked about the role that specialists play and should play in APMs and ACOs.

In addition, some specialty societies have claimed that specialists have very limited opportunities to participate in APMs and ACOs.

So today, we'll focus on two main questions, and I'm going to give away the answers right at the beginning.

First, do specialists have opportunities to participate in APMs and ACOs? They do, and in fact, they account for the majority of physicians who participate in

Medicare ACOs, but each ACO determines the role of specialists and other physicians; for example, whether they are involved in ACO leadership or receive a portion of shared savings. And we don't have details information about these arrangements.

Second, are ACOs with specialists more likely to reduce volume and spending than other ACOs? Thus far, the limited evidence from the literature suggests the opposite, that they are less likely to reduce volume and spending.

To begin, we need to explain why APMs are important.

MACRA set up two payment paths for clinicians. The first path is for clinicians who participate in advanced APMs, or A-APMs, which I will define in just a moment. These clinicians may qualify for an incentive payment worth 5 percent of their professional services payments from 2019 through 2024. They will also receive a 0.75 percent annual update to their payment rates starting in 2026.

The second path is the Merit-based Incentive Payment System, or MIPS. Clinicians in MIPS receive a payment adjustment based on their performance. In 2021,

for example, these adjustments will range from minus 7 percent to plus 7 percent, or higher. Beginning in 2026, these clinicians will receive a 0.25 percent annual update. In 2018, the Commission recommended eliminating MIPS and establishing a new voluntary value program.

An advanced APM is a subset of APMs that requires an entity to use certified electronic health record technology, makes payment based on a set of quality measures comparable with MIPS, and requires an entity to bear financial risk for monetary losses in excess of a nominal amount or be a medical home expanded under Section 1115A. Clinicians with a minimum share of Medicare payments or patients coming through an A-APM qualify for the 5 percent incentive payment.

CMS has developed several APMs with tracks that qualify as advanced APMs and that have opportunities for specialists to participate. There is more detail on these models in your paper, so I am going to go through them pretty quickly.

We group these APMs into three categories. The first is APMs that include services typically furnished by specialists. First, the Bundled Payments for Care

Improvement Advanced model is a voluntary program that includes episode payment models for 31 inpatient and 4 outpatient episodes. This model includes episodes related to spine, bone, joint, neurologic, cardiac, and gastrointestinal procedures.

The Comprehensive Care for Joint Replacement model is a mandatory program that applies to lower extremity joint replacement episodes that occur in an inpatient setting.

The Oncology Care Model is a voluntary model for physician groups that provide chemotherapy to patients with cancer.

CMMI has also proposed future models that would qualify as A-APMs, such as the Radiation Oncology model and Kidney Care First model.

The second category includes the Maryland all-payer model in which hospitals in Maryland are paid using global budgets and the Maryland total cost of care model which sets a limit on Medicare's total costs in the state.

The third category is ACOs. The Medicare Shared Savings Program, as we just talked about, is a permanent model and is the largest ACO program. Some of its tracks,

such as the enhanced track, are two-sided risk models that qualify as advanced APMs.

The Next Generation ACO model is a temporary model run by CMMI.

In the Comprehensive ESRD Care Choice model, nephrologists, dialysis clinics, and other providers join together to take responsibility for quality and spending for ESRD beneficiaries.

And finally, there is the Vermont All-Payer ACO model.

Now I'm going to switch gears and talk about specialists' participation in ACOs.

Beneficiaries are mainly assigned to an ACO based on primary care visits with primary care clinicians who participate in the ACO, but ACOs may also include specialists on their list of participating physicians. Each ACO can determine the nature of its relationship with participating physicians, including specialists; for example, whether they are involved in ACO leadership or receive a portion of shared savings.

So why would specialists want to participate in an ACO? First, ACO participation might lead to more

referrals from primary care physicians in the ACO. Second, specialists could potentially share in savings if the ACO receives shared savings, and third, they might qualify for the 5 percent incentive payment if their ACO qualifies as an A-APM.

On the flip side, do ACOs want to include specialists? They might want to include specialists because they can give them incentives to constrain volume growth, which could help the ACO reduce spending. However, ACOs don't need specialists for patient assignment because beneficiaries are mainly assigned to an ACO through primary care clinicians.

And even if specialists don't participate in an ACO, the ACO can still influence their practice patterns by encouraging primary care physicians in the ACO to refer patients to less costly specialists.

Interviews and focus groups with ACOs and physicians shed light on the role of specialists in ACOs. These findings come from interviews conducted by Commission staff with ACO leaders in 2018, focus groups that we conducted with physicians in 2019, and an OIG report from 2019 that was based on interviews with 20 ACOs.

We learned that ACOs led by primary care physician groups are more selective about their participating physicians than other ACOs, and may not include any specialists.

On the other hand, ACOs affiliated with health systems tend to include all of their employed physicians in the ACO, and these ACOs tend to have more specialists than primary care physicians.

We also learned that ACOs use various approaches to manage referrals to specialists. For example, some ACOs give primary care physicians data on specialists' use of services to help them consider cost and quality when they make referrals.

When specialists know that ACOs are sharing this information with primary care physicians, they have an incentive to reduce spending and improve quality.

We analyzed data from CMS on the share of physicians participating in MSSP ACOs in 2018 who were specialists. Overall, we found that 63 percent of participating physicians were specialists, as shown in the bar on the far left. This is similar to the share of all physicians enrolled in Medicare who were specialists in

2018, 64 percent.

But the share of specialists varies by type of ACO. It was 65 percent in hospital-affiliated ACOs, compared with 50 percent in physician-led ACOs. A potential explanation for the higher share of specialists in hospital-affiliated ACOs is that these types of ACOs tend to include all their employed physicians.

This chart shows the share of physicians participating in Next Generation ACOs in 2018 who were specialists. Similar to what we saw for MSSP ACOs, 60 percent of physicians in Next Gen ACOs were specialists, as shown in the bar on the far left.

A much higher share of physicians in hospital-affiliated ACOs were specialists than in physician-led ACOs, 63 percent versus 36 percent.

I just want to remind you that these charts are based on a list of physicians who participate in an ACO, and we don't know how extensive their relationship with the ACO. Nevertheless, these charts suggest that there are substantial opportunities for specialists to be part of an ACO.

Research on the impact of specialists on ACOs'

volume and spending is limited, but we know of two studies that examine this issue in the context of MSSP ACOs. First, McWilliams and colleagues used a difference-in-differences approach to compare changes in total Medicare spending between different types of ACOs and a control group. They found that primary care physician group ACOs reduce total Medicare spending, but multispecialty physician group ACOs did not.

Second, an article by Barnett and McWilliams also used a difference-in-differences approach to compare changes in the use of office visits with specialists between different types of ACOs and a control group. The authors hypothesized that ACOs that are mostly made up of primary care clinicians have a stronger incentive than other ACOs to reduce the use of specialty care because they do not lose fee-for-service revenue when they provide less specialty care.

By contrast, multispecialty ACOs could lose substantial fee-for-service revenue if they make fewer referrals to specialists.

The article found support for this theory. ACOs with a high share of primary care physicians reduced the

number of specialist visits, but ACOs with a high share of specialists did not.

So to conclude, we'll return to our original questions. Do specialists have opportunities to participate in APMs and ACOs? They do, but each ACO determines how involved specialists are going to be in that ACO and whether they can receive a portion of shared savings.

Are ACOs with specialists more likely to reduce volume and spending than other ACOs? Thus far, limited evidence suggests the opposite, that they are less likely to reduce volume and spending.

This concludes my presentation, and I'd be happy to take any questions.

DR. CROSSON: Thank you, Ariel. Very clear. We'll take questions. I see Brian, Jonathan, Amol. Brian.

DR. DeBUSK: First of all, great chapter. Thank you. I enjoyed reading it. I have two questions, and you mentioned this briefly in the chapter, but do we have any way to measure how much of, say, the MACRA bonus or any of these bundles that are being reconciled or any of these ACO reconciliations, do we have a way to measure how much of

that actually makes it to physicians, and do we have any tools to direct it to ensure that it makes it to physicians? That's my first question.

The second question and then I'll hang up, is, are there examples of population health models, say ACOs and episodic models, say bundles, successfully interacting? I mean, is there anything out there we can go on to show the two living together?

MR. WINTER: Your first question, was that directed towards any shared savings distributed to physicians or the 5 percent incentive payment?

DR. DeBUSK: Basically any of those incentive payments. Is there any way to measure how much of that actually makes it to the physician, with the data we have now?

MR. WINTER: I'm not aware of any data that would measure how much of the savings retained by the entity is distributed to individual clinicians. And some of the models we've talked about only hospitals could be the participating entity, like the CJR model.

But with regards to the 5 percent incentive payment, CMS has released information for at least the

first two performance years of how many clinicians qualify for that payment, and it was 99,000 clinicians in the 2017 performance year, which means they'll get the bonus, and they got the bonus in 2019, and I think it was 183,000 clinicians who qualified for that 5 percent incentive payment in 2018, which means they'll get the bonus this year.

DR. DeBUSK: Are they not paid out by TIN, though? I thought that MACRA bonuses --

MR. WINTER: Paid out NPI.

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

MR. WINTER: And we are working with CMS to get data on the NPIs of those specific clinicians who got the bonus, to be able to identify what specialty they belong to, so we could come back to you hopefully with some analysis, some findings on, you know, what percent were PCPs versus specialist, by type of ACO, by CJR, by BPCI Advanced, for example.

In terms of the dollar amount, CMS has not publicly released the dollars that were paid out through the advanced APM bonus, but they have made estimates. And

so, for example, for 2020, they estimated that total payments would be between $675 million and $900 million for between 185,000 clinicians and 250,000 clinicians. So based on that, the average per clinician would be about $3,600. But as I said, the actual number of clinicians who got the bonus was somewhat lower, was at the lower end of the range, 183,000 clinicians.

So the total dollar amounts might have been higher per clinician. But until we get the total dollar amount from CMS that was actually paid, or that will actually be paid in 2020, we won't be able to calculate the actual average.

DR. DeBUSK: So just round numbers, MACRA money is around $5,000 per qualifying -- I mean, I bumped it up from $3,600 assuming that --

MR. WINTER: Well, I think that the total amount, the total payments were based on how many clinicians would actually get bonus, so it's probably -- I'm not sure I would bump it up. It's probably closer to the $675 million end of the range than the $900 million end of the range.

DR. DeBUSK: So $3,600 --

MR. WINTER: That's where we're at.

DR. DeBUSK: -- is the totality of the MACRA bonus for the ones who qualified.

MR. WINTER: That's what we're estimating, but we'd like to get final -- the final aggregate number from CMS so we can calculate the actual average.

To that part, but was there a second question?

DR. DeBUSK: And then the second question was, can you speak to examples where population health models and episodic models are working together?

MR. WINTER: Okay. I've not look at that in detail but I know Amol does have an article about that, specifically looking at the interaction between, I think was it CJR or BPSI, one of the BPSI episodes, and ACOs, and Amol can talk to that more specifically. And we can look at the larger and see if there are other examples.

DR. NAVATHE: Yes. So we have just simply tried to measure the overlap at the beneficiary level. So there is overlap at the provider level, meaning hospitals or physician groups that are actually participating in both simultaneously, because you are allowed to participate in both simultaneously. That is not a huge amount. I think it's something south of 20 percent of the ACO providers are

in BPCI or BPCI Advanced episode as well.

At the beneficiary level it is higher. It truly is a percentage of the bundles program, so 30, 40 percent of beneficiaries are both attributed to an ACO and receiving care from a bundled payment provider. As the ACO population as the denominator it is a little bit smaller. It is more like 10 percent.

DR. DeBUSK: So this cross-attribution issue is here, whether we like it or not.

DR. NAVATHE: Absolutely, and our estimates, just to be very clear, are from 2016, because that's the data that we had at that time. So it's only likely to have increased, because BPCI Advanced has scaled participation relative to original BPCI, and as Jonathan pointed out, at least until 2019, we had increasing participation and attribution of beneficiaries, up to I think about 30 percent of beneficiaries.

DR. DeBUSK: Final question. If you were tasked with equitably distributing these payments, is this like the rest of your career tied up, or do you think this is something you could knock out?

DR. NAVATHE: It's undoubtedly hard. So I think

my research team is actually working on the fundamental question first, which is other benefits to overlap. And we are about -- well, we are in the process of unpublished work, preliminary data, suggests that there are benefits, and particularly the benefits are outsized for more complicated patients and medical conditions.

So relative, for example, to bundles alone, where we've seen very small effects or no effects for medical conditions, we actually are seeing cost savings for patients who are attributed to ACOs and then go to a BPCI provider for medical conditions, the most common ones like sepsis, CHF, pneumonia, COPD, although we actually look at it across all 48 conditions. So it is the totality of the program.

We also see quality effects. So it seems like quality costs are tied up, but usually admissions tend to be lower by about a percentage point, which is not trivial, for medical conditions. And actually we see a reduction in readmissions also on the surgical side, for hip and knee replacement and others. There's actually a little bit smaller, about 0.7 percentage point reduction in readmissions.

So it's all preliminary data, so take it with a grain of salt, but it does look like there are synergies between the program. And then the other thing that we've done is we've looked at hospitals that have participate in both simultaneously, and it looks like their patterns of care are actually quite -- are different, not quite different -- are different in the sense that the hospitals that are also in ACOs, they achieve pretty similar results to hospitals and bundled payments alone, but they tend to use the ambulatory infrastructure a lot more. So they use less home health, for example, and they use more office visits with ambulatory ACO per participating provider. So it does look like there's some synergy, is my takeaway.

What the accounting looks like to actuate the savings is a whole other beast.

DR. CROSSON: Well, we really, I think, collectively look forward to that work, because, I mean, we've had concerns, as you know, about perhaps a negative consequence of being engaged in two different payment mechanisms. And, in fact, if there is synergy it would not only be useful to know but perhaps to try to understand how that synergy plays out.

Jonathan?

DR. JAFFERY: Yeah, thanks. This is a great chapter. It is really exciting to be getting into this discussion and beyond the things that we've heard about in the chapter and the things you just brought up. Amol raised all sorts of exciting things.

I have a couple of quick questions for round 1. One, actually, I think you addressed. I was wondering about the data on the advanced APM bonus payment, specialty versus primary care. It sounds like that's forthcoming. You don't quite have the data yet. And my guess is you probably won't have this either, but any information yet about groups that are not hitting thresholds, and if not -- I'm assuming you don't have that yet, but assuming you don't, do you anticipate being able to get data about that? Because I can see where there would be some significant issues for specialists, additional issues with specialists hitting the thresholds, assuming they take regional referrals or things like that.

MR. WINTER: And which thresholds are you referring to?

DR. JAFFERY: I'm sorry. The thresholds to

qualify for the advanced APM bonus payments, the number of patients, the amount of revenue. If they're getting referrals for patients outside of the ACO that they are affiliated with they may have -- yeah, the percent of revenue is going to go down.

MR. WINTER: That's a really good question. As you know, the thresholds are increasing steadily over time, so it's going to be more challenging. So that's something we could put on a list for future work.

DR. JAFFERY: Okay. Great. And then the other quick question is about the mix of episodes in BPCI-A. So do you update about the mix between patient, outpatient and chronic and acute?

MR. WINTER: In terms of the number of types of episodes or the actual number of episodes that are being done in each category?

DR. JAFFERY: Like I said, the types of episodes that are being done, in the types that are actually being done.

MR. WINTER: So I'm not aware of any data on that yet. The BPCI Advanced just started in 2018, and I don't think there's an evaluation report yet. But we will track

that closely and as soon as we see anything, we can get back to you with that information. I don't think we have put anything on the website in terms of how many actual episodes are in each of the 31 inpatient categories or the 4 outpatient categories.

DR. NAVATHE: I think that's right. The most recent information we have on that is just based on participation, because it's voluntary. So there's been some sizeable shifts. For example, in the original BPCI program there was a lot of participation in lower extremity joint replacement, especially amongst hospitals, so it slowly shifted towards physician groups.

In the latest wave, in particular, of BPCI Advanced, for example, hospital participation in LEJR has dropped dramatically. Sepsis is the number one condition for hospitals. Participation in the outpatient episodes seems to be more driven by physician groups than it does by hospitals, for example. So there's PCI and outpatient hip and knee.

So the dynamics are shifting. I agree with Ariel that we don't know the actual episode volume in any of them yet, but the participation mix itself is evolving pretty

rapidly, even wave to wave in BPCI Advanced.

DR. CROSSON: You're up, Amol.

DR. NAVATHE: So I had a true, true clarifying question, no undercurrent of a comment in here. So on page 5 of the reading there is this note about some physician specialty societies have expressed the view that many specialists have very limited opportunities to participate in A-APMs, leaving MIPS as kind of the default path for them.

I was just curious, there's a reference to Alliance of Specialty Medicine and I was curious what are the specialties that are represented by Alliance of Specialty Medicine, to get a sense of who are we talking about here.

MR. WINTER: Yeah. It includes -- I'll give you a list of most of them. I think there are 10 altogether, but it includes orthopedic surgery, neurologic surgery, gastroenterology, cataract refractive surgery, echocardiography, plastic surgery, urology, and there are, I think, a few others. I can get you the full list.

DR. NAVATHE: Thanks.

DR. CROSSON: Okay. Dana.

DR. SAFRAN: Thank you. So I've been thinking about the hospital versus physician savings, and I'm wondering what we know about the extent to which the specialists who are part of hospital ACOs are compensated on a salary model versus not. And here's my logic train, is the 5 percent increase in rates, if that's really going to the hospital then of course the hospital wants every one of the physicians that are part of that organization to be counted as part of their ACO. And so then the question is, how they pass down to those specialists any incentives around appropriate utilization?

And I don't want to take us afield but it does bring us back to an issue I know I raise very often, which is hospital-based payment reform, because the hospital is, in this care, really only at risk for the patients of its primary care physicians, but the rest of what they're doing, and, you know, the data I know from the commercial space, is it's far more than half of what they're doing, of total revenue, is not related to their PCPs' attributed population. You know, they're still riding the fee-for-service horse for that population.

So as I think through this issue I feel the need

to understand what we know or don't know about how specialists who are in the hospital models are compensated, and whether that 5 percent that they get by being in an advanced ACO is something they are directly seeing versus that's going to the hospital and the hospital is paying them on a salary with RBU, you know, performance compensation, et cetera. Thanks.

MR. WINTER: So because the first 5 percent advance -- the first 5 percent A-APM payments were not distributed until like late last year, September, I think, it's all a recent phenomenon. So we will certainly keep track of the literature and see if there's any articles that are written about this, and perhaps it's something we can add to the list of topics we ask physicians about when we do our annual physician focus groups this summer. If we get physicians who are employed by hospitals, if we can ask them about how any revenue that they might -- the hospital might receive through an ACO, how is that distributed to them.

DR. SAFRAN: It's a shame Larry is not here because I suspect Larry would know quite a bit about this, so maybe let's tap him as well.

DR. CROSSON: Okay. Seeing no further questions we'll proceed with the discussion, and Paul has asked to go first.

DR. PAUL GINSBURG: Yeah. Thanks, Jay. When I read the materials that Ariel sent out it really stimulated me to think about, well, okay, what should we do about this, policy wise? So I sketched out a few ideas yesterday and thought I'd just put them in front of you to just start a discussion.

I started from the premise that our goal here is to get specialists more engaged in ACOs, and the one tool that we've put out, policy wise, with the A-APM bonus, we want to make sure the A-APM bonus is connected to specialists really being engaged in an ACO, or doing something else that earns the bonus.

An alternative way of thinking about this is that we could view ACOs as really primary care-driven organizations, and whether they want to engage specialist or just steer patients to efficient specialists is their decision, and I'll come back to this in a minute.

So I think the key problem is that -- this is what I've learned so much from Ariel's work, is that the

ACO's decision to list the specialists in its reports to CMS, which triggers the bonus, if it's the right type of ACO, seems to me very kind of casual. You know, these could be people that are sharing savings with. These could be people they're not sharing savings with. You know, if they're not sharing savings, sometimes the ACOs list specialists; sometimes they don't. So I think for those that do not share savings, you know, that's what I'm saying.

So I think the possible approaches you can go is you can either take an active approach, which is say a CMS rule describing which specialists should be listed. It would include those that share financial risk and those who are some measure of having patients steered to them from the ACO, you know, whether it's an objective thing or whether it's a more passive thing.

And actually the passive approach would be just looking at the data and saying that for specialist who would qualify for an A-APM, if a higher percentage of services delivered to ACO patients than average, if they have a higher percentage of ACO services than other specialists in a similar specialty in their area. So in a

sense, if a specialist de facto is seeing a lot of ACO patients, then they would say they are engaged in this ACO and we're going to give them a bonus. If they're not, if they're not getting referrals from ACOs for a specialist then whether they're listed in the ACO or not, they will not get the bonus.

So anyway, those are just some thoughts to start us off.

DR. CROSSON: Thank you, Paul. Again, this is the beginning of some work that's going to proceed, the question being with respect to the role of specialists in ACOs or other alternative payment approaches, what are some policy issues that we should be considering here at the Commission in the future?

So Jonathan, Amol, Warner, Marge, Brian.

DR. JAFFERY: Well, again, it's a great chapter and a great start of the discussion, and Paul, I think, you know, helpful, thanks for kicking those things off. That starts to stimulate a few things, and I want to maybe build on some of that, because I think this really is -- as Paul framed it, the key question to me is how do we engage the specialists with ACOs? And I have a couple thoughts that

maybe are a little bit different direction than some of the reading and what we've heard, because there's a lot of discussion about this idea of how primary care docs steer referrals to, you know, "more efficient" specialists. And I think we're seeing and have talked about how there's some problems there, so if you're part of a big group, that may not be the same as if you're interacting with one or more specialty groups that are not part of your group.

And I guess at a broader level, I'm just not sure that's really the kind of engagement that I think about when I think about what's the best way to do this with specialists, and, you know, full disclosure, I'm struggling with this, not doing a lot of really great work here yet, partly because I think we've been preoccupied by things like building the primary care model and dealing with the programmatic changes that happen every couple years. But it strikes me that this referral steerage idea is sort of more like an ACO version of utilization management, but not a particularly efficient one or effective one. And what I'd really like to get to is thinking about how do we engage the specialists to work with the primary care providers, the team, the ACO, however you want to put it,

to really create new care models, better care models that care for their specific population of patients.

And so just two ideas to throw out there. One is a little more -- well, neither of them are particularly concrete, but the first one goes back to a discussion we've had in the past this year, which is: Should Part D drug spending be part of ACO work? And, you know, there's a lot of the very high cost drugs that are prescribed by specialists, and so I think that that's something for us to think about, and I'm not particularly in favor of the idea of just having ACOs partner with a whole bunch of different Part D plans. I think there's a lot of complexities and challenges. I'm not sure that's where I would go immediately. But if we can think about how to include that, it creates maybe some opportunities for ACOs and primary care docs to work with specialists to say how can we address this area of increasing cost to the program that is not part of the ACO world right now, so it could have benefits in both those areas.

And then I think the biggest question is the one that Brian started to raise, bring up earlier, which is, you know, how do we really incorporate bundles and

integrate them within ACOs? How do we take episodic care and integrate it? And there's a whole lot of technical questions that I think we have to work through. The attribution is clearly one. The distribution of savings, how do we get an idea where the financial model doesn't incent -- have some unintended consequences in terms of incentives?

And then I think also two other points to that. You know, we have to think about to what extent some of the existing specialty models are helpful towards that end, or do they sort of create some other silos?

And then, finally, is there an opportunity to align some of that same kind of incorporating the episodic care into the total cost of care with the MA plans?

So just a few things to think about. Again, not super concrete yet, but let's wait until next hearing.

DR. CROSSON: Amol.

DR. NAVANTHE: Yeah, so I echo a lot of what Jonathan said. I would say first off great chapter, I think a really important topic given that, you know, we know that primary care is something like 8 or 10 percent of spend, influences more, but probably doesn't influence

everything. And so the specialists play such a critical role, and so I would love to see this work developed.

I think there's a lot of open questions. You started to tee up many of them. I think some of them we can partially answer; some of them we probably can't answer at all. And it's great to see us going down the path of trying to actually put a framework out there and really take on how do we get the specialty care into the care redesign and care model process, because I think that's what we're ultimately seeking to do.

Generally speaking, I think there are a number of different ideas, but I think there's the biggest open question in some sense in my mind is, you know, do we -- if we take on an ACO structure which has total cost of care, which intrinsically includes specialty costs, can we effectively and tractably address the types of or stimulate the types of practice redesign that we need to capture those savings? I don't know that we totally know the answer to that. I think it would actually be useful to complement the work, as you have already done to some extent, by talking to health systems and specialists specifically, and ACOs as well, to try to understand, you

know, how to best engage them not only in the ACO broadly, but how to engage them in the right types of practice redesign processes. It may just turn out that in the context of specialty care -- this would be my hypothesis -- that thinking about populations is much more challenging and it's easier to think about these care episodes.

We've seen some of that movement, I think, and it would be good for us as MedPAC, I think, to shift in the direction of being able to align our level of effort and our work with what CMS has been doing to date. So, for example, we noted -- I think you noted in the material the number of different specialty-oriented programs that are out there. Some of them are kind of a blend of ACO and bundles, like the ESRD work. Some of them are much more purely episode, like the OCM. But then in the shadows of that, even in the context of MIPS, for example, Medicare has been thinking about episodes in the context of these episode-based cost measures which could eventually become part of the measurement for all physicians as part of MIPS, which are clinically defined episodes not paid that way but measured in terms of cost and quality that way.

So one view of the world could be maybe what we

really need is we need ACOs as the primary vehicle and we need these episode-based cost measure type pieces as a way to create incentives around them or to create quality metrics around them, and that's going to be enough to stimulate the types of specialty care redesign that we need. Or an alternative view would be, no, we actually need episode-based payment structures a la bundled payments or OCM or what have you, and then we get to the point that Jonathan and Brian had raised. Then how do we actually coordinate those models? Big policy questions, I think, that we don't have answers to, so I think it's important that we take those on because Medicare is already starting to move in that direction either by legislation or by executive action.

So I think it's a very worthy cause. I think there's a lot of different options out there. Very excited that we're pursuing this line of work. Thank you.

DR. CROSSON: Thank you, Amol, and I would add one other element to what you listed here, and that has to do with understanding how specialists are paid in successful models versus unsuccessful models. To what extent is salary used, partial capitation, other kinds of

incentives which either are built on fee-for-service or not built on fee-for-service but fundamentally begin to alter the motivations, as bundled payments can in some circumstances.

DR. NAVANTHE: I think that's a really good point, and I would actually -- I can tell a story that is kind of funny that brings in the organizational cultural sort of economics of how things work.

So, for example, I have a friend who's an oncologist who's in an ACO, in a health system in an ACO, and at one point went to his division chief and said, "Hey, you know, I should really ramp down my volume here. We're in an ACO, right?" And the division chief said, "Well, you know, if our revenue as a division drops within the health system, then are you willing to give up your medical assistant? Are you willing to give up your nurse?" And they were, like, "No, not at all. So we're not going to do that," because, you know, the ACO incentive is so far away, the incentive of "I need my MA to function" is too proximal. So I think we do need to get under the hood and understand how people are paid, how organizations actually function, how specialists engage. Otherwise, we're at risk

of designing models that sound great in theory but aren't going to end up being implemented in a way that we need to actually benefit beneficiaries.

DR. CROSSON: All right. Thanks.

DR. PAUL GINSBURG: Can I follow up --

DR. CROSSON: Yeah, go ahead.

DR. PAUL GINSBURG: -- on what Amol said before? When you were mentioning the other payment types, the bundles, et cetera, to what extent should we be worrying that in a sense a bundle pulling the locus of, you know, care away from the ACO as opposed to really making the bundle one of the tools the ACO can proceed with?

DR. DeBUSK: I can tell you that one. The ACO needs to gate the number of episodes that the bundle does. To me, a bundle is just a sub-routine within a large program. The program is the ACO. But there should be a way to hand off -- whether it's the oncology care model or the CJR model, there ought to be a way, once the ACO deems that this episode is necessary -- and I do think everything should be subject to the ACO. Once the ACO says this episode is necessary, then you run that bundle. When the bundle runs its course, you do a reconciliation, and you do

some type of -- you have to reconcile the payments, too. Some of that needs to go to the ACO; some of that needs to go to the physicians. But now you'd be living in a world where the actual behavior of the specialist is tied back to financial means.

You have got to look at this from a compensation theory perspective. Imagine me as an oncologist doing a great job choosing all the right drugs and doing all the right care at a hospital, and then someone says, "Well, yeah, but for wet macular degeneration those guys chose the wrong drug, so we blew our number. You don't get anything." And there has to be -- I mean, this is just compensation system theory. We're designing a system.

DR. NAVANTHE: Yeah, I think that's right. I think one thing -- so I like the view and I would say I am optimistic and hopeful that we end up in an end-state model that has an ACO total cost of care structure that is aligned with episodes to actually drive the right types of specialty care model behavior change. The part that gives me a little bit of pause is, on the one hand, I was describing -- quoting some statistics on participation and overlap. You could actually have the opposite view, which

is that it's surprising there hasn't been more co-participation and there isn't more overlap, and maybe there are distinct communities of providers that engage in different types of models.

So I don't know that there's that one-size-fits-all solution necessarily, and at least if we look at how providers have been voting with their feet thus far, it looks like they're pretty different communities. There's overlap, but they're pretty different communities, and so I don't know, Paul, if there's a right answer there yet.

DR. CROSSON: Okay. Warner is next. I have you, Kathy.

MR. THOMAS: Just a couple of points, and I think the whole comment around -- and I think Dana brought this up about, you know, do we understand how specialists are paid kind of within these arrangements, and the reality is until we get a much bigger percentage of the overall payment for physicians into some type of global risk model, like ACOs and that there's enough upside there, you know, it is not going to change because the fundamental reimbursement and the fundamental compensation that people have for physicians is not going to change within these

arrangements.

And I agree with Brian's point. You can go to a bundle, but the issue is that it all comes down to avoidance of unnecessary procedures. That's really where it comes down to from a specialty perspective. We're in the Walmart Center of Excellence situation for joints, and about 30 to 40 percent of the patients that we see, we don't do procedures on that have been, you know, essentially okay to have procedures done. I think Jaewon has seen some of the same situations at Geisinger.

So, you know, I think this concept -- I think it is important to have specialists in the model. I really think the issue is we've got to create enough upside for these models for more organizations to lean into them and to lean into them with downside risk. And I think also not take a short-term view that if we don't save money in the first year or two, that they're a failure. I think we have to understand that we need to move the payment mechanism, and they may even cost a little bit more in the first year or two. But over time, if you move more risk to the provider system, including specialists, I think they will pay off over time. But I think we sit here and we say,

"Well, ACOs haven't been successful because we haven't seen huge savings." But we're in the infancy of this process, and I just think we need to think as a Commission do we just want to take the approach that we want to agree to move more risk to the providers and know that over time, changing the incentive will over time change the cost structure. And specialists I think have to be a part of that. If you look at primary care ACOs, yeah, they're successful because they are steering to lower-cost areas. But that is a short-term solution. That will not have a long-term solution.

So I just think we've got to continue to make sure there's enough upside globally for the ACOs and keep specialists engaged and try to incent systems and ACOs to move to sharing more of those dollars so they do, you know, change behavior over time.

DR. CROSSON: Thank you, Warner. Marge. On this point, Sue?

MS. THOMPSON: Just go ahead [off microphone].

DR. CROSSON: Okay. Marge.

MS. MARJORIE GINSBURG: Well, I confess when I read this, I couldn't figure out where the "there" there

was. Every indication indicated that involving specialists simply costs more to the system, that there was no great benefit, and that there was also this issue of I wasn't sure how much of the bonus money comes to them relative to their total income or the issue, in fact, do they care more about the quantity of referrals than they do about whether they're going to get a little bit more money at the end of the year, though now hearing the others, and Warner in particular, summary of this makes me more enthusiastic, shall we say, about whatever research we can do to try to improve this. My own bent is let's keep it with the primary care docs to really run the show. But if that ultimately shows that we get better care at lower cost when specialists are involved, great. I'm just not sure we've seen that yet.

DR. CROSSON: Thank you, Marge. Brian.

DR. DeBUSK: Well, to the point that I made earlier, I do think it's time that we explore ways for population health and episodic models to co-exist. And, again, I do think it's -- this is basic compensation theory. People need to understand how they're getting paid. And I think primary care doctors need to understand

it. Is it the medical expense ratio that they're managing to? Is it avoidable ED visits? Is it avoidable inpatient admissions?

On the specialist side, I do think there's some great models out there. The bundled payments in joints really move orthopedic surgeons. There are orthopedic docs I've known for 25 years who will not change practice patterns, and the moment you show them that target price on that joint, they start looking at everything from blood use to SNF utilization to home health. You know, they get away from writing standing orders of assess and treat, you know, and they get involved in whether or not the patient's getting speech therapy for a stroke they had ten years ago in a nursing home. I mean, these things happen. And I have seen it move these people. And I think if we can figure out how to make these bundles co-exist with population health -- because not everyone is going to be in the same place at the same time. I might not be ready at a system level to do an ACO, but I might have a great group of orthopods and a great group of oncologists who want to do their own models. And I think one of the biggest favors that we could do for payment reform, aside from global

payments, one of the other biggest favors we could do is modularizing these APMs so that they can co-exist together and people understand how they're paid. And I think that's just a fundamental thing that we have to focus on.

I also want to echo Warner's point, too. I think you made a great point. We're launching a new system, a new product here. We're going to have to put our thumb on the scale for the first couple of years. You don't launch a new heart program and say, "Hey, we're going to be profitable in the first 90 days." I mean, it's back to the thumb on the scale doctrine that we talked about a couple years ago.

Thank you.

DR. CROSSON: On that point?

DR. NAVANTHE: On your first point, actually, related to your point, Marge, so you're describing the sort of behavioral anecdotal evidence that you've noted. I think there's pretty systematic evidence that that happens, so, you know, we've described some of that. There's pretty good literature. David has done in the context of mandatory bundled payment, the CJR bundle. So I think it is important, Marge, to also realize that the specialty-

oriented models have generated savings. The ACOs and the specialists in the context of the work we looked at here, maybe a little bit less so, but the specialty-directed models themselves have been -- some of them, at least, have been successful. And so the question is how does that fit into the overall puzzle.

DR. CROSSON: Thank you. Kathy, you're up.

MS. BUTO: Okay. You know, this discussion reminds me of something that I've been thinking about for a long time, and that is that ACOs are intended not to be visible to beneficiaries. In other words, it was supposed to be a nice glide path to better care management, more system-ness in care and so on. But that to me is a fundamental flaw of the ACO, and so this whole discussion about how do we get or include specialty care, not include it, is it going to save money, will it improve quality, is all around the beneficiary sort of unaware that this structure is in place.

And so what I've been thinking is it would be good if we could also think about ACOs as a ramp to a more beneficiary-centered approach, and the issue with specialists is what brings this to mind. In my mind,

specialists are playing increasingly important roles in managing chronic care and chronic disease, and I don't think we ever actually think of it that way. We tend to think of specialists as something that, you know, might be an episodic need and then maybe move on, keep the primary care physician involved.

I think we have to start thinking about it from the beneficiary standpoint. What sort of managed system-ness would work for the beneficiary? And so I hope that as we evolve our thinking -- and we had a good discussion about beneficiaries electing physicians and having a more active role. I think you can move in that direction. But I hear all our discussion about what the appropriate payment is, and I agree with Brian. I think BPCI, the bundled payment approach, is one that begins to capture that sort of focus on the beneficiary-centered care in the payment system and drives, you know, a certain management and system-ness that wasn't already there. But I'm not sure ACOs do that, and so talking about the role of specialists is important, but I really think you have to take it back to what about the beneficiary's perspective. And here is where they're at least engaged and aware of

their involvement.

So I think we have to deal with that, and I think it goes back to the earlier discussion.

DR. CROSSON: Thank you, Kathy.

Dana?

DR. SAFRAN: Thanks.

All of my comments focus on the issues around compensation and the behavioral economics that I raised during the question round and that I think we've heard a lot of here.

I'll start by recounting a very quick anecdote from early, early years of Blue Cross alternative quality contract. I was at one of our hospital systems that was very successful in the model that talked about the day that bonus check went out to the primary care physicians, the specialists, they said, "Wait a minute. How do I get more involved in this? What is it I can do to be helpful so I can get a check next year?" And that's just really always stayed in my mind. How do you get folks' attention that way?

I think it depends. It depends on whether they're part of a hospital or other provider system that's

paying them on salary with some other compensation or how they're being rewarded versus whether they are living in the community and living off of the fee-for-service revenue that they can generate, because in the latter scenario, it is very hard to imagine how you can provide bonuses that are sufficiently high that it outweighs the compensation they get or what they get from doing that next procedure, unless referrals start todtry up because the PCPs referring to them know that they're overusing procedures.

That's the problems we all know and the complexity we all know. I'll try to put a couple ideas on the table. One is that if I go back to the conversation we are having about NPI and I think that if a hospital system, let's say, lists a group of specialists, NPIs, as part of their ACO, might they then be required that for every one that they're listing as part of their ACO that they have some requirement to indicate that the compensation for that individual aligns to the incentives of the ACO; that is, it's not RVU-based? That the way that provider is compensated -- let's say they're on salary, and there's a bonus -- that that bonus is tied to the same kinds of quality measures and overall cost control that the ACO is

trying to accomplish so that the incentives move down the line. That's one thought. I know there's administrative complexity to that but something to think about in terms of the hospital is going to get that 5 percent for every one of those NPIs that they list. So what do they have to attest to in return for that?

The other thing that I'm attracted to out of this conversation is the idea of the episode payments within the ACO. I've never been a big proponent or fan of episode payments on their own, because of the fee for bundles problem, but I think, you know, I like -- to Brian, put it about -- you know, the ACO is sort of the gatekeeper to the episode, and then once they know that they want an episode to be kicked off, the specialist group that's going to be accountable for that is held accountable for how that episode is going to go, the cost and quality of that episode. That has a lot of appeal, all the complexity notwithstanding of how the savings then gets shared.

And also, the other complexity I'd want to guard against is having so many episodes that people are really just -- we're back to a world that's fragmented, and people, patients looked at as like body parts and not

individuals. Besides the fee for bundles problem, that sort of whole person care problem is the other piece that's always been a concern.

But I think we have the start in this conversation of some ideas for solutions and couldn't agree more with the conversation that we have to address how to get specialists meaningfully engaged in ACO programs, because without them, we can't succeed, I think.

DR. CROSSON: Thank you, Dana.

Sue and Pat.

DR. NAVATHE: Can I add to that?

DR. CROSSON: On this point, okay.

DR. NAVATHE: Just only on the fee for bundles thing, David's paper looked at it. We've looked at it directly. Arkansas has state bundles mandated across commercial and Medicaid. They've looked at it. Nobody has ever found a fee-for-bundles effect yet, at least in four big evaluations that we've seen.

I think conceptually, it could be worrisome. I think the question is, from a behavioral perspective, if you're paid under a general fee-for-service system anyways, so your incentive is to do the procedure to make money,

does the bundle really have a margin of action on it? I think to date, we have not found that that actually has -- there's no evidence to suggest that it exists.

DR. SAFRAN: Is there evidence that it's driving inappropriate procedures down, or is it just making the -- within the episode, it might be making us more efficient, but is it actually getting rid of some overuse?

DR. NAVATHE: We don't have data on that piece. We know that there can be some small case-mix shifts. Whether those case-mix shifts are appropriate, is it appropriate not to do high-risk procedures when they're elective? We can't comment from the data that we've seen. The literature thus far has not been able to address that. So I think that's a fair point.

I would say we're probably more confident that conditional on doing a procedure or having a hospitalization, there's greater efficiency from episodes than we can comment on the other pieces.

DR. CROSSON: Okay. I've got Sue and Pat, and then we're going to have to end. Sue?

MS. THOMPSON: All right. I want to echo my support for this work on this chapter and our commitment to

diving deeper into the role of specialists and value-based contracting and the work of ACOs.

I'm also supportive of thinking of a new way to talk about ACOs. I think it's a little bit of a worn-out term that has taken on some baggage, but in the spirit of doing good work to save the Medicare program, I think this is important work.

It's important we align incentives, and I think this conversation this morning certainly has demonstrated we have so many counter-incentives.

From a specialist standpoint, not only do the incentives have to be in line, but the programs they engage in need to be meaningful. And they need to be meaningful from a standpoint of how they care for their patients as well as how they are compensated. So I don't think we can overstate the need to align incentives as an operating principle for all of this work.

Just as a point of context, in terms of specialists, in the ACO that I work with, out of roughly 8,300 providers, 3,600 of them are specialists who we do not employ, but who have come to the table and have wanted to become a part of our network because of the work we're

doing and for all of the other opportunities of being part of an advanced APM.

So the appetite for this work by the independent specialists in addition to those that we do employ is there, and I think we need to take advantage of it while they're still interested and becoming part of the solution.

We care for roughly 550,000 lives, and we've been in the work since 2011 as one of the pioneers, but it was not until 2017 that we actually covered the cost of the infrastructure and ongoing operating expenses to do the care coordination and analytics required to be in this business. So this is not something you see a return on in the first nine months. This is an enormous investment made, and I want to call out how important I think the work is, how meaningful I think the work is, and frankly, thank you.

DR. CROSSON: Thank you, Sue. Good points.

Okay. Pat?

MS. WANG: I should have verified this in Round 1, but to the extent that I am a hospital-based ACO or any ACO that includes specialists, are all of those specialists automatically entitled to the A-APM treatment and MACRA

boost, the bonuses as well as the update factor, just by virtue of being on my list?

DR. CROSSON: Pat, he couldn't quite hear you.

MR. WINTER: I think the question is if the specialist is on the list of a hospital-oriented ACO that qualifies as an APM, does the specialist automatically get the 5 percent incentive payment? And the answer is yes, as long as they meet that threshold.

In 2018, to get the 5 percent payment in 2020, in 2018, at least 25 percent of their Medicare professional services payments had to come through that ACO or 20 percent of their patients had to come through the ACO.

MS. WANG: Okay.

MR. WINTER: There is that threshold requirement as well as being on the list.

MS. WANG: So my next question, how are the extra MACRA bonuses treated in the calculation of shared savings for the ACO?

MR. WINTER: Right.

MS. WANG: Is it an expense? Is it in the benchmark? How does it --

MR. WINTER: I think David might know the answer

to this. I don't know offhand. David, do you know if they're counted as part of the performance?

MR. GLASS: [Speaking off microphone.]

MS. WANG: So the benchmark is calculated without my specialist, my 65 percent of my physicians in the ACO. My benchmark does not have the bonus included, but my performance year will. Is that right?

DR. CROSSON: No, I don't think so.

MS. WANG: Okay.

DR. JAFFERY: I think we should clarify that because I'm not sure that's --

DR. CROSSON: That doesn't sound right.

MS. WANG: The only reason I was asking that question is that to the extent that it puts more pressure on the ACO to demonstrate shared savings because the total payments that are being made to providers in the ACO has gone up, that that would probably be a good thing. And I would leave it to the ACOs. I'm a little bit more in favor of market-based solutions to figure out how to leverage that to do things with their specialists to kind of keep that thing going.

DR. CROSSON: We'll try to get that fully

clarified, Pat.

All right. This has really been a very valuable discussion. Ariel, thank you, and we look forward to your future work.

Thank you, Commissioners, for a very rich discussion that went well beyond, I think, what we might have expected. Appreciate it.

So we now have time for a public comment period. If there are any of our guests who wish to make a comment about the material we've discussed today, this morning, please come to the microphone.

* [No response.]

DR. CROSSON: Seeing no one approaching the microphone, we are adjourned until one o'clock.

[Whereupon, at 12:10 p.m., the meeting was recessed, to reconvene at 1:00 p.m. this same day.]

AFTERNOON SESSION

[1:08 p.m.]

DR. CROSSON: Okay. I think we are ready to begin. Jim had one point he'd like to make that's a carryover from this morning.

DR. MATHEWS: Yeah. I just wanted to loop back with respect to the question about whether or not the A-APM bonus payments are counted as spending for purposes of assessing ACOs' performance relative to their benchmark, and it was incorrect to say that those bonus payments are counted. They are not counted as spending, nor are they in the benchmark. So I just wanted to correct the record.

DR. CROSSON: Okay. Next, we're going to turn to our continuing work, multi-year work really, on Part D, and we are beginning to approach a point at which we are preparing for a vote on a set of recommendations at the next meeting. Today we will have a reiteration of a large degree of our discussions as well as initial presentation of draft recommendations.

Rachel, Eric, and Shinobu are here, and Rachel is going to begin.

* DR. SCHMIDT: Good afternoon. Today we are here

to discuss draft recommendations to realign incentives in Medicare Part D. The approach used for these draft recommendations was discussed extensively in our June 2019 report to the Congress and in 3 meetings we've had this cycle. This iteration reflects your earlier discussions and throughout this presentation we will flag where we've tried to reflect your comments.

Part D is different from fee-for-service Medicare because it uses private plans to deliver drug benefits that compete for enrollees based on premiums and other factors. Plans set up networks of pharmacies, develop formularies to encourage use of preferred drugs, and negotiate with manufacturers for post-sale rebates.

Part D law restricts the federal government from interfering in negotiations among private plans, pharmacies, and drug manufacturers. The commission's 2016 recommendations kept with this overall structure -- Part D plans would bear more financial risk for their enrollees' drug spending—much as they did at the start of the program, yet gain flexibility in their tools to manage spending.

The draft recommendations we will present today are also consistent with Part D's market-oriented approach

and, of course, we will continue monitoring drug prices, beneficiary access, and Medicare program spending.

Trends in Medicare's program payments to plans suggest that Part D needs to be restructured. Medicare's cost-based reimbursements for reinsurance in the catastrophic phase and for low-income cost-sharing subsidies have grown, while the risk-based portion of Medicare's payments has declined. Those trends are counter to the original intent for Part D that plans bear insurance risk and cost-based payments undermine plans' incentives to manage benefits.

Part D's benefit design, with its coverage gap, has also dampened incentives to manage spending. Because brand manufacturers discount prices by 70 percent in the coverage gap, the relative price of brands to generics is artificially lower. Also plans have low or no liability for benefit spending in the coverage gap and catastrophic phase.

Plans typically compete for enrollees based on premiums, and plan sponsors tend to use rebates they negotiate from drug manufacturers to offset premium costs. Pursuing rebates has become more of a focus of plan

sponsors and in some cases, rebates can be larger than the benefit costs plans are responsible for covering.

Manufacturers know that Medicare provides a lot of cost-based reimbursement in Part D and that plans want to pursue rebates to keep premiums down. In turn, those factors may affect drug manufacturers' decisions about how they price their products. Sometimes drugs with competing therapies have high list prices but the manufacturer provides large rebates to the plan. However, beneficiaries often must pay a percentage coinsurance of the gross prices at the pharmacy, which are higher than prices net of rebates. And those list prices also affect Medicare's program payments.

Let's look at the benefit structures for enrollees without the low-income subsidy on the left and with the low-income subsidy on the right. These figures depict the benefit for brand-name drugs and biologics. The region between the initial coverage limits and the out-of-pocket threshold is called the coverage gap.

In the coverage gap, plans, which are shown in blue here, are responsible for just 5 percent of spending on the left and, on the right, none of spending for low-

income subsidy enrollees. Plan liability is 15 percent in the catastrophic phase for both types of enrollees. Rebates for some brand-name products can exceed plans' benefit liability.

For beneficiaries without the low-income subsidy on the left, the 70 percent manufacturer discount in the coverage gap applies only to brand-name drugs. Instead of 5 percent, plans are liable for 75 percent of the cost of generic drugs in the coverage gap. The discount distorts price signals between brands and generics.

There's no manufacturer discount for low-income subsidy enrollees on the right. Medicare's low-income cost sharing subsidy pays for nearly the entire coverage gap. Medicare's reinsurance pays for 80 percent of the costs above the out-of-pocket threshold.

What this shows is that the current structure doesn't give plans strong incentives to push back on high drug prices or to manage spending.

As we showed you last month, plan sponsors are responsible for much less benefit spending today than at the start of the program. On your left we compare estimated benefit costs net of rebates for beneficiaries

without the low-income subsidy, with LIS enrollees on your right. Just to remind you, we assumed that plan spending and Medicare reinsurance were reduced by the average percentage rebates reported in the Medicare Trustees report. We applied the same percentage rebates to non-low-income subsidy enrollees and LIS enrollees.

Looking at 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. 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.

One way to restructure the benefit would be to eliminate the coverage gap. Plans would become responsible for 75 percent of benefits 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 higher capitated

payments from Medicare to plans, and a new manufacturer discount.

We think this approach would restore the incentive structure that plans faced at the start of the Part D program and remove features of the benefit design that distort incentives and create inflationary pricing pressure and higher program costs.

MR. ROLLINS: During our January meeting, the commissioners discussed whether our Part D recommendations should have specific parameters for the redesigned benefit, but there was no clear resolution. Since then we have considered this issue further and, after consulting with the chairman, decided to supply specific parameters. One reason we made this decision is because we need to have specific parameters so that CBO can estimate the budgetary effects of our recommendations.

Having said that, the parameters we have chosen are the same ones we used in the illustrative reform package that we discussed at the January meeting, so they should look familiar.

This table shows the key elements of the restructured benefit and how they compare with the current

benefit. Under these reforms, the annual out-of-pocket threshold would roughly equal the amount that beneficiaries now pay under current law.

Starting with the top half of the table, under the restructured benefit, the coverage gap discounts for non-LIS enrollees and the coverage gap for LIS enrollees would both be eliminated. These changes would make plans responsible for a consistent 75 percent of spending between the deductible and the out-of-pocket threshold.

Moving now to the second half of the table, let's look at the changes in the catastrophic phase. Enrollee cost sharing would be eliminated to provide complete insurance protection. Medicare's reinsurance would be lowered from 80 percent to 20 percent, as in our 2016 recommendations. There would be a new manufacturer discount of 20 percent for brand-name drugs and high-priced generic drugs.

Note that the new discount program would differ from the current coverage-gap discounts because it would apply to high-cost generics, as opposed to just brand drugs, and because it would apply to all beneficiaries, both LIS and non-LIS. The remaining costs, 60 percent for

brand drugs and high-priced generics, and 80 percent for all other drugs, would be plan liability.

So here's a graphic where you can see how the restructured benefit would look. The bifurcated structure that you saw earlier is gone and there's a single benefit structure for everyone. The coverage gap has been eliminated, discounts have been shifted from the coverage gap to the catastrophic phase, and plans have more liability than they do now. Medicare would still cover 74.5 percent of the costs of the basic Part D benefit, but more of its subsidies would be provided through capitated payments instead of cost-based reinsurance. Note also that the LIS would continue to cover most or all out-of-pocket costs for low-income enrollees.

We think that some related policy changes would help make the implementation of the restructured benefit successful. First, there would be a transition period where the share of spending covered by reinsurance would gradually decrease and plan liability in the catastrophic phase would gradually increase. This would give plan sponsors time to adjust. Second, as Pat has emphasized, CMS would also need to recalibrate the Part D risk-

adjustment model to ensure that payments to plans are adequately adjusted for differences in enrollees' health status. As we have noted previously, CMS made a similar adjustment when it implemented the ACA's provisions that filled in the coverage gap for non-LIS enrollees.

Finally, commissioners such as Pat and Larry have expressed concern about the ability of smaller regional MA plans to bear more financial risk. After considering alternatives such as private reinsurance, we think that policymakers could guard against unexpected financial losses by temporarily making Part D's risk corridors more generous during the transition period. This could be done by reducing the losses that plans must bear before they qualify for risk sharing, having the government cover a larger percentage of plan losses, or both.

The Commission also believe that there should be reforms that make it easier for Part D plans to control drug spending and thus manage the additional risk they would bear. During our work, we have identified three changes that we think would be helpful.

First, LIS enrollees could be required to pay somewhat higher cost-sharing for nonpreferred drugs. These

beneficiaries now pay the same nominal amount for all brand-name drugs, which, as Commissioners such as Pat and Amol have noted, gives them no incentive to use a preferred product.

Second, plans could be allowed to use formularies that have separate preferred and nonpreferred tiers for high-cost specialty drugs. Plans are currently required to put all specialty drugs on the same tier, which makes it harder to obtain rebates. Adding a nonpreferred tier could help plans encourage the use of biosimilars for Part D drugs when they become available, which is an area of concern that Bruce has raised.

Third, plans could have greater flexibility to manage spending in the protected drug classes. The Commission's 2016 recommendations included changes to the protected classes, and last year we also expressed support for a CMS proposal that would have given plans more flexibility.

Stepping back a bit now, we wanted to highlight how the restructured benefit would affect two specific groups of plans: those that serve low-income beneficiaries and employer-sponsored plans. Plans with heavy LIS

enrollment would see larger increases in plan liability because LIS enrollees are more expensive and are more likely to reach the catastrophic phase.

However, we have found that the overall drug costs for LIS enrollees are actually less variable than the overall costs for non-LIS enrollees. In other words, LIS enrollees are more expensive on average, but their costs are in some ways easier to predict.

Recalibrating the risk-adjustment model would help ensure that payment rates remain adequate, and we think this is feasible given CMS's prior experience updating the model. The temporary enrichment of the risk corridors would also provide additional protection, particularly for smaller regional plans.

We also talked to several Part D sponsors and consulting actuaries about whether plans could bear more risk for LIS enrollees. Our interviewees largely thought plans could bear the added risk, but many said that such a change should be accompanied by a transition period, a recalibration of the risk adjusters, and more tools for plans to manage drug spending. The restructured benefit that we are discussing here has all of those elements.

Part D also has substantial enrollment in employer group waiver plans, or EGWPs, which provide coverage to an employer's Medicare-eligible retirees. These plans receive a disproportionate share of the coverage-gap discounts because they typically provide richer coverage that keeps their enrollees from reaching the catastrophic phase due to Part D's true out-of-pocket provision. These plans would receive fewer manufacturer discounts under the restructured benefit, but they should have a couple of years of lead time to modify their benefit packages.

MS. SUZUKI: This brings us to the Chairman's draft recommendations. There are three parts. The first part would restructure the Part D benefit and the other two parts would make concurrent changes to provide plans with more tools and flexibility to manage spending while providing greater risk corridor protection during transition to the new benefit.
Concurrent changes are structured this way because some changes fall under the purview of the Congress while others fall under the purview of the HHS Secretary.

The recommendations are intended as a package of

policy changes that are essential to balancing the goals of ensuring financial sustainability with beneficiaries' access to needed medications.

The combination of Chairman's draft recommendations would lead to savings in program spending relative to baseline. For the April meeting, we will have a single estimated spending impact that reflects the combined effects of the entire package of recommendations.

The Chairman's first draft recommendation reads: The Congress should make the following changes to the Part D prescription drug benefit: below the out-of-pocket threshold, eliminate the initial coverage limit; eliminate the coverage-gap discount program; above the out-of-pocket threshold, eliminate enrollee cost sharing; transition Medicare's reinsurance subsidy from 80 percent to 20 percent; require pharmaceutical manufacturers to provide a discount equal to no less than 20 percent of the negotiated price for brand drugs, biologics, biosimilars, and high-cost generics.

This last piece could be a higher rate, for example, based on how quickly spending in the catastrophic phase grows, like Bruce suggested earlier.

The Chairman's second draft recommendation reads: Concurrent with the first recommendation, the Congress should establish a higher copayment amount under Part D's low-income subsidy for nonpreferred and nonformulary drugs; give plan sponsors greater flexibility to manage the use of drugs in the protected classes; modify Part D's risk corridors to reduce plans' aggregate risk during the transition to the new benefit structure.

The Chairman's third draft recommendation reads: Concurrent with the first recommendation, the Secretary should allow plans to establish preferred and nonpreferred tiers for specialty-tier drugs; recalibrate Part D's risk adjusters to reflect the higher benefit liability that plans bear under the new benefit structure.

The recommendations are intended as a package of changes that would provide better formulary and pricing incentives which in turn would lower costs and premiums and cost sharing paid by beneficiaries. But there are many moving pieces and uncertainty in how stakeholders may respond. In this and the next few slides, we highlight some of the key implications for Part D beneficiaries, plan sponsors, and manufacturers.

One major implication is that the elimination of cost sharing in the catastrophic phase would provide all non-LIS beneficiaries with more complete financial protection. That, in turn, would improve access to both clinically appropriate and inappropriate therapies. LIS beneficiaries using preferred drugs would not be affected by the change to add a higher cost-sharing tier for nonpreferred drugs.

Similarly, beneficiaries using drugs on preferred specialty tier would either see no change or a reduction in their out-of-pocket spending. However, beneficiaries taking medications on nonpreferred tiers would need to switch to another medication, pay higher, nonpreferred cost sharing, or seek tiering exceptions.

Finally, the effects of restructuring on beneficiary premium would depend on the policy parameters like the catastrophic discount rate chosen, and other factors such as changes in drug prices and the distribution of spending across different phases of the benefit, and how well plans are able to manage benefit spending.

For plan sponsors, the restructured benefit would restore the risk-based payments and provide stronger

incentives to manage spending. It would also reduce the financial benefit of including high-price, highly rebated drugs on their formularies.

However, because there would be no cost sharing once a beneficiary reaches the out-of-pocket threshold, plan sponsors would have fewer tools to manage catastrophic spending. Formulary flexibility and new tools may give plan sponsors greater leverage to negotiate higher manufacturer rebates for some products.

Risk-adjusted payments would compensate sponsors for new plan liability and reduce incentives for risk selection, and modified risk corridors would provide greater financial protection during transition. The protection would be available to all plans, but in practice, it would be more valuable for smaller plans with lower capacity to absorb large and unexpected costs of new therapies.

There may be effects on manufacturers that are broader than Medicare, such as the effects on investment and R&D, but here we will focus on the effects that are specific to Medicare. In general, eliminating the coverage gap discount and replacing it with a new manufacturer

discount in the catastrophic phase would shift much of the discount liability from manufacturers of brand-name drugs and biologics with relatively low prices to manufacturers of drugs and biologics with higher prices.

We anticipate that that change would affect manufacturers' pricing behavior, but the effects on pricing probably would vary, depending on factors such as Medicare's market share and the degree of competition within the therapeutic class.

Because plans would have stronger incentives to manage spending and have more tools, some manufacturers may experience lower Part D revenues or diminished ability to raise prices.

At the same time, some manufacturer may launch at a higher price.

This final slide provides a summary of all of the Chairman's draft recommendations. As I said earlier, the recommendations make up an interrelated package that is designed to restore market-based incentives.

Here, we list major changes. Under the restructuring, plans become responsible for 75 percent of spending between the deductible and the out-of-pocket

threshold. Enrollees would be protected from high out-of-pocket costs. Insurance risk for the catastrophic benefit would shift from Medicare to plan sponsors and pharmaceutical manufacturers. At the same time, the recommendations would provide plans with more tools and flexibility to manage spending.

These changes would restore the risk-based capitated approach envisioned in the original design and eliminate program features that distort market incentives that create inflationary pricing pressure and higher program costs.

We'll keep this slide up for your discussion today. We're particularly interested in getting your input on the specifics of the Chairman's draft recommendations that would inform our preparation for the next month's meeting.

DR. CROSSON: Thank you, Shinobu, Rachel, Eric, not just for the presentation but for the development of this rather excellent body of work.

We are now open for clarifying questions, and I'm going to emphasize to the Commissioners that we want to try to preserve as best we can the time for discussion.

Questions? Brian. Brian, Bruce, Amol.

DR. DeBUSK: First of all, thank you for a great chapter.

If you could go to Chart 12, just for clarification, when you say a discount equal to no less than 20 percent of the negotiated price, this is pre-rebate price. This is not net of rebates.

MS. SUZUKI: Yes.

DR. DeBUSK: Okay. And second question, are we going to assume that DIR is back-allocated in a manner similar to how it's done now? Are we going to be silent on how we --

MS. SUZUKI: So, currently, CMS allocates the DIR based on the spending in the catastrophic phase that's for the insurance versus the rest of the spending, which is gross spending.

In changing the benefit structure and reducing the reinsurance of 20 percent, plans would keep the rest of the DIR, but they would also be liable for spending on the remainder of the benefit.

So if CMS doesn't change the formula for reallocating, they would continue to use the proportion of

DIR that's attributable to reinsurance, and the remainder is kept by the plan sponsors.

But I guess what I'm trying to say is under the policy, plans are liable for a much bigger share of the benefit cost.

I think you're remembering a couple years back when we raised this as an issue, and I think that is no longer a major concern.

DR. DeBUSK: Okay. Thank you.

DR. CROSSON: Bruce?

MR. PYENSON: I've got a question on Slides 9 and 13. If we could go to 9.

Could you describe what your criteria for successful transition is? Does that mean that the LIS, that people stay in the same plans, they like their plan and they stay in it, or does it mean a lot of choices? What is your criteria for successful transition?

MR. ROLLINS: I think for successful transition, you're hoping to avoid sort of unexpected outcomes. So, in this case, I think mostly what we had in mind were unexpected large losses in certain types of plans.

To the extent that you have evolution in the

plans that are offered during beneficiary choices about the plans, where they want to receive their Part D benefits, you would expect some changes, I think, as a natural course of some of the recommendations we're remaking. Plans will take another look at what they put on their formularies and what their coverage looks like. So it's reasonable to expect that beneficiaries may change which plans they're enrolled in, and I think that's part of the normal course of Part D.

I think we're looking to guard against sort of unexpected sort of bad outcomes.

MR. PYENSON: It sounds like more the financial outcomes for the plans.

MR. ROLLINS: Yes, I think so.

MR. PYENSON: Thank you.

On Slide 13, the items there on particular changes to allow Part D plans to better manage formularies and spending and utilization, we had some discussion on mandatory generics, which are routine in the commercial world. Is that included in one of these bullets, or is that undefined? I'm curious why that's not in the Chairman's recommendation.

MR. ROLLINS: That had been a topic that had been raised at some of our previous discussions, but I don't know that it ever really at least sort of -- in my mind sort of crystallized to a point of something where I thought there seemed to be a consensus. So that's certainly something that's been discussed, but it's not specifically part of this recommendation.

MR. PYENSON: Finally, on Table 5 of the reading material, there's a list of 1,021 plans that the LIS are enrolled in, including 187 basic PDPs and 126 PACE programs. Do you have a thought on how many plans there really are in terms of the administrators? My impression is the market is heavily consolidated, and there's only a handful of PBMs that are behind that.

DR. SCHMIDT: Yes. I think that's accurate.

In our March report to the Congress, which will come out any day now, we've got some discussion about the relative concentration of plan sponsors, enrollment, plan sponsors for PDPs versus MAPDs. It's less concentrated for MAPDs and PDPs, but you're correct that many of the MAPDs are contracting with large PBMs. So it's a bit more concentrated than even we show in that report.

DR. CROSSON: Thank you, Bruce.

Amol?

DR. NAVATHE: On page 51 of the reading, you had outlined -- I think it's also in Table 9. You looked at the variation, the coefficient variation in the spending for LIS and non-LIS beneficiary enrollees as a way to think about the adequacy of risk adjustment, essentially, and I was curious. So I agree with the interpretation that you guys had, which was it doesn't suggest that this would create an automatic disadvantage, but part of what I was wondering, have we looked at either the outliers or the residual? Because while variation could be larger, what we'd be more interested in from a risk adjustment perspective is what of that variation is not explained by the risk adjustment model. So, in some sense, we're most interested in the variation of the residual as opposed to the outright variation itself in the spending. I was curious if you guys have looked at outliers or variation of the residuals.

MS. SUZUKI: We have not looked specifically at the residuals, but what we have looked at is above the catastrophic threshold. Spending for LIS has a lower

average and lower variant than spending for non-LIS enrollees, which seems to indicate that they, again, will probably not be disadvantaged relative to non-LIS enrollees in the risk adjustment model.

DR. CROSSON: Kathy?

MS. BUTO: I wonder if you can remind us how much Medicare spends in Part B and then sort of what is the rate of growth in Part D versus, say, in pharmaceutical spending overall, even though I know it's harder in the overall because that's combined with health plan spending. Do we have a sense of that?

Then, secondly, whether this proposal restructuring would have an impact on the rate of growth, I suspect it would, although it looks to me as if we're mostly about restructuring the incentives here. But I'd just be curious to know if you think it's going to make a difference in the spending growth.

DR. SCHMIDT: So total spending, we have, again, from our March report in 2018, about $98 billion, and part of that is including enrollee premiums. So net of enrollee premiums, it's closer to 80-ish.

Let me pull up the tables on rate of growth and

spending. Do you remember that off the top of your head?

MS. SUZUKI: Six to 7.

DR. SCHMIDT: Six to 7 percent, I think, is the overall average. How that compares relative to commercial spend --

MS. BUTO: Is it about the same?

DR. SCHMIDT: It's maybe roughly the same.

MS. BUTO: But you'd expect this to have an impact in lowering that rate of growth since Medicare will absorb less than the catastrophic or will take on less risk in the catastrophic phase, or have you not thought about that or estimated it?

MS. SUZUKI: I think there are a lot of moving pieces, and we do think that providing plans with stronger incentives would tend to slow the growth potentially because of their formulary decisions. And that may in turn affect manufacturer pricing and rebate decisions.

But at the same time, with the cap discount, there are certain cases where manufacturers may launch at a higher price, and depending on the market share for Medicare, they may continue to increase prices. So there are a lot of uncertainties where it's really difficult to

say how growth rate would change.

DR. CROSSON: Assuming that next month we approve this, there will be, I can guarantee, many analyses of the impact of this set of proposals.

But I would point out the one, which is the potential for higher launch prices, and I do anticipate that that's likely to happen, and that this Commission or Congress will need to address that at some point as, in all honesty, is already being considered. And we've already at this Commission discussed some ideas about how to deal with that.

Marge, Pat.

MS. MARJORIE GINSBURG: Yeah. This is a very quick question related to this discussion.

On page 17, down at the bottom, it says that Medicare's total payments to plans for the basic benefit would remain unchanged if there are no behavioral responses by plan sponsors, manufacturers, and beneficiaries. Is that what we're talking about here? Is the behavioral responses to this, it assumes it will be static, therefor will do fine? If in fact manufacturers, plans change their MO, then, of course, it's a different ball game. I just

wanted clarity to make sure that's what we were referring to here.

DR. SCHMIDT: Give us a second. We're catching up with you with where you saw this. Right. Bottom of page 17, we're seeing.

So that was, frankly, giving us a little headroom. We don't know what all of the behavioral responses will be. Obviously, the goals of this is to try to encourage some behavioral response. That's the point of having this in the first place, and we're hoping that plans by bearing more risk will have greater incentive to take a look at their formularies and try and ensure that it's both giving beneficiaries access to good therapies but also looking for those therapies that are lower cost. So that's the overall goal here.

We're trying to make the point that when we are changing the nature of the subsidy, we're keeping the overall subsidy the same, and it's just more of it taking place in a capitated form as opposed to a cost-based form.

DR. CROSSON: Pat?

MS. WANG: On Slide 9, can you say a little bit more about the transition period and what would be

transitioned? So this might contemplate that the benefits are standardized like right off the bat, and that the reinsurance layer is what transitions?

Okay. So the first bullet describes phasing in the higher plan liability vis-a-vis CMS. What about the manufacturer discount? Where's the cap discount in the transition?

MR. ROLLINS: So I think as we have thought about the transition, there would be certain -- obviously, we have a lot of moving pieces in this package. There would be certain things that would be implemented immediately or all in one go, and one of those would be the discount program. The current coverage gap program would run through December 31st of a particular year, and then starting January 1st, you would have a new discount up in the catastrophic phase of the benefit.

Similarly, in our thinking, the filling in of the coverage gap and having plans be responsible for that interval of spending would also be implemented all in one go. The part that would be transitioned in would be in the catastrophic phase once you have the discount there of the remaining sort of 80 percent of spending, what mix is going

to be reinsurance, and what mix is going to be plan liability.

DR. CROSSON: Okay. Let's proceed with the discussion again. What we're doing here at this meeting is preparing the minds, collectively, for the vote that we're going to have next month.

We've got a summary slide up there that you can refer to, any one of the three recommendation pages, if you wish, but I would like to see Commissioners' level of support for this package.

It is a package. To the extent that you support that, I'd like to hear it. To the extent that you would not, I would like to know that and any suggested changes that you have in mind.

Brian?

DR. DeBUSK: Again, fantastic chapter. I've watched this work evolve since 2016. It just keeps getting better and better.

I did do a really clean read twice of this chapter because I've been seeing the incremental version for so long. You guys put it together. Not only is it technically outstanding, but it also -- I mean, it's just a

very well-written document.

I do support all the changes -- I mean all the recommendations as proposed.

What I want to ask is that we keep a close eye on rebates because -- they're running about 27 percent. We have built a structure that should create a drag on rebates, and I think if we see rebates creep up above the 27 percent mark, it means that someone has figured out how to undo the reforms that we've done.

But it looks very well thought out and very, very methodical, and I really appreciate the way you guys brought this together and just incrementally kept making it better and better.

So, again, I wholeheartedly support all the recommendations.

DR. CROSSON: Amol?

DR. NAVATHE: I also agree. Very well written. I think very well done. Excited to support this wholeheartedly.

I think the part that I'll just circle back to my question on is I think it will be crisper for us in terms of articulating the rationale behind the risk adjustment

model to actually look at the unexplained variation.

From everything you are describing here, it looks like we'll be fine, so to speak, but if we're really going to talk about risk adjustment model, suggest that it's equitable, looking at variation by itself is not enough. So we would need to take that next step, and it seems like analytically it should be a feasible step. So I suggest that we do that.

DR. CROSSON: Let's see. I've got --

DR. PAUL GINSBURG: Jaewon.

DR. CROSSON: Yeah. Bruce is in there too. Hang on a second. I'm trying to catch up here. I've got Jaewon, Kathy, Bruce, Warner. Did I miss somebody? Pat.

Okay. Jaewon?

DR. RYU: So I would echo that, and in particular, I just appreciate that I know in the earlier discussions, there was some concern around the regional and smaller health plans and the exposure to a lot more risk, and I think you've done a really great job capturing some of the ways that we could dampen that through the transition, whether it's the risk corridors or the stop-loss protections or some of these tools. So I just

appreciate that.

One thing that I wanted to -- sort of a quasi-question and comment. On Slide 17, when you talk about the higher launch prices -- and I know in the reading materials, there was some discussion about, well, it could cut both ways as far as the implications on the launch price, but I thought there was a concept in the reading materials that I think is worth maintaining as a design feature of sorts, which is the discount, the manufacturer's discount in the catastrophic, if there's a way to sort of anchor it against a benchmark, and then if there's a rate of inflation beyond the benchmark, to proportionately increase that discount. I thought that sounded like a way that we can mitigate some of the effects of potentially higher launch prices, and in the slides at least, it didn't make its way in there.

I know there was some discussion in the material, but I think it would be helpful to keep an eye on that.

DR. CROSSON: I agree with that, Jaewon, and I think we should make sure it's emphasized at least in the text. It is one type of approach that's being talked about more broadly in government circles about indexing

increases, and I think in this regard, it's useful to emphasize it. I agree.

DR. SCHMIDT: Could we mention something in the first recommendation? If you look at the wording of Recommendation No. 1, the last, very last bullet there at the bottom, it says no less than 20 percent. So we were trying to give some wiggle room to that concept there, and I think our intention was to have wording around the recommendation.

If you guys want to do this, that's along those lines. That's consistent with what you're talking about, Jaewon.

DR. RYU: Gotcha.

DR. CROSSON: Okay. Bruce. I've got Bruce, Warner, and Pat. Kathy, I'm sorry.

MS. BUTO: Very short. I want to support the overall structure. I really commend you because I think this is a brilliant rethinking of the benefit and will address some of the big distortions in the current benefit package.

I think you've done a really good job of addressing the issues around LIS plans and some of the

mitigating factors in the structure. So I just want to thank you for that. And, yeah, I support it.

DR. CROSSON: Thank you, Kathy. Bruce.

MR. PYENSON: Yeah, thank you very much. I am an enthusiastic supporter of the structure that has been created here, and the work that's gone into it is fantastic.

I am very much opposed to a transition as it has been described. Part of my enthusiasm for the new structure is that it creates an opportunity for new market entrants who have a different model of bringing prescription drug benefits to Medicare beneficiaries.

As Brian has talked about and others have talked about, the current model is heavily based on rebates and driving financial feasibility. The transition that's being proposed basically creates a barrier to new market entrants. It does that because any new market entrant is going to need to succeed at the current rebate game or face large financial losses in the transition period. And that means it either has lots and lots of capital, or if it doesn't have a lot of capital, it's going to be impossible to play in both -- have a foot in both boats.

So I'm very much opposed to the transition of catastrophic, and I think it's really not necessary. I think there's other ways to protect the financial viability of plans. Risk corridors is one way, but there's other ways to do that. But I think if we go with a transition, we're going to miss the kind of opportunity that we saw when the ACA was launched, the marketplace, and we saw new entrants coming into the market and launching new products and new ideas and new styles. And if we had a transition from the old individual small-group insurance into ACA, that probably wouldn't have happened.

So I think there's a real value in not having a transition, which would encourage new entrants. And some of the ways that can happen is with organizations that may go direct with delivery as opposed to through drug stores. There's all sorts of things being out there and talked about, but having the transition in catastrophic is going to either force large losses on new entrants or discourage them.

DR. CROSSON: Okay. You both want to come in on this point? So do I.

So, Bruce, what you're talking about is not a

permanent phenomenon, correct?

MR. PYENSON: It's permanent. We have an opportunity, a one-time opportunity to allow new entrants.

DR. CROSSON: That's what I don't understand. Why do you see it as a one-time opportunity?

MR. PYENSON: Because there's going to be -- currently, for example, you look at the stability in the market for LIS. The LIS had been an attractive market for new entrants because there were plans coming and going and there was auto assignment and things of that sort. That has gone away. So the ability to go out and sign up lots of people, which is critical for any kind of insurance business and volume, depends on either the fluctuation in LIS or having a really attractive product out there.

Now, take those one at a time. To have an attractive product at launch means a low premium and great benefits. Currently, you can do that if you're very successful at getting rebates. So that's the old market, and the financial viability depends largely on the low plan liability and catastrophic and also the gap. So a transition basically preserves that, and it's very hard for a new plan without volume to get the rebates to make an

attractive offering. Therefore, you have to plan on large losses for a couple years while the transition goes on.

DR. CROSSON: I see that, but, you know, given the number of Part D plans that already exist, I think -- and my inference here is that you believe that these new market entrants would be so dramatically more effective, lower cost, providing better service, or whatever, that that's an opportunity that should not be let go. Is that what you're saying?

MR. PYENSON: Yeah, I think there's organizations with ideas on how to do this and how to deliver, and we shouldn't anchor them one foot in the old model and one foot in the new model.

DR. CROSSON: Okay. I understand. Kathy and Brian wanted to come in.

MS. BUTO: This is on this point also.

DR. CROSSON: Just on this point. All three of you on this point.

MS. BUTO: I guess my question to Bruce would be, or maybe to Rachel and Shinobu, would be: Would it be possible to allow new entrants that want to adopt the total model -- the new model right off the bat to come in without

having to go through that rebate transition while allowing existing plans that need that transition to adopt it? If they really want to get in without having to go through that model that they don't want to adopt, is there a disadvantage or additional risk to a plan that wants to go whole hog? That's my question. If they're anxious to get in and they can offer a better model, is that a possibility?

DR. CROSSON: Okay. So Dana, Brian, and Pat also want to come in on this topic. Dana first.

DR. SAFRAN: I was going to ask the same question, and the idea was it could actually accelerate the move to this for the existing plans because, otherwise, they risk losing market share to the new entrants who are giving a much better deal to the beneficiaries.

DR. CROSSON: Thank you. Brian.

DR. DeBUSK: That's exactly where I was going.

[Laughter.]

DR. DeBUSK: Bruce, you started the point. You two finished it really well. There's an opportunity here to tease apart the plan risk by using the risk corridors. You can mitigate as much of that risk as you want to with

the risk corridors. But the transition, you do have an opportunity to disrupt the rebate-based business model. So it's exciting to be able to not disrupt the plan but disrupt the business model, and I think Bruce touched on it, and you guys really drove that point home.

DR. CROSSON: Is there agreement breaking out here?

[Laughter.]

DR. CROSSON: I'm not exactly clear, but go ahead, Pat.

MS. WANG: So, you know, if it's feasible without creating market distortions to do some sort of hybrid model, I guess I wouldn't object to that. But, you know, I'm not really sure what kind of innovative, new sort of thing you're describing there and whether it's mainly on the PDP side, Bruce. But as an MAPD, I have to tell you I really want a transition. The risk adjustment is not known and how well that's going to cover things. So I think it's sort of going all the way, sort of let's just go straight into this with so many unknowns out there, you're kind of betting the farm on a lot of plans that today serve a lot of people very well. And I for one would not be in favor

of that.

The other thing is I'm not really sure we could have this conversation of the new entrants from the ACA that you thought were so kind of disruptive, because the ones that I'm familiar with all went bust -- the co-op plans, some of the new hospital launches, sponsored plans. The plans that have succeeded in the ACA are Medicaid plans that were here for a long time. There are regional Blues plans. So I guess I'm not sure -- you know, it's good to hope for disruption in the market, but I'm not sure that I -- maybe I'm not familiar with everything in the ACA, that came from the ACA, but like I said, the plans that I'm familiar with that have actually succeeded and managed to stay without disrupting the whole market because they left a lot of providers unpaid and created a lot of chaos were here before and belonged to that old-fashioned -- sorry -- traditional model.

MR. PYENSON: You're right. A lot of the new entrants went away. There's a few notable exceptions. But I think getting an opportunity that the Medicaid plans had to get into the commercial world was not a bad thing, and that's probably one of the successes of the way ACA was

done. I'm not sure that they would have been able to do that if there had been a slow transition. And for sure, the ACA had its issues with rollout.

DR. CROSSON: Okay. So I think what we'll do here, and recognizing that we've only got a few weeks before the material for the next meeting needs to be put together, is to take a look -- if I've got it right, to take a look at -- Eric is making a face like I've never seen.

[Laughter.]

MR. ROLLINS: I just wanted to clarify it is a single week.

DR. CROSSON: Very quickly, approach the question of whether or not there could be a mechanism by which new entrants, as yet to be defined, could come in under a different set of rules and still maintain market equilibrium or fairness in the market, and if we can develop such a model, then we will have it in the text in the next version. And if not, we can't.

MR. PYENSON: If we're going to do that, I'd like discussion of a no-transition.

DR. CROSSON: You'd like discussion -- I'm sorry.

What? That's what we're talking about. I'm missing -- go ahead.

MR. PYENSON: So you proposing the hybrid model, but in addition, you know, there could be reasons why a hybrid wouldn't work, but to put on the table the no-transition model that we --

DR. CROSSON: When you say put it on the table, you've already done that, so I'm fast-forwarding this to April. Let me try to put words in your mouth. I think what you're saying is, were we to come up with some feasible hybrid model, if you want to call it that, you would still want to make the case in April for no transition. Is that right?

MR. PYENSON: For sure if we decided a hybrid wouldn't work, I'd want --

DR. CROSSON: Yeah, okay.

MR. PYENSON: -- push for the --

DR. CROSSON: Well, then, get yourself warmed up.

[Laughter.]

DR. CROSSON: Because that could happen. I mean, you know, this is how we do it. Everybody says what they think, and in the end, when we come to the package at the

end of the April meeting, we'll have to take a vote. But if you are not satisfied with what we come up with or what we come up with doesn't work and we all agree with that, then you are absolutely free to bring forward this point of view and then determine how it affects your vote.

MR. PYENSON: Well, I heard something else, though. I heard that the staff is going to look at the feasibility of a hybrid model.

DR. CROSSON: We're going to try in the time that's available.

MR. PYENSON: I would ask staff to also look at the feasibility of the no-transition model.

MS. BUTO: Bruce, I think you would have a lot -- I mean, I'm speaking for myself, but a sense that that's a bigger discussion. I think at least my comfort level was increased because of the transition model and the risk corridors and a number of other things. If we go back to how about no transition, I think that's a whole different discussion and just an added section in the --

DR. CROSSON: I'm not sure -- actually, help me here. I'm not sure what the feasibility of no transition -- what kind of analysis that would be.

MR. PYENSON: Well, there's been representations that the need for a transition is because of the financial stability of plans, and that's something that is a routine modeling exercise to show that, whether or not that is important, because if we don't show it, then all it is is a giveaway to the status quo.

Now, I can accept evidence that there is a need, you know, and maybe that modeling will show that there's actually a need from a financial stability standpoint for transition.

DR. CROSSON: Bruce, I -- sorry. I understand the point you're making. My only concern is that to do an analysis in the next week of the financial -- or the likely financial stability of not one plan but many different varieties of plans is not practical. I'm not sure that we would all feel, if the staff tried to do that, that it would be comprehensive enough to answer the question that you're fundamentally raising or to support or, you know, work against the point that you're making. I can't determine that. I'll talk to Jim. We'll talk to the staff. I can't commit to that. If there's anything simple based on just existing information that we could add to

help you in your determination, we'll do that. But an understanding is that we have been working on this for a long time, and I realize that the issue of transition came up more recently than some other issues. But we are faced with the schedule that we have. Okay? Yeah, Paul.

DR. PAUL GINSBURG: One more thing that I want to say is that, you know, the issue of transition, it's not just from things that we can model. It's really a vast array of uncertainties faced by each individual plan as to how effective will their new approaches to formulary management be. And I don't think it's -- I think, you know, in the policy world, the reason we have transitions often is that uncertainty and the ability to get support or to defuse opposition to a policy that in the aggregate is a real improvement. And I think that's why we talk about transitions to be able to generate more support for what to me overall is a very compelling policy.

DR. CROSSON: And where there are a significant number of uncertainties and the potential during a transition phase to make mid-course corrections. You know, you may say -- you may point how difficult that would be to do, but it can be done from a regulatory perspective if, in

fact, during the transition period of time unknown consequences are manifest early and can be corrected. So that's --

DR. PAUL GINSBURG: Yeah. I think the other point I wanted to make is the analogy with the ACA, one of the problems is that there was a significant part of the individual market that were products that were not worth protecting. I don't think we have that situation here if only because the program is new and it's been getting regular policy attention.

DR. CROSSON: Okay. Warner.

MR. THOMAS: Just a couple of points. Generally I'm supportive of the policy. I know we've worked on this a long time, and I think it's great to shift more of the risk away from the Medicare program. Just a couple of comments I would make.

One, I actually disagree with Bruce. I think that there should be a transition given the amount of risk moving from the Medicare plan back to the health plans, because it's a significant amount of risk above the threshold. It goes from 15 percent to 60 or 80, depending upon whether it's high cost or generics. I think that's a

lot of risk to just kind of do day one. So, anyway, sorry to my colleague to my left here, but it's just a different view of that transition.

I would say on the manufacturer discount, I would actually advocate that it's higher than 20 percent. I think the rate you indicated, you created some flexibility there. This has obviously created a big opportunity in the manufacturer area. I think raising their amount of responsibility or discount over that threshold should be something we should consider. I don't necessarily have a number in mind, but maybe it should be split equally with the plan. Or maybe it should be, you know, 80-20 -- you know, I think there should be more than just this 20 percent component, so I would really advocate to put more responsibility over the threshold onto the plan -- or onto the manufacturer. Onto the manufacturer.

DR. CROSSON: Thank you, Warner. Pat.

MS. WANG: So I want to thank you for all of the iterations of the work here, and I do think that the chapter now is really pretty phenomenal. I'm still nervous about the fundamental change, but I really feel much more comfortable because of many of the mitigating things that

you've put in here, including a transition, which I feel strongly needs to be in here.

I am in agreement with Warner's comment about -- I think that you used the example of 20 percent and 35 percent, just, you know, sort of by way of example in the chapter, and I think would really support, absent some compelling reason to the contrary, like it's going to trigger some undesired behavior or impact to increase the manufacturer discount. I think the cap discount itself, the concept of it is a brilliant concept and very, very important in the entire proposal.

I want to echo Amol's comment about trying to understand more about risk adjustment because it is really important. Risk adjustment doesn't really today pertain to the catastrophic layer very much, and so sort of like, you know, modeling it all the way out into the unknown and understanding as much as possible to I think be able to maybe make some helpful suggestions to CMS would be critically important.

I know that we're still having a discussion about the formulary presentation. I appreciate the ability to do that. Notwithstanding the recommendation that I support of

being able even for LIS beneficiaries to differentiate cost sharing for preferred and non-preferred, there's a very large component of LIS beneficiaries who have no cost sharing. The footnote made that clear, you know, nursing home residents, those who are receiving LTSS services in the community, and so I don't want to lose sight of the fact that there's still -- I believe strongly should be some way that plans can at least demonstrate to prescribers with no cost-sharing impact that there's a difference, there's a nudge, there's a suggestion that these are the preferred drugs because the plan has gotten large rebates or whatever on them and would help to manage the risk.

On Slide 14, which is Recommendation Number 3, since this is a package I just wanted to suggest that maybe the wording be slightly modified to say "concurrent with the first and second recommendations." The way it reads now it's like, you know --

DR. CROSSON: Sorry, Pat. I can't quite hear you.

MS. WANG: Okay. Recommendation Number 3, the introduction should say "concurrent with the first and second recommendations." Right now it simply says first.

DR. CROSSON: Good point.

MS. WANG: Thank you.

DR. CROSSON: So Pat, first of all, I think we've already said, as Commissioners, how grateful we are to the staff for this work, but I'd also like to thank the Commission for the many discussions we've had and how rich this has become.

And Pat, I would like to single you out, because I think your contributions to that, based on concerns -- we all understand that -- have really brought this forward into something that is one of our best pieces of work in the last few years. So thank you for that.

Paul.

DR. PAUL GINSBURG: Oh, this is anticlimactic. I just wanted to congratulate the staff and Commissioners and especially Pat.

DR. CROSSON: All right.

DR. PAUL GINSBURG: Back to the one thing of substance I want to say, is that we need to play with the writing to indicate that, whereas we are talking about a 20 percent discount, that Congress could very well decide to go for a larger one, and it wouldn't compromise the

workability of this approach.

DR. CROSSON: So that's a point I think I'd like to test right now. So I've heard a number of comments, including Paul's just now. When we come back with the recommendation for final vote in April, how many Commissioners would like to see that 20 percent number higher?

[Show of hands.]

DR. CROSSON: Fair enough. Okay. Thank you very much Shinobu, Rachel, Eric. Wonderful work again.

We will move on to the next presentation.

DR. CROSSON: Okay. Now we are going to return to our body of work designed to improve the Medicare Advantage program, and we're going to specifically focus once again on the notion of changing the quality bonus program. And we have, again, in this case, a set of draft recommendations to discuss.

So Ledia, Andy, Carlos, Sam, hiding in the wings, bullpen, something. Okay. And who is going to begin? Ledia? Thanks.

* MS. TABOR: Good afternoon. We are here to continue the discussion of the redesigned value incentive

program for MA, or MA-VIP, which addresses the flaws of the MA quality bonus program. The MA-VIP design was initially published in the June 2019 report to the Congress, and discussed at the last November and January Commission meetings. We have incorporated your feedback into the latest chapter you received before the meeting and will highlight some of these changes in today's presentation.

Before moving on, we would like to acknowledge Sam Bickel-Barlow for his work on this analysis.

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.

The QBP uses broad, contract-level quality results that have led to contract consolidation and unwarranted bonus payments, which I'll discuss more on the next slide. The QBP ineffectively accounts for social risk

factors of plan populations, because QBP plans that serve high-needs population are less likely to be classified as high-quality plans. Also, the QBP adds $6 billion per year in program costs, unlike nearly all FFS quality incentive programs, which are budget-neutral or produce program savings.

Many contracts between 2013 and 2018 have been consolidated meaning lower-rated plans are moved to bonus-rated plans and subsumed under the star rating of the higher-rated plan, and therefore receiving unwarranted quality bonus payments. The majority of 2020 MA enrollees are in plans that have some level of consolidation.

Although recent legislation narrowed the opportunities to obtain unwarranted bonus payments through the consolidation strategy, the legacy remains, which means the Medicare program has increased expenditures in unwarranted bonuses; the program and beneficiaries have inaccurate information on quality; the quality data is not representative of performance in a local area; and some plans have unfair competitive advantage in a given market.

The Commission's MA-VIP will address the flaws of the current QBP design, which are presented on the left-

hand side of the table. The redesigned MA-VIP will meet the five key elements of design presented on the right-hand side of the slide, which we'll walk through over the coming slides, followed by modeling results of an illustrative MA-VIP. These design elements form the basis for the draft Chairman's recommendation.

The MA-VIP scores a small set of population-based measures that focus on patient outcomes and experience, as opposed to the current QBP set of 45 measures which includes administrative measures such as Call Center Foreign Language Interpreter Availability.

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.

It is also important to note that this measure set is being used for payment. Medicare could publicly report additional measures of interest to beneficiaries, such as plan disenrollment rates.

In our illustrative modeling of the MA-VIP, we scored the six measures 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, as opposed to the contract level, because as I mentioned earlier, plans have also been practicing contract consolidations to receive unwarranted bonuses. Using market-level measure results provides 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 we'll present today, our reporting unit is a parent

organization within a local area that had sufficient enrollment to reliably calculate measure results.

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 adjustments. Comparing groups with similar patient compositions accounts for social risk factors without masking disparities in 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 is a readily available data source and 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 to 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 that if they improve it can impact their rewards, which can drive quality improvement. 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.

In our illustrative modeling, we set each measure's 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 the last design element and modeling results.

DR. JOHNSON: Rewards in the value incentive program would be financed through a pool of dollars that is funded by a share of plan payments. A key change from the current quality bonus program is that the bonus increases to plan benchmarks would not be used. Instead, the value incentive program would redistribute a share of plan payments based on quality performance.

Reward pools could be distributed within each

local market based on local performance. With this approach, rewards and penalties would be equal in each market, with some parent organizations receiving rewards and others receiving penalties. We conducted our modeling using this local approach.

Given Commissioner interest during the last meeting, we also discuss an approach that would incorporate national distribution. Using a blended approach, reward pools would be split, with one part distributed based on local results and the remainder distributed based on national results. Either approach is consistent with draft recommendation we are presenting today.

This slide compares some key implications of a local or blended distribution approach.

Local distribution controls for varying market conditions, that could cause a plan applying a uniform quality strategy to have different results across markets. Market conditions include the availability of Medicaid and food assistance programs, transportation infrastructure, the level of social risk factors in the population, and the underlying organization of providers.

Local distribution does not redistribute plan

payments across markets, and maintains equal treatment of the MA and fee-for-service programs in each market.

A blended approach would incorporate some distribution of the reward pool based on national results. A national distribution holds plans accountable for local market conditions, and redistributes plan payments from markets with the lowest average MA plan quality to markets with the highest MA plan quality, leading to some markets that have only rewards or only penalties for all parent organizations in the market.

A blended approach shares the strengths and weaknesses of local and national distribution, where plans are held partially accountable for local market conditions, and there would be some redistribution of plan payments across markets.

Now we will turn our modeling of the value incentive program for MA. Our modeling relied on claims and survey data for various measures. The scope of our modeling was limited to the availability of survey data, which are currently collected at the contract level, not at the market level. To address this limitation, we assigned each available survey to a parent organization and to a

market area.

We used local distribution of reward pools in our modeling and limited our analysis to market areas with three parent organizations having sufficient data. This prevents the direct transfer of reward pools from one parent organization to another when only two organizations are present in a local market.

We were able to include 78 unique parent organizations in 61 market areas, for a combined 258 reporting units in our modeling.

When implementing the value incentive program, MA plans would collect survey data in every market to provide sufficient data for local quality assessment.

Over the next few slides, I will discuss the distribution of points scored in a few example markets and the distribution of overall rewards and penalties. In these slides, a zero percent adjustment means that a plan's payments are unaffected by quality performance. Positive adjustments, or rewards, increase a plan's overall payments, and negative adjustments, or penalties, reduce a plan’s overall payments.

In this example, we look at how the MA value

incentive program would distribute rewards and penalties using local distribution.

This figure shows the results for parent organizations in three example markets for the non-fully 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 vertical axis. The top parent organization in Market 2 achieved about 7.3 points, and the bottom achieved about 4.5 points.

With local distribution, the reward or penalty threshold, shown by the three lines, is unique to each market, guaranteeing rewards for the highest performers in each market and penalties for the lowest performers. Parent organizations in green above the line receive a reward, and those in red below the line receive a penalty. The size of any reward or penalty increases the farther the circle is from the line.

Finally, average MA performance varied

significantly across markets in our sample, ranging from about 3.5 to 7.5 points across the 61 markets. We think variation in average market performance is due in part to differences in local market conditions.

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

Our modeling used a reward pool funded with 2 percent of total MA payments. Results from our modeling show that payment adjustments tended to be small, ranging from negative 1.5 to 1.5 percent for parent organizations in a single market. Nearly 80 percent of all payment adjustments were between negative 0.5 and 0.5 percent.

We chose modeling parameters based on other quality programs, but given the small size of the payment adjustments in our modeling, policymakers could increase the size of payment adjustments, by either modifying the performance to points scale so that points achieved were distributed more widely toward the extremes, or by increasing the size of the reward pool. For example, if

the reward pool were increased from 2 to 4 percent, the magnitude of each payment adjustment in this figure would double.

Now, I'll turn it over to Carlos.

MR. ZARABOZO: There are differences in how plans fare in the MA-VIP as compared to the current QBP. Plans enrolling large shares of duals fare better. Large organizations that had an advantage in the QBP system have less of an advantage in the MA-VIP, and a number of organizations not in bonus status under the QBP have positive financial results in the MA-VIP. These organizations are all what are known as regional plans, that is plans that operate in single markets or limited geographic areas.

To look specifically at certain populations, 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 in the next set of bars. 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 stratification in a MA-VIP system.

The QBP benefits larger organizations, which are also the organizations more likely to have been involved in consolidations to boost star ratings. In January 2020, 85 percent of enrollees in the 10 largest parent organizations are in bonus status, compared to 73 percent in other organizations.

Under MA-VIP, organizations receiving net rewards have lower enrollment on average than organizations with net penalties.

In our modeling there were 20 parent organization that received no 2017 QBP bonus payments in any of their markets. Of the 20, eight would receive net rewards under the MA-VIP. The eight organizations were small and operating, as I mentioned, in single markets or a small number of markets.

This brings us to the Chairman's draft recommendation, which reads:

The Congress should replace the current Medicare Advantage quality bonus program with a new MA value incentive program (MA-VIP) that scores a small set of population-based measures; evaluates quality at the local market level; uses a peer grouping mechanism to account for differences in enrollees' social risk factors; establishes a system for distributing rewards with no "cliff" effects; and distributes plan-financed rewards and penalties.

And so the rationale for the draft recommendation, the QBP is flawed and does not provide a reliable basis for evaluating MA quality in meaningful way.

Plans have also received unwarranted bonus payments under the QBP system.

The QBP costs the Medicare program $6 billion a year in added program payments. Making the MA-VIP a plan-financed system that does not involve additional dollars will mean that the Medicare program will be equitable in its treatment of quality incentive programs by putting the MA program on a par with nearly all fee-for-service quality incentive programs, which are budget-neutral or produce program savings.

Compared to the QBP, the proposed MA-VIP will provide the program and Medicare beneficiaries with more accurate information on MA quality, and it is designed to produce a fairer distribution of incentive payments across markets and across the different population groups enrolled in MA.

The implications of the draft recommendation are that it would reduce payments relative to current law. It is not expected to affect beneficiaries' access to plans or plan participation in MA.

It is possible that beneficiaries will see a reduction in extra benefits because plans will have lower

payments. How much of a change there would be in extra benefits depends on how plans respond to lower benchmarks. Bids could go up, but plans may also choose to reduce profits or otherwise lower their cost of providing the Medicare benefit; that is, they become more efficient.

To the extent that more money flows to plans serving high-needs populations, enrollees in those plans could have better extra benefits. From the plan point of view, in addition to possible payment increases, the plans serving high-needs populations would be on a more even footing in competing with other plans in their area because of the stratification approach in determining rewards and penalties.

With the MA-VIP, beneficiaries will have better information on the quality of plans in their area. Plans, however, will have higher administrative costs because of the use of the local area as the reporting unit. For example, more surveys will have to be administered.

We will now put the Chairman's draft recommendation for your discussion. Thank you.

DR. CROSSON: Let me start with one question. Carlos, on the higher administrative costs, I guess I had

the notion that by shrinking the number of quality measurements so dramatically that we might actually see lower administrative costs with the new program, but I think what you're saying is that you think that would be outweighed by the cost of additional surveys?

MR. ZARABOZO: Right.

DR. CROSSON: Okay.

MS. TABOR: I will say it all depends on what the illustrative measure set ends up being. If there are the patient experience and patient-reported outcomes, which are survey-based measures, that will raise administrative costs. If there are measures that require a medical record review, like diabetic control, those will impact plan administrative costs for collecting the results.

DR. CROSSON: Got it. So this is a question of getting to an adequate end because we're going to be dealing with this. Okay. All right. Thanks.

Other clarifying questions? Let's go to David, Jaewon, Brian, Dana. Marge, did I miss you? David, Marge, Jaewon, Brian, Dana, Bruce. Got that. Where do we start? David.

DR. GRABOWSKI: Great. Thanks.

First of all, great work. I really like the way this has progressed.

I think this is a simple question. Maybe I've just forgotten it or missed it in the chapter, but are the special needs plans in this program or not? And if they are, then I guess a follow up to that would be just do you expect any kind of movement, that this will be advantageous for plans serving high-needs groups, and will we see greater entry or just anything to entice duals into those models?

DR. JOHNSON: So far, the special needs plans are in this modeling and would be included in the MA-VIP. In each local market, all of the plans under a parent organization would be grouped together, and then the stratification would happen, so that in our modeling with just full duals and non-full duals. But if additional groups were warranted -- or it could be accommodated, I think that's where it would. Concerns about the selection of plan types would be addressed there.

MS. TABOR: One nuance is the demonstrations were not included in the modeling.

DR. JOHNSON: Correct.

MS. TABOR: Yeah.

DR. CROSSON: Okay. Jaewon? No. Marge. I did it again. Sorry. Marge.

MS. MARJORIE GINSBURG: Thank you. This is such exciting work. It takes my breath away.

A question on page 84 of the report. About halfway down under Conclusion, the Commission has discussed moving Medicare into more value-based payment arrangements where an entity is accountable for both cost and quality of care. I actually don't understand where cost actually comes in here because, theoretically, a health plan can do all these things fabulously and turn around and raise the cost sharing for their beneficiaries, but that's not -- doesn't seem to be reflected in here anywhere about the impact that this may have on the beneficiary.

The original question, other than the overall cost to Medicare by getting rid of the bonus issue, I'm not sure this sentence refers to cost provided to Medicare beneficiaries. Where do you see that?

I have a couple other questions after that, but let's --

DR. JOHNSON: That's a fair characterization. I

think the sentence is more of a general statement about what we believe about MA plans in general, and the cost, holding plans accountable for cost is addressed elsewhere. In this section, we're just looking at the quality of care.

MS. TABOR: One small piece also would be, again, depending on what measures make it into the measure set, is readmissions, for example, does affect beneficiaries if they have cost sharing associated with any subsequent hospitalizations.

MS. MARJORIE GINSBURG: Okay.

MS. TABOR: It's a small piece.

MS. MARJORIE GINSBURG: Well, sort of indirectly.

MS. TABOR: Yeah, exactly.

MS. MARJORIE GINSBURG: And this may be beyond where we are right now, but as we know, with a five-star plan, health plans that are five-star, maybe even those with four-star, have the bragging rights, and with that comes the ability for people to pick their plan outside the annual enrollment period. Are we estimating any kind of effect this might have that allows health plans to have that same power, if you will, that they currently have, or is that an issue for a later day?

DR. JOHNSON: I think an issue for a later day. We have mostly been focused on the ways to redistribute payments as a way to incentivize higher quality.

MS. MARJORIE GINSBURG: Okay. I think that's fine for now. Thank you.

DR. CROSSON: Thank you, Marge.

Jaewon?

DR. RYU: Yeah. You referenced, I think, $6 billion of additional payments flowing through the system right now, and it seems like there's still some elements of what I'll call "gamesmanship" that you also talk a lot about. If those elements of gamesmanship were to come out of the system -- let's say we were able to close those off -- what would the number be? It would be less than 6. What would that excess dollar amount be?

And that gamesmanship, some of it was the consolidation that was minimized through some of the recent rule changes, but I think you also mentioned there's still this dissipation effect, the residual carryover effect until that completely washes out.

There's a new contract kind of dynamic. There's deconsolidation. I think these are some of the things you

talked about in the reading.

If you were to close all of that off, what would that $6 billion turn into?

MR. ZARABOZO: Well, the point about mentioning the, currently, 83 percent using the 2020 stars are in bonus status, and that the dissipation effect that we talked about, the only effect left over from consolidations where we definitely know they move from non-bonus to bonus is that 2 percent.

So going forward, it is at least $6 billion a year because we know 81 percent in the bids coming up will be people in bonus-level status.

So it would be difficult for us to figure out what it would be had there been no consolidations in the past, for example. We would have to go through and figure out, well, where would this contract have landed if this was their service area and here is what they are reporting on, and we really wouldn't be able to do that because we would have to deal with whatever data that we have, which are reported again at the contract level.

So we have these 411 medical records coming from across the United States. So we really have no way of

saying, "Well, what would have happened had these consolidations not happened?"

DR. RYU: What about the other --

MR. ZARABOZO: Well, that's sort of forthcoming. It would increase from 81 percent to a higher proportion, so over $6 billion, in other words.

DR. CROSSON: Okay. Brian.

Pat, on that point?

MS. WANG: Is it all useful to look back to when the ACA was passed? Because the quality incentive program was created there in its current structure as an add-on to the benchmark rates. Was there maybe a score or some projection of how much it would cost? Would that be informative to answer Jaewon's --

MR. ZARABOZO: I believe -- well, looking at the scoring, I believe I could only find like a combined scoring, without separating the quality bonus. But, anyway, at that time also, very small share of people in bonus-level plans. So the expectation would have been lower than where we're at today of 83 percent.

DR. JOHNSON: I think there is a figure in the chapter that shows the share in bonus status over time.

But the hard part about answering the original question, I think, is that even in the initial years of the program, it was still based on contracts, which is not necessarily the level of assessing what the amount of bonus dollars should be in an ideal situation.

DR. CROSSON: Brian?

DR. DeBUSK: Great presentation. It's really nice to see this work evolve.

I have three questions. Number one, I'm assuming market area is MedPAC units? So our bids are county. Our quality is now MedPAC units.

DR. JOHNSON: That's correct.

DR. DeBUSK: Okay. Second question. Are we doing the risk adjustment before or after we separate the populations into the two peer groups?

MS. TABOR: Concurrent with traditional quality measure -- methods were doing it before.

DR. DeBUSK: So you're doing the risk adjustment before, even though the HCC models are split now. For example, there's a dual eligible actually gets a different set of HCC coefficients for -- say for risk adjustment in MA, but for peer grouping this, we're going to wait. We're

going to do them all at once and use one set of coefficients and go down.

MS. TABOR: That's the way we did it in the modeling. That's not saying that's the right way to do it, but that's the method we chose.

DR. DeBUSK: Okay. Just for methodological consistency with the previous?

MS. TABOR: Like with the HVIP.

DR. DeBUSK: That's fine. With HVIP, yeah.

Now, third question, page 44 of the reading material -- and I promise this is not a Round 2 because I have a Round 2 on this, but I want to make sure that I don't embarrass myself by not understanding page 44.

So page 44, you walk us through what happens when a plan goes from bonus to non-bonus, and when they're risk-adjusted benchmark, instead of increasing $72, let's say they -- let's say they stayed at the same status. The risk-adjusted benchmark would go up $72. If they go from bonus to non-bonus, instead it goes up to $46. So, obviously, the rate of increase is curtailed.

And I understand that. I really appreciate all this that you did about the behavioral response, so thank

you. This is great.

But I want to make sure. I'm reading the third row from the bottom. It looks like when their benchmark goes relatively down $26 from $72 to $46, it looks like their dollar change in net medical expenses goes from $53 to $30. So the delta is $26 in the benchmark, and it seems to translate to a $23 delta in net medical expenses. That tells me that 88.5 percent of the benchmark decrease gets passed on to physicians and other providers? Am I reading that right or no?

MR. ZARABOZO: That would be one way to read that.

[Laughter.]

DR. DeBUSK: But is that the correct way to read that?

MR. ZARABOZO: So this would be looking at the very same plan, so to speak. Let's say they made a mistake in the bidding, it turns out. Well, we did this bidding this way, expecting a bonus, and now it turns out we didn't get the bonus. So, yes, this is our circumstance.

So, yes, if you subtracted $53 from the $30, you get a $23 change in the cost of the provision of the

Medicare A and B benefit. That does not mean that providers will get $23 less. It just means that the plan incurs the cost that is $23 lower. How they arrive at getting the $23 lower, because it's in their bid, they're saying we can do it for now, $23 less, than these other plans. They could say, "Well, we've been bad on readmissions and avoidable admissions. We're going to curtail that. We're going to save money there," or "We're having too many specialty referrals. We're going to curtail that. We're going to become more efficient in different ways, which enables us to bring down our bid."

DR. DeBUSK: Yeah. The -- okay.

MR. ZARABOZO: That's what this component is, is the bid for the A and B benefit.

DR. DeBUSK: So the $23, though, is coming out of something --

MR. ZARABOZO: Right.

DR. DeBUSK: -- whether it's readmissions or specialist visits or something.

MR. ZARABOZO: Right. Yes.

DR. DeBUSK: Okay. Thank you.

MR. ZARABOZO: In other words, they have lowered

their bid.

Now, historically, MA has been lowering their bids year over year. We're now at 88 percent compared to fee-for-service is where the bids are. So they do lower bids over time.

DR. DeBUSK: Thank you.

MR. ZARABOZO: Yep.

DR. CROSSON: Okay. Bruce. Oh, did I miss Dana? Dana, I'm sorry. And then Bruce.

DR. SAFRAN: Thank you.

Just a couple of questions. One is I may have missed this before, but is the characterization of the measure set as illustrative new?

MS. TABOR: I believe that in the January -- I think we've always kind of referred to it, but I think in January, I know we made a case to make sure it was called illustrative because -- and if there were even different opinions within the Commission about what measures should or should not be included.

DR. SAFRAN: Push that a little bit farther because every other quality program that we've put forward, unless I'm mistaken, we've put it forward as here are the

recommended measure -- like here's the recommended domains. Here's the recommended measures within the domains. So I'm not understanding why we're treating this one differently.

MS. TABOR: So I will say in the HVIP recommendation, the language is actually very similar here. We say it should score a small set of population-based measures, and the language underneath the recommendation talks about here are the types of outcome measures we could include. And we plan to say the same thing here.

DR. SAFRAN: Okay. Got it.

DR. CROSSON: Dana, we did have one discussion that I remember. I can't remember if it was January or when it was. I think it was before that where we went through the issue about whether to include preventive measures.

DR. SAFRAN: Yeah.

DR. CROSSON: There was a large number of Commissioners, including myself, that felt we did do. So we did have some discussion about content.

DR. SAFRAN: Yeah. I remember that.

DR. CROSSON: Okay.

DR. SAFRAN: That may be part of my confusion,

but I get that we added a domain because of that.

DR. CROSSON: Yes.

DR. SAFRAN: But I was just not following before now that this was illustrative and not the recommended set.

Second question, are you presuming that because most of these are claims-based measures that an additional benefit of this will be improved quality of the dummy claims data based encounter data?

DR. JOHNSON: We hope so.

[Laughter.]

DR. JOHNSON: I don't know that we're presuming, but that is one of the indirect goals. Yeah.

DR. SAFRAN: Okay. And then since I don't expect to have anything at all I need to say on the second round, this is a quasi-comment/question, and that is, what you said about your assumption about increased administrative cost seems like it was primarily based on surveys. I just want to highlight that that doesn't have to be the case, meaning these organizations should be having electronic ways of communicating with their beneficiaries, and that will make the surveys virtually free.

Thanks.

DR. CROSSON: Thank you, Dana. Sorry for the confusion.

On this point, Amol?

DR. NAVATHE: Yeah. On the point of the quality of the claims measures, I feel like I have a recollection. I'm having some memory loss issues myself. But haven't we at some point put in text of a recommendation or at least in a chapter that we recommend sort of higher quality claims data or the encounter data?

DR. JOHNSON: We have recommended that in the past, yeah.

DR. NAVATHE: Just out of curiosity, is there a reason not to include that as part of this recommendation set? Just because it's so fundamental to the quality measurement? It's sort of hard to --

DR. MATHEWS: We can easily cross-reference it and make the point that by including among our small set of measures, measures that rely on encounter data, that that might provide an additional incentive for plans to produce complete and accurate data and cross-reference the prior rec.

DR. NAVATHE: Great. That would be awesome.

DR. CROSSON: Bruce.

MR. PYENSON: A question on the domains, and this picks up on, I think, Dana's question. I recall the last time we discussed this there was an interest in expanding the domains, and I think that led us into some of the expensive ways of getting information such as controlling high blood pressure, hemoglobin A1c.

I wonder if there's measures that can fill in some of the domains without that, without the chart audit. Dana suggests probably surveys of patients can be done inexpensively. But I think there's also -- I wonder if there's ways to put a price tag. There's probably -- I don't know if you've seen dollars per chart audit or something like that. That might be in addition to this. So I think you're nodding your head yes.

MS. TABOR: Well, I will say that I've looked at this before in a previous job, and I think it would vary a lot by plan, by how much it costs to collect a medical record. It depends on how centralized your EHRs are, how integrated your systems are, whether you actually have to go send the nurse out to do a patient record review. Even with the CAHPS surveys, you know, plans spend different

amounts because they may have the survey vendors work especially hard and contact members multiple times to get the surveys back.

So I would just say that there are additional expenses in going to the market-level approach, but I think it would vary a lot by plan. It would be hard to estimate.

DR. CROSSON: Pat, on this point?

MS. WANG: I think that the cost is going to be felt more by plans that are bigger than the market. There are a lot of plans that are in the market right now, and so they're going to have the same level of expense. I don't think it's going to change for them because they're doing whatever sample sizes there are and they're in that local market. So it won't apply to everybody.

MR. PYENSON: Yeah, another question on the applicability of this approach, the MA-VIP, to setting the percent of rebate retained by the plan. Do you have thoughts on applying this instead of stars?

DR. JOHNSON: We haven't discussed it much. We thought that could be taken up at a later date once MA-VIP was settled on.

DR. CROSSON: Pat, new point?

MS. WANG: No.

DR. CROSSON: Sorry. Go ahead.

MS. WANG: And I apologize if this was covered when I stepped out of the room, but on Slide 10, can you remind us what the different advantages and disadvantages would be for a local versus a blended approach?

DR. JOHNSON: So I think the biggest one we discussed is the varying local market conditions. We highlighted availability of Medicaid and food assistance, transportation infrastructure, and different levels of social risk factors in different markets. And to some extent, using a local approach would account for some of the differences across markets. And we did see in our modeling results, of the 61 markets that the average MA quality varied quite a bit, so there's a case to be made that some of those different market conditions played a role in the average difference across markets.

The other aspect we highlighted here was the distribution or redistribution of payments across markets so that those markets that have lower average MA plan quality would see a net decrease in payments across the parent organizations. Those markets and that money would

flow to other markets where the average MA plan quality was higher.

MS. WANG: And then it's somebody's judgment call whether that's desirable or not desirable, right?

DR. JOHNSON: Correct.

MS. WANG: Okay.

DR. JOHNSON: I should say the redistribution would take place under a national distribution. The local distribution would maintain the dollars that come from each market would be redistributed within that market.

MS. WANG: Okay. I have two other quick questions. Have you thought about what happens to the Part D star measures? Where are they in this redesign?

MS. TABOR: So we have thought about -- you know, we're focusing on just replacing the quality bonus program, which applies to MA and MAPD plans, and, you know, the stars for Part D is kind of a separate question that we're not tackling today. And we do think that there are measures in the illustrative measure set that do apply to Part D and prescription benefits in general, like if you have good diabetic medication adherence, then hopefully your diabetes is going to be controlled. So I think we're

capturing that in the illustrative set.

MS. WANG: Okay. Just maybe something to look at because if you're an MAPD, it's just one measure set. I don't think that MAPDs consider them to be separate. It's one bonus program, so it's just something to think about.

The final question that I had is: In the Commissioner's recommendation that the new program be plan financed, is there an opinion that the financing comes from the current benchmark system or are you just reiterating the principle that it should be self-financed? There has been work here on benchmark rates and all the rest, so I'm suspecting that this is agnostic to what the plan payment is so long as this program is self-financed or not, is the question.

DR. JOHNSON: I think that's the right way to look at it, that it is not taking into account some of those other discussions. It's more of a principle.

DR. CROSSON: Okay. Marge.

MS. MARJORIE GINSBURG: Yeah, I just remembered another question I wanted to ask. So we're talking about doing it in locations where there are a minimum of three plans, and I believe there was also discussion that if

you've got too smaller locations, that you might combine together so that you can make them -- but there may also be places where there is no way to logistically combine it, which means we might have some isolated plans scattered throughout that would not be a part of this.

So are they just simply not a part of this, we don't take money from them, we don't give money to them?

MS. TABOR: We considered that kind of an implementation issue. We chose three as kind of a good amount of parent organizations you need to move rewards and penalties around within a market. It could be that there's another number that we should use, and that's something we'd want policymakers to look at. But I think that's -- it could be that you continue to combine up until you get all beneficiaries covered, or it could be that you decide if a plan in a market area doesn't cover at least 100 beneficiaries, they're just left out of the program. So I think that's kind of an open question.

DR. JOHNSON: When we looked at the current enrollment within parent organizations in a market, we thought about 89 percent of beneficiaries would be included in their parent organization in their market before doing

any of the aggregating of geographic areas for small numbers. We didn't model the extent to which we could combine areas and how many more we could gather into the program, but --

MS. MARJORIE GINSBURG: That [off microphone.]

MS. TABOR: Yeah.

DR. CROSSON: Okay, good questions. Now we'll move on to the discussion period, the draft recommendation up there, looking for support, lack of support; if lack of support, why; and how you would recommend a change. I saw Warner's hand first and then Brian.

MR. THOMAS: Yeah, I would just say generally I support this. I think this makes sense. I think we've had -- I think actually Brian has brought this up in prior meetings, you know, this idea that we've got several different changes going on in the MA plan world that are being proposed and what's the aggregate impact of that. So I think that's the thing I get concerns about: Are we getting these rolled up and looked at them kind of in total? Understanding that, you know, they may not all be accepted. You know, maybe none of them will be accepted. But if they're all accepted, I guess the question would be:

What is the impact on MA plans in aggregate?

DR. CROSSON: Brian -- sorry. Go ahead.

DR. JOHNSON: I took that as a question.

DR. CROSSON: Perfectly right.

[Laughter.]

DR. CROSSON: I couldn't tell if it was a rising voice at the end, but it's okay.

DR. JOHNSON: In our March chapter, we looked at current MA plan payments and found that they're about 2 to 3 percent higher than the average fee-for-service rate. And so if we were to remove the effect of coding intensity, which is the unaccounted-for share of coding intensity, which is related to one of our standing recommendations, and if we removed the effect of payments related to the quality bonus program, that would bring average payments down to about 98 percent of fee-for-service. That's from our chapter.

The two other outstanding recommendations that have a direct impact on plan payments are to base the benchmarks on A and B enrollees, which would increase plan payments. The other one is to get rid of the benchmark caps, which would also increase plan payments. I don't

think we have an exact estimate of the amount of payments, but it is greater than 98 percent of fee-for-service, maybe up to 99 or even with fee-for-service, with those four potential -- three recommendations and the issue on the board today taken into account.

MR. THOMAS: So I guess --

DR. CROSSON: Let me just add -- sorry -- that the next topic we have to discuss, which is basing payments on two years of data, would also have an impact. Is that not correct?

DR. JOHNSON: That would be taking into account during the coding intensity recommendation. So that would not be an additional impact out of the four that I just walked through.

DR. CROSSON: Okay. I'm sorry. I didn't understand that. Thank you. Go ahead. I'm sorry, Warner.

MR. THOMAS: So I guess it comes back to is your goal then to target the 100 percent of fee-for-service? Is that the goal? Or is the goal that there should be something slightly above fee-for-service because there's risk being assumed? Or how do you think about that?

DR. JOHNSON: I think from some of the comments

we've heard over the years on the Commission, there's some recognition that the fee-for-service program has a lot of induced demand related from incentives to provide more services. I think Bruce has mentioned the effect of Medigap and having -- limiting the impact of cost sharing for beneficiaries further increases the number of services used in fee-for-service.

I think in some ways it's up to the Commission to decide what the right level is, but leveling to fee-for-service does not seem like a standard that demonstrates a certain amount of efficiency.

DR. CROSSON: Okay. Brian and Amol, and then Jaewon, Bruce.

DR. DeBUSK: Again, really good chapter. I'm going to focus on the way the reductions stack up in a moment, but I do want to say the chapter was technically excellent. I mean, I really like where you guys are going. It's very consistent with the methodology. You're moving toward standards. And I noticed you're getting really close to having ACO comparability. I mean, we could actually do some -- well done. It's just really well thought out.

Just to provide a little help here, I do think you're going to have to do a blended approach. You know, you talk about local versus national. I think blended is probably -- for the reasons that you described really well in the chapter.

I do want to talk about how the cuts stack up. You know, I have talked around this for a while about this idea of progressive MA versus regressive MA, because I definitely think that there are plans that are providing global payments and incentives, at least partial global payments and incentives, to manage a panel of enrollees to a medical expense ratio. I think they're doing some really progressive things in payment. But I also think there's a very regressive MA out that that just codes high and pays low.

It concerns me when we stack up the different cuts that I've seen, because, you know, I see 6 billion in the quality bonus program; I see about another 5, 5.5 billion using two years of fee-for-service diagnosis data to calibrate the HCC model. And to your point, obviously that would come out of the coding intensity adjustment that we would do the other way. But if I'm not mistaken, I

think moving from RAPS to EDS and using two years of that data I think also takes about another 2 percent out. I think I'm looking at 5 billion on either end, and then I'm looking at about 6 billion in the cuts, and then I thought it saw 3 percent in the benchmark reductions. I understand that chapter has been pulled, but we presented it, you know, several months ago. Was it 3 or was it 5 in the benchmark reduction when we linearized the benchmarks?

DR. JOHNSON: I don't know that we came to a conclusion on that. There was some discussion from the Commission about that.

DR. DeBUSK: Did the material present 3 or 5 in the --

DR. JOHNSON: As an example?

DR. DeBUSK: As an example.

DR. JOHNSON: I think it was 5 percent --

DR. DeBUSK: Was it 5? So there's another 7 or 8 billion. You know, billion here, billion there, it adds up. And I'm looking at a stack of about, as I do my math, 20-ish billion. And I don't know that anyone here -- I don't want to put words in anyone's mouth. I don't think anyone here says, hey, let's cut MA by 20 billion. I do

think having a discussion here and doing a chapter on what the appropriate level of funding for MA is would be really, really important. And I do think that directionally this sense that there are excessive payments in the program, I think that's absolutely correct. Just my personal feeling.

But my head's spinning a little bit because we're doing, you know, a few billion here and a few billion there. It would really be nice to see all these really wonderful technical things you're doing, and this is excellent work. What would be nice is to see the technical work not interfering with the overall level of funding of the program. Then let's have the discussion on what the overall level of the funding of the program is and then decide where to insert the reduction. Is it on the quality side? Is it on the benchmark side?

Because getting back to this idea of progressive versus regressive MA, I would like to selectively address or engage or cut the regressive MA, because for the people who are out there trying to work to move toward global budgets and change the relationship with physicians and hospitals, I want those guys unimpeded. And it really struck me on page 44 when I watched the plans that lost

their MA bonus status, when $26 came out of their benchmark, they appeared to take $23 out of their medical expense. And to your point, we don't know if that's utilization or price. But I think we need to understand that a little bit better. And I don't -- again, and I'll be quiet in a moment. I don't want this to be perceived as resistance to reducing MA payments, because I think a reduction is appropriate. But I'd like to see it done in a separate context, even to the point of maybe splitting the draft recommendation that we've seen into one that addresses the technical aspects of the MA-VIP and then a second recommendation that talks about determining the adequate or the appropriate level of funding for MA and then doing that within the context of some of the other technical changes we've made as well.

DR. JOHNSON: Before we get too far away, I just want to say I don't think the $20 billion is a correct summation of the outstanding recommendations. I think that the two big proposals we have or recommendations that would cut out a coding intensity, which address a few of the items you mentioned, and the other one is this one, the VIP program, and collectively that would take MA payments from

about 2 to 3 percent above fee-for-service to 2 percent below fee-for-service.

DR. DeBUSK: So that's about a 5 percent swing?

DR. JOHNSON: Between 4 and 5.

DR. DeBUSK: What's the coding intensity adjustment? How much would that number be?

DR. JOHNSON: Unfortunately, both numbers come out to exactly 2.3, which gets confusing. But it's between 4 and 5.

DR. MATHEWS: Andy, let me jump in here if I could. So Andy is correct that there is a certain nuance to how one might, to use your phrase, stack these things up. And there are recommendations that we've made that would increase payments to plans, but all of these are done under the auspices of increasing the accuracy of payments to MA. So we'll posit that.

The second thing is that when we made any single one of these recommendations, the impacts are assessed and scored by CBO in isolation -- no offense to CBO, but in a fairly isolated and static way. At this point in time, if you did this thing, it would save this many dollars or cost that many dollars. But no one would expect that all of

these recommendations would be implemented at the same time without considering interactive effects or changes in practice that have occurred over time.

So, for example, the coding offset, at the time we made the recommendation, the differential between MA and fee-for-service coding might have been this much; now it's this much.

Similarly, with respect to the recommendation at hand, everyone is a little bit fixated, understandably, because we've emphasized this number exhaustively, on the $6 billion figure. But when this recommendation is implemented, given all of the other puts and takes that are likely to transpire, the kind of washing out of the excess quality bonus payments, you know, that have occurred via consolidation versus the new quality bonus payments that are occurring under the auspices of deconsolidation, the number isn't necessarily going to be $6 billion. And so the recommendation language is agnostic. It's simply plan-financed, and the exact dollar amount might change at the point in time that any such legislation is passed.

I'll say one more thing, and then I'll stop talking. It is obviously a completely rational thing for

all of us at the table to want to think logically about how all of these things fit together, and I absolutely understand that. I agree with it. But we also have a certain utility for, you know, the Congress, and so the Congress is often looking for options, and they aren't necessarily looking for a complete synthetic set of recommendations that would be implemented all at the same time, but they might have a number in mind: I need to get $10 billion out of MA. And one of the functions that we can perform is say, well, you could do it this way, you could do it that way, here's the pros and cons, and to some extent we are providing Congress with options.

And so that's a slightly different way of thinking about, you know, our own policy development process, and I guess it's easier for me to do that because I'm operating in both worlds. You know, from an analytic perspective, I do like to think about how the totality of things fit together. But at the same time, in a very pragmatic perspective, I like to be able to say, hey, you could do it this way, you could do it that way.

So, with that, I will stop.

DR. CROSSON: Sorry. Before you respond, Paul

wanted to come in as well.

DR. PAUL GINSBURG: I was going to say some of the things that Jim said. You know, when we're developing recommendations that are somewhat unrelated to each other -- and by unrelated, I mean you could do some and not others -- you know, our track record with Congress is very good. It's not 100 percent in the sense that, you know, I don't think we should be worried about what happens if they take them all.

You know, I think we do have --

[Laughter.]

DR. PAUL GINSBURG: Congress will worry about that.

DR. CROSSON: Go ahead. That was an ambiguous statement, but that's okay.

DR. PAUL GINSBURG: Okay, yeah. But the other point I made is that I think this Commission -- I don't remember the specific -- has already had an opinion about how MA should be funded in the aggregate compared to fee-for-service, and presumably that still stands unless we go back to it and make a change in that. So I don't think we should lose too much sleep or energy into adding up every

single thing we're thinking of recommending in MA and worry about what they all add up to, because that's just not going to be used in Congress. As Jim said, they're going to see what appeals to them, and if they have a budget goal, they'll make it fit their budget goal.

The other thing I wanted to say is that you also brought up this issue about the progressive MA plans and the regressive ones. I think that's a totally different topic, and that's probably worth discussing, probably at another time. I come into it with some skepticism about what happens. If you try to describe a good plan and a bad plan and everyone lobbies and gets into the good plan rating, you know, I don't know how effective that could be, but it's certainly worthy of a discussion.

DR. DeBUSK: To that point, I mean, you could identify something relatively simple like, say, 30 or 40 percent of their medical expenses flow through global budgets. I mean, there aren't -- it wouldn't be that esoteric how to differentiate.

And Jim, back to your point, I really appreciate what you're saying in that these are independent plans, and I understand you sort of grabbed this chapter off the shelf

or grabbed that chapter.

For the purposes of portability, though, is there any harm in structuring the technical fixes so as to not affect the net flow in or out of the MA program, and then do a chapter that says here is the aggregate net flow and here are the mechanisms you may choose to use to do it.

I think we're saying the same thing. I just -- it's a little odd for me to have -- and I don't know, I mean, Andy, back to your point, it may not be $20 billion. It maybe $16 billion, or whatever the number is on the shelf. It's a little uncomfortable for me to have that almost like overlapping additive recommendations like that. And if I'm the only one then I'll vote yes with the rest of you.

DR. CROSSON: Go ahead.

MS. BUTO: I just wanted to add a couple of thoughts to your point, Brian. One thought is, when you started talking about maybe we ought to look at total payments to MA, my back when up, because having spent as much time in the program as I did on the operational side, the idea that we could somehow figure out what that right number is really -- I'm convinced we could not, number one.

Number two, why wouldn't we want to do that for hospitals, for pharmaceuticals in total? I mean, there are just whole categories of things that you would want to take on, if you had that kind of wisdom, which I don't think we do.

And then, thirdly, I think the other thing that I keep thinking about is this is the MA program and the formula for paying plans now. There may be, as we've done work in the past, a movement towards something more like premium support or some other form of competitive process, for setting the MA plan rates, that we wouldn't want to spend our time doing that kind of what's the right level of, you know, payments to MA plans, because there might be a better way to pay MA plans than we're currently paying, and I think there is.

So I would rather the Commission actually continue work in that area, which is, you know, what's a better way to pay MA ACOs and fee-for-service going forward, and then let the chips fall where they may, rather than focus just on what's the right level of payment for MA plans.

DR. DeBUSK: And I do agree about finding a better way or a more novel way to pay MA, to pay

physicians, to pay providers, all that.

I do note, you know, in our hospital report that we're going to publish, we did add money back in through the bonus program. I mean, any day it's going to come out, where we saw the efficient providers dipping into negative margins.

So, I mean, there's precedent here for using this to adjust the level of funding up or down. Again, if we could make it a little easier to understand and sort out it would be beneficial to me, because I do agree that the levels may be excessive. I just -- it's a little uncomfortable to have them coming from every side.

DR. CROSSON: Let me -- I want to -- go ahead, Carlos.

MR. ZARABOZO: I wanted to mention one thing, that the changes to the QBP, in terms of taking the dollars away, are not quite the same as all the other changes that might reduce payments to MA. Because, of course, not every contract, not every plan gets money from the QBP. And so if you move -- moving from the QBP to the MA-VIP is beneficial for some contracts that are not currently in bonus status and they will, in fact, get more money.

And then the other issue is we've said $6 billion, but something else that can happen is the star system could be such that instead of 83 percent of the people being in bonus status, depending how you do this because of the model, it could be reduced to a far fewer number of people in bonus status.

So this is not -- you can't sort of look at this in the same way as you do the other changes that you might be making, which are across-the-board changes to payments in MA.

DR. CROSSON: I might have, but it's still $6 million savings to the Medicare program.

So let me -- I want to try to see if I can't adjudicate this. God help me. Because I do see several points here. We do have, on the record, and coming up -- which is going to be folded into one other -- a number of recommendations that impact the total payment to MA plans. I don't think that it's going to be terribly valuable, nor do we have time, to try to quantitate that and argue about how many billions it is in the three or four weeks we have left before we have to get to this recommendation.

I also -- I am disinclined to break this

recommendation into pieces. I think we've come this far. I think our position here with respect to how the quality bonus program should be financed is consistent with principles this Commission has used for the last 16 years, because I first dealt with this in 2004, when I was a new Commissioner.

Having said that, I do think that in the final iteration of the chapter that, Jim, we should use language similar to what you just used with us, which is to essentially say we are not taking a position with this recommendation on what the correct level of payment to MA plans ought to be. We have, and acknowledge, that, in fact, we have other recommendations as well that could theoretically impact the total payment to MA plans, and that in the consideration that Congress should take from our recommendation, it should be to take this recommendation as it is, but in thinking through how it goes about its approach to MA payment, should understand that the process of determining what that level ought to be, which we don't know, is likely to be an iterative process.

The reason and the example, Brian -- and I agree

with your example you used about our changing course in terms of how we pay hospitals, which has basically been across the board, and as we did that we watched the Medicare margins fall for efficient hospitals, fall below a level that we thought was appropriate, we midcourse adjusted.

And so we engaged in an iterative process of saying we don't know what the right level of payment to hospitals is, but now we think the right level -- we're not at the right level, and we need to change that.

So I think in the next of how we describe this, making it very clear that again we have multiple recommendations. Neither one individually, nor the sum of them all, should be an indication from this Commission that we think we know what the right level of payment to MA plans ought to be, but that as Congress goes forward and considers our recommendations it ought to make sure that that consideration includes a recognition, over time, of what that level ought to be, and it's likely to be an iterative process.

Does something like that work for people? Okay. Thank you.

DR. PAUL GINSBURG: Amol is next.

DR. CROSSON: Amol.

DR. NAVATHE: So I definitely broadly support the approach and I like what you just outlined, because it struck me that there is a bunch of other design considerations or ways we could structure even the slopes of the point system in terms of what boundary you get, higher bonus or something like that, and a lot of that is not going to be adjudicated in time for this to be -- and shouldn't be, I think, because it's important to get this out there.

I had a couple of points. One thing, I would actually be kind of curious to hear Brian's rationale about wanting to support the blended piece, because as I read you guys', it seemed to me that your conclusion, after going through that analysis -- and I think I may have been one of the people who suggested looking at the blended piece -- was that you landed, say, on recommending more of staying exclusively with the local approach, which I have to say your exposition convinced me of that. And so, Brian, I would love to hear your thoughts on that, actually, as to what, in the chapter, actually convinced you to actually

support the blended rather than the local.

DR. DeBUSK: My concern was the complexity, obviously, of having to do both. But my thought -- you know, you run the risk if you do the national program, or if you do the measurements nationally, you could create these deserts where no matter how well I do I'm not going to stack up well nationally. Obviously, locally you don't want to pay bonus payments in reward for care.

So my thought was if you just -- if you had a blend there, plans could see the opportunity to excel in their own market and then work their way up the national ladder, or plans that are there already at a good spot on the national ladder would see themselves jockeying for position, even within good.

I just like the fact that it could float, was my rationale.

DR. NAVATHE: I see. Yeah, I think the part that convinced me was actually some of the variation analysis that you guys did, that looks like there's so much of the variation is driven by these local market factors, that at the end putting any portion of that payment that's driven at the national benchmark level in some sense is -- it's

moving money or sort of subsidizing certain markets where the conditions might be more beneficial, and it's not really per se rewarding higher quality.

And to the extent that you create this situation where you have on average, lower-performing plans in a particular market, and it's not because of the local market factors, and you might imagine that there would be plan entry to capture on that arbitrage, I would think.

So I felt reassured by the analysis that we could probably be a little bit more assertive if we wanted to. I don't know that we have to, but to be more assertive about sort of exclusively focusing on the local market as the means of sort of adjusting and financing the bonuses around that.

DR. DeBUSK: I could get on board with that. That wasn't -- that was my impression. That wasn't a hard and fast position.

DR. NAVATHE: Got it. Okay.

DR. CROSSON: But to be clear, at the moment we do not have it in the recommendation. We basically have it in the text, leaving it open to policymakers to take our arguments, which I agree, to open that direction, but to

take it under advisement, essentially.

DR. NAVATHE: Right. So I guess we're saying we evaluate quality at the local market level but we're not necessarily specifying the payment mechanism.

DR. CROSSON: That's correct.

MS. TABOR: I think we envisioned that we could, if the Commission wanted to, at the last bullet, add "and distributes plan finance rewards and penalties at a local market-area level," if the Commission wanted to add it in.

DR. NAVATHE: I would be supportive of that, based on what we've understood thus far. I don't know how the other Commissioners feel. I'll let them speak for themselves.

One part, I think, that is worth noting, though, in the paper itself, is on page 51 there was a discussion, particularly starting with the second paragraph, where it talks about distribution according to a plan's performance ranking in the local market. And then I think we started using this language around ranking and eventually moved away from it.

But I got confused temporarily, because it sounded like we were literally going to rank the plans and

not look at the spread between their performance, which could create all kinds of distortions. I figured out eventually that's not at all what we're doing. So if we can ditch that language I think that would be helpful, because it's totally misleading, and not consistent with what we're doing anyways. So I don't think we need it.

DR. CROSSON: Thank you, Amol. Jaewon.

DR. RYU: Yeah. I think at a broad level I like the draft recommendations as well, you know, small set. I do kind of gravitate towards the local market measurement for the same reasons that Amol had said. Peer grouping -- you know, those things all resonate.

I think two points I would make. One is I forget if it was one, two, or three meetings ago, but it was Jon Perlin mentioned, you know, any implications on what we pay the MA plans, just reminding folks that that does eventually get passed on to the provider. So there is, you know, an impact that's not solely health plan. It is provider as well. And as we take all of these things into account, whether it's with the payment updates that we just discussed in the last meeting, or otherwise, I think that's good context to maintain.

The second is around the $6 billion number. So I think what troubles me a little bit is if you go to page 13 of the readings, you say that 37 percent of enrollment in contracts with the current bonus had no history of consolidations; 44 percent had at least one consolidation. And maybe I'm not reading it right, but I kind of interpreted that as, you know, roughly 37 percent or so truly would have earned the bonus -- and I'll use the term "earned" -- versus another 44 percent gamed to get the bonus.

And so if the 37 percent that truly earned is baked into that $6 billion, and there were some folks who have gamed to get it, but if the program had been plan financed from the beginning then those that had gamed presumably would have gotten penalties, and those that had earned would still have earned. And now to go back and take the $6 billion off the table feels like we're rewarding those, or actually not rewarding, but penalizing similarly those who earned and those who gamed.

And so that's the part that doesn't quite feel right to me, and I don't know if you all have any thoughts on that. But it feels like, you know, that would speak

towards a slightly different baseline as opposed to, you know, taking the $6 billion off the board. That's all.

MR. ZARABOZO: Well, I would say, on that point, that those who earned are also more likely to continue to earn. That is, they will be in a positive situation like, you know, the 1 percent added to their, yeah --

DR. RYU: Positive situation but from a baseline that's $6 billion in the aggregate lower.

MR. ZARABOZO: Right.

DR. RYU: Yeah.

MR. ZARABOZO: So instead of being 2.3 percent more, let's say, in payment, it would be maybe 1 percent more in payment.

DR. JOHNSON: I think the other consideration is that 37 percent earned a bonus based on a different set of measures that we think are less relevant to than the MA-VIP measures, and that 37 percent is based on contract configuration that existed at the time, which does not necessarily represent an ideal contract configuration. There could be some historical consolidations or, you know, aggregation of contracts nationally that existed at that time.

DR. RYU: Yeah. Just in no way am I defending the current program. I totally agree, there's a lot of flaws inherent with the current program. It's just the way it was set up, you know, there was still this segment that sort of earned within those confines, and then it feels like there's a segment that's sort of gamed within those confines, and we're treating those two groups similarly, which doesn't feel -- it feels a little draconian. That's all.

MR. ZARABOZO: And we did try to estimate, if CMS were using just the measure set that we were using for determining stars, it would be something in the range of 35 percent of enrollees would be in bonus-level plans. So a lot of the, you know, administrative measures and all these other measures that go into the stars, at least administrative in particular, raise a lot of plans to star level.

DR. CROSSON: Pat, on this point?

MS. WANG: So I appreciate what you're saying about, you know, the plans, in Jaewon's words, that earned are likely to still earn. The difference is, though, that the plans that did not earn are going to actually lose from

their benchmarks, because this is, quote/unquote, "self-financed." And the difficulty that I have, and why I asked before, is the term "self-finance" really more a matter of principle with being agnostic as to what the plan financing is, what the premium level.

Is that -- I just can't help but sort of continue to point out that the current benchmark system produces very, very different comparisons to a fee-for-service equivalent spending. So if in the aggregate, you know, as we've been talking, there are -- you know, it's higher than fee-for-service now, that is certainly not true in 95 percent counties. They are below 100 percent of fee-for-service, and have been consistently.

This proposal does nothing about that fact, and says, well, you're going to go down even further if you don't earn this bonus -- what, 93 percent of fee-for-service?

And, you know, I understand that we can't do everything at once, but I'm also a little sensitive to the wording, Jay, that I think is helpful that you suggested, that it kind of, at least, emphasized that this concept of plan finance is really not a commentary on the adequacy of

the current payment system. And like Jaewon, I am concerned about plans that are not national plans -- they are market-level already -- that kind of have worked their butts off to get the star bonus, and better for their members that are, you know, facing the prospect of a cut.

So it just doesn't -- I feel like at least part of -- and it's deserved. There's been so much gaming of the star system. I think it's really very unfair, and it has cost the program unwarranted amounts of money. But I can't help but feel that the emotional reaction to the gaming is perhaps sort of giving an extra impetus to sort of say, just get rid of it all. I may be wrong about that.

So I think that from my perspective, it's a lot to tackle in here to sort of say we're going to perfect the underlying payment system. But at a minimum I'd really request that we make it clear in the clarifying language, Jay, along the lines that you suggested, that there does need to be a close look at the overall payment system. Maybe in the aggregate people want to bring it down. But looking at the sort of equity across different regions. We've talked about it a lot here. The benchmark system that was enacted with the ACA may not really make very much

sense anymore and it might be time to go to something that's a little more uniform across the country, what have you.

So that's my comment. But as far as the programmatic aspects, I really do want to hasten to say that I think it's great and that what Brian was describing as the technical aspects or just the redesign of the MA quality program is really terrific. I do think we should address Part D. I would have preferred to separate the programmatic change from the financing change, but I'm respectful of the Chairman's preference here, with the caveat that I mentioned.

DR. CROSSON: Thank you, Pat.

Kathy, are you commenting on that?

MS. BUTO: I'm commenting on this.

I wonder if there's a way -- first of all, I cannot remember why we didn't finish -- haven't yet finished the benchmark work, so somebody can remind me.

But in your caveat or your additional language, it might be useful to say something like the Commission continues to look at some of the flaws or shortcomings of the current benchmarking system and would -- I don't know

how to say this without being a little too squishy, but the notion that before eliminate the $6 billion altogether, that we would -- we think that benchmarking should be part of the consideration, something along those lines, maybe not going quite that far. But it just strikes me that there is a relationship between some of the flaws in the benchmarking system and how well we're going to do with eliminating the $6 billion.

DR. CROSSON: Personally, I would be in favor of the first part of that, which I think is accurate, but I wouldn't necessarily go so far as to undercut our own recommendations and say don't do that until you do something else, because we haven't done that work. The reason we haven't done that work is we can't do everything at once.

MS. BUTO: Yeah. That one is super critical, though.

DR. CROSSON: Okay. Bruce is next.

MR. PYENSON: Yeah. I want to congratulate the authors for extraordinary work. In particular, you've convinced all of us of the virtue of a tournament model, which I think is appropriate.

[Laughter.]

MR. PYENSON: Just a couple of things along the lines of nuances. I think finding a way or language to suggest harmonizing the bonus program with the rebate percentage -- and perhaps there's various ways to do that. Make sure stars include all of these or vice versa, all of the domains in particular measures. I think that would be important to avoid proliferating yet another set of metrics out there. That's one issue.

I do want to say I do support Brian's thought of having a penalty for MA plans that don't have a portion of capitated kinds of arrangements or global arrangements, something like that. In particular, that might address some of the -- ties in with the benchmark issues since PPO plans tend to be in rural areas and may be less likely to do that. So I think that's another avenue, another issue to put on our list.

DR. CROSSON: So, Bruce, I'll pile on there because I've tried this before, to not much effect. But I do believe -- and I'm translating, I think, what you're saying is that we have a little dualistic thinking here. We can't resolve it now or even in this term.

The question that I have posed in the past, do we care, should we care as a Commission how MA plans pay their providers? We have split opinions because one point of view is perfectly reasonable is know the risk is being transferred to the plan. The plan ought to be free to decide how it pays its providers.

The other point of view is, well, wait a minute. We spend a lot of time on ACOs and alternative payment models, and they're all focused in on what's the most efficient way to pay providers to try to get the best quality and cost. If that's what we believe in fee-for-service Medicare, why do we simultaneously say on the MA side, we're agnostic to how the plans choose to pay?

I'm bringing this up because -- I brought it up before, and I would commend it to the Commission for future consideration because I happen to think it makes a lot of sense, although I know not everybody does.

Yes, Amol.

DR. NAVATHE: Just out of curiosity, when you say should we care --

DR. CROSSON: Yeah.

DR. NAVATHE: -- I'm curious what all is tucked

under that. Is it should we be collecting that information and measuring variation based on how different plans pay, or is it stepping as far as saying should we be making recommendations around legislation on how Medicare Advantage should be required to pay providers? I guess --

DR. CROSSON: That is what ¬-

DR. NAVATHE: -- that is too extreme.

DR. CROSSON: -- or incented is what you just heard from Bruce. Incented.

DR. NAVATHE: Incented.

DR. CROSSON: Incented. And I purposely was vague.

Marge?

MS. MARJORIE GINSBURG: My question would be -- or is it gathering this information just because it's a big piece that we know nothing about and that we have, if you will, a moral obligation to understand this as completely as we can how Medicare actually functions in this country.

DR. CROSSON: Well, and that would be a starting point. That would be a starting point. Sure. But it has to fit into the workflow.

Jon?

DR. JAFFERY: Yeah. I can't recall where I've seen this, but I have heard some reports that -- and I think it would be good for us to try and collect that data, but the number of -- the percent of MA plans that then turn around and pay their providers fee-for-service is very, very high, in the neighborhood of 85 percent.

I had another comment, and I'll wait my turn. But on this point, I would also be very supportive of this direction, and I will sort of put out there a pragmatic reason that most systems, delivery systems operate in both -- if they're operating in an MA world, they're also operating in the fee-for-service world, and if they're in an ACO trying to get movement in a certain direction. I mean, frankly, it's just not working the other way. So it would be really helpful to have that impetus to help us move in that directly.

DR. CROSSON: I don't want to try to adjudicate it now, but I thought I heard it in a little bit in what Brian was saying as well in terms of is that one way that plans are different.

DR. DeBUSK: I think that is a really good basis of differentiation, and there are some progressive MA plans

out there. I think we need to learn from them. We need to be learning from them.

DR. CROSSON: Yeah.

David, on this?

DR. GRABOWSKI: Yeah. Just quickly to react to Jonathan's point about the 85 percent, that's totally true for hospitals and physician payment. I think in post-acute, they often pay quite a bit below fee-for-service. So I think that's worth understanding some of that variation where these plans might have market power.

DR. PAUL GINSBURG: Yeah. I thought Jonathan was talking about the mechanism --

DR. CROSSON: Mechanism, yeah.

DR. PAUL GINSBURG: -- is fee-for-service rather than the rate.

DR. CROSSON: Okay. Paul is next.

DR. PAUL GINSBURG: I just want to say, first, I suppose the recommendations and appreciate the great work that's been done.

I've thought about the issue of local versus blend with national since we discussed it last meeting, and I came down in favor of local myself. Part of it is that

the MA program has always been a local program, and the competition envisioned is between the MA plan in an area and fee-for-service in the area.

I'm not concerned about a desert in an area. If there are no MA plans that can complete with fee-for-service in an area, then we don't need them. That's not going to be the case in many places, but I suspect we should allow that to happen.

I would be comfortable with actually putting the recommendation -- if everyone feels that way as far as local, we should probably move it back into the recommendation.

DR. CROSSON: Paul, I'm going to bring that up at the end of the discussion for a straw vote.

Jonathan, on that point, then?

DR. JAFFERY: So I'm just trying to make sure I understand it.

If we think about our other value-incentive programs or quality programs in different areas, they are generally national?

MS. TABOR: They are.

DR. JAFFERY: And the rationale, as I recall from

the reading and discussion prior, that a big rationale is that unlike hospitals or ACOs, plans are pretty mobile?

MS. TABOR: That's the predominant reason as well as the other listed out in the paper.

DR. JAFFERY: So, Paul, your comment about if they're not competitive, we wouldn't have them in that area, it seems that that might favor a blend.

I'm not convinced that that's a good enough reason to necessarily just have it all local and not have any national piece of it, just because the plans could move, and if we think that a national approach makes sense in other areas, which I think we have --

DR. PAUL GINSBURG: Well, the moving wasn't a concern of mine.

I think we have national standards for hospitals because our policy thinking has always been about what should hospital quality be.

MA has always been seen as an option for beneficiaries compared to fee-for-service. So we have a situation where fee-for-service from a national perspective is really good as far as high quality, low cost. Why should we care whether we have MA plans at all in that

area? It seems as though, in a sense, to have an MA plan's bonus in a local area, depending on other MA plans in other areas, it just doesn't move my boat or something.

[Laughter.]

DR. JAFFERY: That's not the right vibe.

So would the same thing be true for ACOs, then, and quality metrics around ACOs?

DR. PAUL GINSBURG: No. I would think ACOs would be national, the way we do hospitals nationally, just because our whole approach to -- I think we've had a national approach to how good quality should be.

MS. BUTO: Also, the rates are national.

DR. PAUL GINSBURG: And the rates are national.

MS. BUTO: They're not for MA plans at the moment, anyway. It's a whole different dynamic there, national rate that are wage-adjusted and so no. So I think it's a very different --

DR. JAFFERY: But this is really talking about that quality outcome, not the benchmark or the -- not sure why the rates are the big -- are a big factor here.

MS. BUTO: Well, and --

DR. JAFFERY: I think it's because it interacts -

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MS. BUTO: -- these guys really covered a lot of the local factors that convince me that local made more sense. I was sort of more in the blended camp, but I thought they did a good job of going through many of the local considerations and the fact that MA plans really are a local choice. In a way, you're choosing a system of care, if you will, in a way that you don't necessarily with total fee-for-service, where it's a local system, but they're all paid at national rates. Anyway, I just --

DR. DeBUSK: But if we took an ACO and build sort of like a virtual MA plan out of out, sort of back-constructed its network, I mean, we could apply these same quality measures at the local level. I mean, that's a good local argument just to say let's compare the three MA plans and the two ACOs in this geography just head to head. I mean, there would be some advantage to that.

DR. NAVATHE: I agree with that. I think in the long run, you could end up there when you have the ability to compare across these different programs head to head, but I think Kathy's point is very important, which is the participation mechanism here is tied to the benchmark, is

tied to the bid, is tied to the payment mechanism, and the quality piece is also part of the -- effectively part of the payment mechanism here. And that's different than the ACO program, which is still built on the pure fee-for-service chassis, which is all nationally standardized in terms of rates. So although it's still a voluntary program, as you point out, I think that distinction and how bids and how all that stuff happens at the local level can create a dynamic that supports a local head-to-head competition situation. Whereas, in the national ACO program, that would be harder to construct.

DR. JAFFERY: So, again, I'll go back to the benchmarks. So ACO is a local phenomenon, and I guess I'm still not convinced that there should be a difference here. And the benchmarks for at least some of the ACO programs are adjusted --

DR. NAVATHE: Yeah.

DR. JAFFERY: -- by quality metrics.

DR. NAVATHE: I actually don't disagree with you in the sense that as we're seeing the ACO benchmarks also themselves move to more of a regional -- have a regional component to that, I think the argument could be made that

the problem is not that MA should be national, but rather that ACO should be migrating to more of a regional, because, again, I'm so convinced by the data that shows that so much of a variation --

DR. CROSSON: All right. I'm sorry. We're getting a little off track here.

DR. NAVATHE: All right. Sorry.

DR. CROSSON: We need to move on. I mean, it's a good discussion, but we're behind time.

Before we do finish, I think we've got to -- I want to get a straw poll. So I'm going to give you a choice here in a minute.

Right now, we have the issue not of measurement but of distribution in the text open, preferring local, but making the comparison to a blended distribution, blend of national and local.

We've had a proposal to elevate that preference to a part of the recommendation, which would be attached to the last bullet point there. Is everybody clear on that?

So those of you who would like to leave things as they are in the text and not change the recommendation, please raise your hand.

[Show of hands.]

DR. CROSSON: I'm guessing that everyone else prefers the option of adding that to the recommendation. Please raise your hand if that's what you think.

[Show of hands.]

DR. CROSSON: Okay. I see pretty much everybody there, and therefore, that's what we'll do. So you'll see that again. You'll see that change reflected in April.

Okay. Ledia, Andy, Carlos, Sam, and the bullpen, thank you very much for your work on this, and we'll see you again in April. And we'll move on to the next presentation.

[Pause.]

DR. CROSSON: Okay. We're ready to move on here. We're going to take on -- I think our final discussion, Jim? Yeah. On a mandated report which asks us to look at the impact of changes that the 21st Century Cures Act required the Secretary to make all, but -- most, but not all of which have been made, and Dan is going to take us through that work.

* DR. ZABINSKI: All right. Thank you.

The 21st Century Cures Act of 2016 directed the

Secretary to make several changes to the risk adjustment system for the Medicare Advantage or MA payments, and the Cures Act also directs MedPAC to evaluate the effects of those changes and report our findings to the Congress. And today we'll discuss our work on that mandate.

Before specifically talking about our work on this report, I think it's a good idea to discuss how capitated payments work in the MA program and the role played by risk adjustment.

MA plans are paid monthly capitated amounts for each enrollee, and these payments are the product of a base rate and a risk score, where the base rate is the payment a plan would receive for an enrollee who is expected to cost as much as the national average beneficiary in fee-for-service Medicare, while the risk score is an index that indicates how much an enrollee is expected to cost relative to the national average fee-for-service beneficiaries.

The purpose of the risk scores is to adjust each MA payment to approximate expected costliness. This minimizes incentives for payment selection in which plans would try to find favorable financial risks.

In MA, risk scores are based on beneficiary

characteristics. First, demographic data in the current year, also called the payment year, including age, sex, institutional status, Medicaid status, and a few others, but also beneficiaries' conditions that were diagnosed in the previous year also called the base year.

The mode used by CMS to produce risk scores is its own version of a hierarchical condition category risk adjustment model, or the CMS-HCC model. This model collects conditions that were diagnosed in the base year into larger categories called HCCs that reflect conditions such as stroke, acute renal failure, and 3 HCC for diabetes.

CMS uses regressions to determine how much each demographic variable in each HCC in the model affects a beneficiary's spending on average, and then to determine risk scores for a beneficiary, CMS just adds coefficients from the regression for the beneficiary's demographics in HCCs that apply to them.

The Cures Act requires CMS to make several changes to the CMS-HCC model. One is that the law requires risk score adjustments that are distinctly different for beneficiaries who have full Medicaid benefits from those

who have partial Medicaid benefits.

Previously all beneficiaries who had Medicaid benefits had the same risk score adjustment.

Second, CMS must add or modify HCCs for beneficiaries who have mental health disorders, substance abuse disorders, or chronic kidney disease. Also, CMS is required to add adjustments based on the number of conditions or HCCs for each beneficiary.

And, finally, the Cures Act does not require but does suggest that two years of diagnosis data could be used to determine beneficiaries' HCC when it's available. The CMS-HCC model has always used a single year of diagnosis data.

And CMS has incrementally addressed the changes required by the Cures Act, adding mandated changes one at a time. With each change, CMS kept the previous changes in place. Before 2017, CMS used a version of the CMS-HCC model that didn't include any of the required changes in the Cures Act. Then in 2017, CMS created a version that addressed the requirements for separate risk score adjustments for beneficiaries who have full Medicaid benefits from beneficiaries who have partial Medicaid

benefits. CMS did this by creating separate estimates for six population segments defined by whether they have full Medicaid benefits, partial Medicaid benefits, or no Medicaid benefits, and also by the beneficiary's reason for their Medicare eligibility -- aged or disabled.

Then in 2019, CMS created a new version by building on a 2017 version and adding new or modified HCCs for mental health, substance abuse, and chronic kidney disease. And in 2020, CMS created another new version by building on the 2019 version and adding indicators for the number of conditions for each beneficiary.

CMS has not created a version that uses two years of diagnosis data, but the Cures Act allows until 2022 to fully implement the changes in the law.

Nevertheless, we created our own model that includes all of the changes made by CMS in the 2017, 2019, and 2020 versions and then used two years of diagnosis to determine HCCs in that model.

So to fulfill our mandate for the Cures Act, we evaluated the performance of the five versions of the CMS-HCC model -- one that CMS used before implementing any of the changes indicated in the Cures Act, and then one each

for the four changes that are indicated in the Cures Act.

We used an analytic file of 27.2 million fee-for-service beneficiaries, and these beneficiaries participated in both Part A and Part B of fee-for-service Medicare for all 12 months of 2016, which is our base year, and they also participated in both Part A and Part B of fee-for-service Medicare in at least one month of 2017, which is our payment year.

We then randomly divided that file in half and used one-half for each of the five model versions, where we performed regressions to determine coefficients on each demographic variable and each HCC.

Then using the other half of the file, we used the results from the regressions to determine predicted Medicare spending and risk scores under each model version for each beneficiary in our file.

Now, to minimize incentives for patient selection, a risk adjustment model should produce predicted costs that are, on average, accurately reflective of the actual costs for a group of beneficiaries.

To evaluate how well the different versions of the CMS-HCC model predict beneficiaries' costs, we used a

variable called "predictive ratios," which are the total predicted costs for a group divided by the actual costs for the group.

If a group of beneficiaries has a predictive ratio greater than 1.0, then predicted costs are greater than actual costs and costs are said to be overpredicted by the model. In this situation, Medicare would overpay plans.

And if a group of beneficiaries has a predictive ratio less than 1, then predicted costs are less than actual costs, and costs are said to be underpredicted. In this situation, Medicare would underpay plans for that group.

Then if a group has a predictive ratio of 1.0, predicted costs equal actual costs, and that's what we want.

We started our analysis by evaluating the model that CMS used before 2017, which was before CMS implemented any of the required changes under the Cures Act.

In this model, we found that costs are underpredicted by about 5 percent for beneficiaries who have full Medicaid benefits, and also costs are

overpredicted by about 5 percent for beneficiaries who have partial Medicaid benefits.

In 2017, CMS implemented a model that provided separate adjustments for beneficiaries who have full Medicaid benefits and for beneficiaries who have partial Medicaid benefits. We found this version accurately predicts for both of those who have full benefits and those who have partial Medicaid benefits, meaning predictive ratios are 1.0 for both groups.

However, this version of the CMS-HCC model produces systematic cost prediction errors for some beneficiary groups, especially underprediction of costs for beneficiaries who have ten or more conditions, high base year costs, or conditions that are not represented by the HCCs in that version of the model; and also overprediction of costs for beneficiaries who have relatively low costs in the base year.

Of particular concern is the underprediction of costs for those who have a lot of conditions or who have high base year costs. This tells us that the model does not adjust payments adequately for beneficiaries who are in poor health.

In 2019, CMS began using a version of the CMS-HCC model that continued to have separate adjustments for full and partial Medicaid benefits, but this version also added or modified HCCs for mental health, substance abuse, and chronic kidney disease.

This new version improved on the 2017 version by accurately predicting the costs for beneficiaries in these new HCCs in general.

However, systematic prediction errors remained under this 2019 version. Costs are underpredicted by beneficiaries who have many conditions or high base year costs and overpredicted for those who have low base year costs.

Finally, in 2020, CMS made a change to the CMS-HCC model, resulting in a version that includes the changes from the 2019 version plus indicators for the number of conditions for each beneficiary, which is determined by the number of HCCs.

This version improves on the previous versions by predicting costs quite accurately for beneficiaries who have ten or more conditions in the model.

In addition, there is a small victory under this

version because it slightly improves the cost prediction for beneficiaries who have high base year costs.

Nevertheless, there is still a fairly large underprediction for beneficiaries who have high base year costs and continued overprediction for beneficiaries who have low base year costs.

Now, up to this point, we've discussed what CMS has done, and the Cures Act does indicate that CMS has discretion over using two years of data to determine HCCs, but CMS has not implemented such a model.

Use of two years of diagnosis data has been a feature that MedPAC has advocated for risk adjustment as far back as 2000, so we felt it would be beneficial to evaluate such a model.

In general, use of two years of data produces similar cost prediction results as the other versions that we evaluated, with one exception being that this version has larger underpredictions for beneficiaries who had high base year costs.

Your paper has an explanation for why this happens, and it's kind of complicated, but the underlying reason is that the use of two years of data produces lower

coefficients on the HCCs in the model, which produces smaller adjustments on those predicted costs for each HCC, which results in lower predicted costs for those who have many conditions and high base year costs.

However, use of two years of data has the benefit that it is a simple, effective alternative for addressing the problem of differences in coding intensity between fee-for-service and Medicare Advantage, which leads to overpayments for MA plans. In addition, use of two years of data produces more accurate estimates of the costs for each condition and would help produce less volatile revenue streams for plans.

When we weigh the benefits and disadvantages of using two years of data, we still believe that use of two years of diagnosis data would be beneficial for MA risk adjustment.

Now, our focus for this report is to satisfy the requirements specified in the 21st Century Cures Act.

For today, we will address the Commissioners' questions and concerns about the method and the content of the report.

Then we will address the feedback that we

received and finish the analysis, which will be in the June 2020 report.

In addition, we would like to discuss any issues or ideas for improving risk adjustment in the future.

Thank you.

DR. PAUL GINSBURG: Thank you, Dan.

We are open for clarifying questions, and Brian and Jonathan and David and Amol.

DR. DeBUSK: First of all, thank you for a really interesting report. Great read.

The first question is going to be super, super technical, so surprise. The V24.1 model, the 2020 model that began to incorporate the number of clinical conditions, the HCC conditions themselves are dichotomous variables, right?

DR. ZABINSKI: Right.

DR. DeBUSK: One or zero. You have it or you don't. So the count of your conditions is really just equal to the sum of those dichotomous variables.

DR. ZABINSKI: Correct.

DR. DeBUSK: So if you do get a coefficient when you do the regression that ties back to that count,

couldn't you just distribute that coefficient right back across the individual coefficients that go with the dichotomous variables? Aren't those mathematically equivalent?

DR. PAUL GINSBURG: Yeah, Bruce?

MR. PYENSON: They would be if it was one factor. But the model actually has a variable factor, depending on the count, the number of conditions.

DR. DeBUSK: But you have to pick the top one in the hierarchy. You don't get to pick like two diabetes and then count it as one --

MR. PYENSON: Well, but if you look at the coefficients where the number of HCCs -- it's not a -- it's a funny shape curve.

DR. DeBUSK: Okay, so there is a nonlinearity introduced there.

MR. PYENSON: Yeah.

DR. ZABINSKI: Tell me if I'm wrong on this. I think there's some interaction amongst the conditions that can go on that can --

DR. DeBUSK: Well, there are interaction terms. There are HCC interaction terms on top of that.

MR. PYENSON: The old model had those, too.

DR. ZABINSKI: Yeah, yeah.

DR. DeBUSK: Yeah, they've always been there -- well, not always. They've been there for years. I'm back to -- I couldn't quite understand why we would use the number of conditions, and I was going to ask if we've looked at anything like an inverse sigmoid or introduced some nonlinearity in there, is what I was getting at, because then you could address that where a phrase on the end was really concerning because it does create an incentive to sign up healthy people and enjoy the overpayment.

DR. ZABINSKI: Personally I'm not against using any sort of nonlinear model, but I do know that CMS likes to keep life simple for everybody.

DR. DeBUSK: Well, okay. But this was going to cross over into discussion, but I think using like an inverse sigmoid, like a logic function, would get them, because I was trying to figure out what the congressional intent was around capturing the number of conditions. If you're going to use a sum of dichotomous variables in a linear model, it seems like you don't get anything out of

that.

DR. DeBUSK: Well --

DR. SAFRAN: Can I interject?

DR. DeBUSK: Yes.

DR. SAFRAN: From having built models like that, you do, because the coefficient is going to be -- is different from the coefficients you get on the individual binary variables. The individual binary variables are carrying the effect of that specific condition, and what the sum of the number of conditions that you have is trying to get at sort of the -- it doesn't really get at what you'd get if you had interaction terms, because the complexity of CHF plus diabetes is different from the complexity of diabetes plus depression. But it still gets you a different effect from what you get from the individual binary variables. And models that have the sum of conditions -- I've seen six or more; I've never seen ten or more -- really get a lot more explanatory power than models without the count of conditions.

DR. DeBUSK: Okay. Thank you.

DR. PAUL GINSBURG: Good. Jonathan?

DR. JAFFERY: Yeah, I had the same exact

question. Not really.

[Laughter.]

DR. PAUL GINSBURG: Should we move on?

DR. JAFFERY: I was just happy that I could follow it somewhat. Mine just uses like really small words.

So in the reading it talks about adding -- and in the report -- chronic kidney disease, and the reading talks about adding CKD 3. And I'm just curious why it would not have CAD 4 as well. Do you know the history of that?

DR. ZABINSKI: My guess is that, you know, it -- there might be a couple reasons I can think of. One is that CMS doesn't --

DR. JOHNSON: 4 is already in the model [off microphone].

DR. ZABINSKI: Is it? Thanks, Andy.

[Laughter.]

DR. ZABINSKI: Andy says 4 is already in the model.

DR. CROSSON: David.

DR. GRABOWSKI: So thanks. I also like this work quite a bit. In terms of evaluating the models, you relied

on the predictive ratio. Typically when we see risk adjustment models, we have an r squared that's reported. Did you run that and look at that? My prior is that it didn't probably move a lot, but I think a lot of readers will want to see that in this work.

DR. ZABINSKI: Yeah, maybe I hid it too much. It's in a footnote. The r squared, depending upon hat segment of the population you're talking about, like from 0.09 to 0.12, in that range, is kind of what --

DR. GRABOWSKI: 0.09 to 0.22.

DR. ZABINSKI: 0.12.

DR. GRABOWSKI: 0.12.

DR. ZABINSKI: And, you know, that's what was even before they made this. Making these adjustments had pretty minimal effect on the r squared.

DR. GRABOWSKI: The other question, you used the base year. Why not use the spending year in terms of using the model to predict spending? What's the rationale for using --

DR. ZABINSKI: Okay. Base year spending could be used as a way of observing people who are -- you know,

beneficiaries who are really sick or really healthy. They offer an opportunity for selection. And so if you're not paying -- say you've got somebody who's really sick, you know, last year, and a plan might really want to avoid them, so, you know, that's the sort of information that could be used for selection.

DR. GRABOWSKI: But this is a risk adjustment issue, right? You're just evaluating how much predictive power you're getting from -- but you could do this as a modeling exercise right on that spending year, right?

DR. ZABINSKI: Oh, sure.

DR. CROSSON: Amol.

DR. NAVANTHE: So I'm going to continue some in-the-weeds questions. A couple questions. One, the ESRD status, it looks like on page 14 you're outlining the 2017 beneficiaries must not have had ESRD. So what happens to the ESRD folks in terms of the risk adjustment model?

DR. ZABINSKI: Oh, they have a separate, totally separate, model, and they were not included in the bill, in the legislation.

DR. NAVATHE: Great. Second question. You also noted that, on the slides in here, that the 2017 group only

required one month of enrollment, yet the 2016 required continuous enrollment in the entire year.

DR. ZABINSKI: Right.

DR. NAVATHE: So have we looked at the ability to predict that partial enrollment, because that clearly also impacts the spending.

DR. ZABINSKI: Let's see. How to say it? I hope this answers your question. Okay. They're all the same people. They have to be all in 2016, the whole year, and then they also have to have at least one month in fee-for-service in 2017. Okay? And the reason why we want the entire 2016 is so that we can get a full year of diagnosis data. Okay? And then in 2017, we need a year of -- one month of fee-for-service to get some spending data. That's the year that's used to –

DR. NAVATHE: No. My question is why not requirement enrollment in 2017?

DR. ZABINSKI: I guess because so you can get --

DR. NAVATHE: Effectively some part of the -- there's a likely nonrandom censoring that's happening in 2017, how many months of data you have, and so how many months of data you have is going to be intrinsically

related to the opportunity for spending, right? Somebody who is only enrolled for one month can't spend as much as somebody who is enrolled for 12 months.

DR. ZABINSKI: Yeah. But we annualize it, the spending. If they're in one month they get divided by -- their spending amount gets divided by one-twelfth.

DR. NAVATHE: So again, I guess this is in the weeds, out of curiosity. That would be fine as long as exit from enrollment is effectively random across the duration of enrollment in 2017.

DR. ZABINSKI: True. The only -- again, I could talk all day about this.

DR. NAVATHE: Unfortunately, me too.

DR. ZABINSKI: Yeah. Just one question I would have, where do you want to stop on, okay, to run two months? Three months? You know, what's --

DR. NAVATHE: I guess, I mean, we could dichotomize it. We could quartile. I would just be curious to see if there's differential performance across that enrollment piece itself, because that could be introducing some bias into the model as well. So if it doesn't matter, it doesn't matter, which is great, but if

it does matter then it would be to know that it does matter.

DR. ZABINSKI: I mean, I guess the bottom-line reason why we selected this method is it largely matches the way CMS does it, and we didn't want to deviate from what they do. You know, we want to show, okay, here's what CMS does, and here's what results out of it. And, you know, if we use some method that's a little bit different than what they do then it may not be indicative of, you know, what they would produce with their method.

DR. NAVATHE: Okay. Fair enough.

So the last question I have is, so there's -- when we look at the number of conditions and are adding that to the model, one of the suppositions, in some sense, is that -- and I'm not sure I understood how exactly that variable was added, if it was categorical, if it was continuous, or what have you. But nonetheless, the thought, in some sense, is that the number of conditions itself, all conditions are, to some extent, counted equally. And in other risk adjustment models that are used, you can actually have conditions that are identified, that are negatively associated with outcomes.

And so I was curious if we know if there's any HCCs that have a negative relationship, because if there are any that have a negative relationship then that could potentially be a little squirrely in terms of what we're doing there.

DR. ZABINSKI: You mean a negative relationship in terms of adding to the patient's cost?

DR. NAVATHE: Yeah.

DR. ZABINSKI: Again, following CMS's usual procedure, if a coefficient on an HCC comes out as negative, it's dropped, because CMS is not -- by rule, you know, by their own belief on how a model should work, they don't want to have a situation where, you know, plans would not want to diagnose a condition or potentially avoid somebody who's got a condition because actually their costs are going to be lower.

DR. NAVATHE: Okay.

DR. ZABINSKI: Or the payment is going to be lower because of it.

DR. NAVATHE: So that mechanically answers the question. Thank you.

DR. CROSSON: Okay. Seeing no more questions

we'll go on with the discussion. David, I think you're going to lead off.

DR. GRABOWSKI: Great. Thanks once again, Dan, for this work. I'm going to make just two sets of relatively quick comments, the first on the evaluation criteria that you used and then the second on the ideas that were raised in the 21st Century Cures Act.

So first on the evaluation criteria, I'm also not a big fan of the r-squared but I do think it should be brought out a little bit more in the report. There will be careless readers, like me, that can't see it in the footnotes. I would put it on every kind of column there, table, such that -- that's just a statistic that needs to be reported and evaluated by reviewers and readers.

The second point, and I touched on this with my questions, I'm not certain that the base year is the right year to use for the purpose of checking fits of different parts of the spending distribution. I think the better year is the prediction year. That is, after all, what you're intending to match with these models. This is the spending that determines plan impact.

And if, as you would expect, there is some

regression to the mean -- regression to the mean is on my mind today -- very high spenders in that last year, that base year, are going to tend to fall in spending, and obviously the reverse is going to be true as well.

So I actually think the predictive ratio for that prediction year, those spending percentiles, will look better than those reported here. So I actually think we could do a little bit better in terms of PRs, if we use the sort of spending year versus the base year. So that's a couple of comments on the evaluation criteria.

On the ideas in the 21st Century Cures Act, I think adding additional variables and stratifying by group is perfectly reasonable and a great idea.

I just wanted to react to the two-year lookback period. I understand that we gained something in terms of fee-for-service coding, and I think that's really important. I would note, however, that that applies to some HCCs but not all HCCs, so there are gains there to increase coding but they're not across the board.

The potential downside I wanted to raise with the two-year lookback, so basically you're turning on a flag for an illness two years back but not in the prior year, if

I'm understanding it correctly. And my concern is that less seriously ill individuals are going to be introduced into the HCC group. This will tend to reduce the payment weight on these particular HCCs. And the implication here is that payments are going to be reduced for those more seriously ill that are assigned to that HCC. So you can think of this as diluting the meaning of any particular HCC where this occurs.

And so I think it's a concern. It doesn't mean it's a deal-breaker but it's something you could check, and there's a pretty simple check here that, frankly, can be done without any re-estimation. So what I would recommend is take a look at the payment weights for some of the more important illness groups that you have in your model, and then just compare the two-year to the one-year model. Falling weights here may signal a problem. And so I would recommend we do that check and just make certain that we're not introducing any kind of issues here around sort of less seriously ill individuals in these particular HCC groups.

MR. PYENSON: Is it less serious individuals who are just more individuals? Because when you pick up more people that tends to dilute.

DR. GRABOWSKI: It's going to dilute --

MR. PYENSON: -- everything. It's not necessarily more or less of --

DR. GRABOWSKI: So I think you're making a point maybe about accuracy. Is this actually a more accurate read of the HCC group, that we're getting a more complete group, or is there something different about that individual you're picking up two years back relative to somebody who is in both years?

MR. PYENSON: The big operational thing, the reason I'm very much in favor of the two-year lookback is that some plans spend a lot of money looking for those people that seem to have cured diabetes or other things, you know, things like that, and some plans don't. So by using two years of data you diminish the value of those vendors that are in that business, and it's kind of fairer across the board.

DR. GRABOWSKI: We could have a philosophical debate on what's the preferred measure. I would love to see the statistics here on kind of what the weights look like across the two-year versus the one-year, and get a sense of this issue.

DR. CROSSON: Other comments? So I take that as suggesting that perhaps either everyone is tired and/or there's general support for moving in this direction. Bobbleheads? Yeah.

Okay. Dan is setting some sort of a record here with your presentation and the discussion, but you deserve it. So thanks very much for a very clear presentation, thank you to the Commissioners, and we'll move ahead now to the public comment period. This is an opportunity for any one of our guests who wish to make a comment on the matters before us this afternoon, please come to the microphone so we can see who you are.

* [No response.]

DR. CROSSON: Seeing no one coming to the microphone we are adjourned until 8:30 tomorrow morning. Thanks.

[Whereupon, at 4:25 p.m., the meeting was recessed, to reconvene at 8:30 a.m. on Friday, March 6, 2020.]

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MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Friday, March 6, 2020
8:30 a.m.

COMMISSIONERS PRESENT:

FRANCIS J. CROSSON, MD, Chair
PAUL GINSBURG, PhD, Vice Chair
KATHY BUTO, MPA
BRIAN DeBUSK, PhD
MARJORIE E. GINSBURG, BSN, MPH
DAVID GRABOWSKI, PhD
JONATHAN B. JAFFERY, MD, MS, MMM
AMOL S. NAVATHE, MD, PhD
BRUCE PYENSON, FSA, MAAA
JAEWON RYU, MD, JD
DANA GELB SAFRAN, ScD
WARNER THOMAS, MBA
SUSAN THOMPSON, MS, RN

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29999 W. Barrier Reef Blvd.
Lewes, DE 19958
302-947-9541

AGENDA PAGE

P R O C E E D I N G S

[8:30 a.m.]

DR. CROSSON: Okay. I think we can begin. I'd like to welcome our guests to the Friday morning meeting of the March MedPAC meeting. This morning we have two topics on the agenda. The first one is going to focus on the end-stage renal disease payment system, and Nancy and Andy are here, and Nancy's going to begin.

* MS. RAY: Good morning. Today's presentation will focus on the two policy options to improve Medicare's payments for dialysis services.

I will take you through the first policy option, which is to eliminate the transitional drug add-on payment adjustment, the TDAPA, for new dialysis drugs in an existing ESRD functional category that are already included in the payment bundle. The Commission discussed this option during the January 2020 meeting.

Andy will follow up with the second policy option to replace the low-volume payment adjustment and the rural adjustment with a single payment adjuster. The Commission discussed this policy option during the April and October 2019 meetings.

We will present the Chairman's draft recommendations for both policy options for your consideration.

We anticipate that this material will form the basis of a chapter for the June 2020 report.

So here is some background on the ESRD PPS. I'm going to go over this quickly because you have seen this all before.

The two items to focus on that is relevant to today's presentation:

First, the Medicare Improvement for Patients and Providers Act -- MIPPA -- required all ESRD-related drugs to be included in the ESRD PPS payment bundle. That includes drugs and biologicals that were paid separately before 2011 and the drugs that were bundled before 2011. So when implementing the ESRD PPS, CMS categorized all ESRD drugs into 11 functional categories. The functional categories are listed in your mailing material. They are like therapeutic classes and important for paying for new drugs.

Second, MIPPA required CMS to include a low-volume payment adjustment and gave CMS discretion to

include a rural adjustment. Andy will talk more about these adjustments soon.

So let's move to how Medicare pays for new ESRD drugs. They payment depends on whether the new drug is in one of the 11 functional categories that I just mentioned to you or not.

Looking at the center column, these are new drugs that are not in an existing functional category. 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. Beginning in 2016, CMS established a policy to pay for these drugs for at least two years. After CMS collects sufficient rate-setting data, the drugs are then included in the payment bundle, and the agency adjusts the base payment rate if appropriate.

Our policy option does not change this policy. Rather, our policy option focuses on the right column, the ESRD drugs that are in an existing functional category.

New drugs in an existing functional category are already included in the bundle, and payment for these drugs is covered by the base payment rate. As of 2020, no drug

has qualified under either TDAPA policy.

Our policy option addresses two concerns associated with the current policy of paying a TDAPA for drugs in an existing functional category.

First, 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 drug manufacturers to constrain drug prices.

In contrast, competition increased in 2015, before the TDAPA policy was implemented, when a new erythropoietin-stimulating agent that was not a biosimilar -- and these biologics are used to treat anemia -- entered the market and was directly included in the ESRD bundle. Within one year, about a quarter of patients had switched to the new, lower-cost biologic and total drug costs 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.

The policy option that we discussed in January 2020 calls for eliminating the TDAPA for new drugs in a functional category.

Its goals are to maintain the structure of the ESRD PPS and to create pressure on drug manufacturers to constrain the prices of new and existing ESRD drugs.

Drugs entering the market would immediately be included in the ESRD bundle with no changes to the base rate.

It will be important to monitor how Medicare's payments align with providers' costs and the need for future rebasing. The Commission's annual payment adequacy analysis can help inform policymakers. Each year we also track dialysis drug use and changes in patients' outcomes over time.

As I said up front, this policy option would not

change the TDAPA for new drugs that do not fit into a functional category or the TDAPA for calcimimetics.

So this brings us to the first Chairman's draft recommendation, which reads: The Congress should instruct the Secretary to eliminate the transitional drug add-on payment adjustment for new ESRD drugs in an existing ESRD functional category.

The implications of this draft recommendation is we anticipate it would decrease future program spending for beneficiaries and providers. It is expected to generate savings for beneficiaries through lower cost sharing. It is not expected to affect beneficiaries' access to needed medicines. We anticipate that it would reduce future payments to dialysis facilities, but continue provider willingness and ability to care for beneficiaries.

DR. JOHNSON: We are now going to discuss a replacement for the current low-volume and rural payment adjustments, including a draft recommendation for the Commission's consideration.

Several factors motivated our analysis to develop an alternative to the current low-volume and rural payment adjusters.

First, Commissioners raised concerns about the disparity between urban and rural facilities' financial performance under Medicare, particularly those facilities that are necessary to ensure beneficiary access to care. Dialysis treatment volume is the main driver of the Medicare margin in a given facility, and rural facilities tend to provide fewer treatments and have lower Medicare margins.

Second, the design of the current low-volume payment adjustment, or LVPA, and the rural payment adjustment does not align with the Commission's principles on payments to rural providers.

These principles say, first, that the rural payment adjustments should target facilities that are critical for beneficiary access, meaning those that are both low-volume and isolated; second, that the magnitude of the payment adjustments should be empirically justified; and, third, that the payment adjustments should encourage provider efficiency.

We'll start by discussing the current LVPA. Of the roughly 7,000 dialysis facilities in 2017, about 5 percent received the LVPA which increased the base payment

rate by 23.9 percent for all treatments. Eligible facilities are those that furnished fewer than 4,000 treatments in each of the three years before the payment year in question.

When considering proximity to the nearest facility, the LVPA only considers facilities that are owned by the same parent organization and within five miles from one another.

We have three main concerns about the LVPA's design.

First, the single volume threshold of 4,000 treatments may encourage some facilities to limit services or report inaccurate data in order to maintain eligibility.

Second, the LVPA does not address the higher cost of facilities with volumes between 4,000 and 6,000 treatments per year.

Finally, some facilities are receiving the payment adjustment even though they are not isolated. In 2017, 40 percent of LVPA facilities were located within five miles of another facility.

Now turning to the rural payment adjustment, in 2017, 18 percent of all facilities received the rural

adjustment, which increases the base rate by 0.8 percent. All facilities located in rural areas receive this adjustment, regardless of their treatment volume or proximity to another facility.

Our main concern is the targeting of the rural adjuster. In 2017, about 30 percent of rural facilities were located within five miles of another facility, and about half of rural facilities were higher-volume facilities, furnishing more than 6,000 treatments per year.

Finally, as Nancy noted, the adjustment for low treatment volume is mandated by law, but the rural adjustment is not mandated. CMS introduced the rural adjustment in 2016.

Now we are going to review the low-volume and isolated, or LVI, policy option. The LVI is a single adjustment that would replace the current low-volume and rural payment adjustments and would be targeted to facilities that are both low-volume and isolated.

To model the LVI adjustment, we required facilities to be farther than five miles from any other facility to be considered isolated and to exhibit a low volume of treatments during each of the three preceding

years.

There are a few ways to implement the low-volume criteria. One is to use a continuous function to determine the adjustment size. There is more information about this approach in your mailing material.

We used a categorical approach in our modeling, establishing three different categories of treatment volume, for facilities providing up to 6,000 treatments per year.

Either approach would help mitigate the cliff effect of the current low-volume adjustment and would better account for the higher costs in relatively low volume facilities.

This figure shows the number of facilities eligible for various adjustments on the vertical axis, grouped by the number of dialysis treatments provided in 2017 on the horizontal axis.

For the current low-volume adjustment (in blue), nearly all eligible facilities provided fewer than 4,000 treatments in 2017. Some of these facilities were located within five miles of another facility. The LVPA generally doesn't apply to facilities with between 4,000 and 6,000

treatments per year that also have higher costs.

For the 0.8 percent rural adjustment (in red), about half of eligible facilities were not low-volume, providing more than 6,000 treatments in 2017.

The green bars show the number of facilities eligible for the LVI adjustment. In the lowest treatment category, somewhat fewer facilities are eligible for the LVI because the adjustment targets facilities that are isolated. In the middle two treatment categories (between 4,000 and 6,000 treatments) the expanded definition of low-volume results in more LVI-eligible facilities than those eligible for the current low-volume adjustment.

We think that the requirement that facilities are isolated along with the expanded low-volume criteria more effectively target facilities that are important for ensuring beneficiary access to care.

That brings us to the second Chairman's draft recommendation, which reads: The Secretary should replace the current low-volume and rural payment adjustments with a single adjustment for dialysis facilities that are isolated and consistently have low volume or low-volume criteria are empirically derived.

The draft recommendation is intended to be budget neutral with current policy.

Beneficiaries' access to care would be maintained at facilities that are critical for access to dialysis treatment. Providers' willingness and ability to serve Medicare beneficiaries would be unaffected.

Our analysis shows that payments would increase for providers with lower treatment volumes that are not in close proximity to another facility and currently do not receive the low-volume payment adjustment.

Payments would decrease for providers currently receiving the low-volume adjustment that are in close proximity to another facility. Payments would also decrease for providers currently receiving the rural adjustment, but that have higher treatment volumes or are in close proximity to another facility.

That concludes our discussion of the TDAPA and low-volume payment policies. We would appreciate hearing the Commissioners' discussion about the two Chairman's draft recommendations.

The material covered in today's presentation will be included in a June 2020 chapter on ESRD PPS design

issues.

Thank you. I'll turn it back to Jay.

DR. CROSSON: Thank you, Andy and Nancy. Very clear. We'll now take clarifying questions. I see Brian, Amol, Jonathan, Kathy, Bruce. Brian.

DR. DeBUSK: Warner, I know you want to go deep on these regressions. I'm teasing. I will not go in that direction.

I had a couple questions. Can you tell us the background on the rural adjustment? You said it was introduced in 2016. Was there a specific rationale? Did it come out of nowhere?

And then, also, how difficult operationally -- in the materials you spoke to this a little bit. If you were to try to do the adjustment continuously as opposed to with the thresholds at 4,000 and 6,000 procedures, how hard is that to operationalize? Are there precedents or are there other programs that have similar continuous adjusters?

And then my final question was: Walk me through -- you know, I know there's a lot of consolidation in the industry, and if there was a dialysis center with 3,000 treatments and say one of the two large independent

dialysis centers, and one of the two larger companies decided to say move next door with another 3,000 treatments, I think under this new policy basically the small facility that was already there would get a 23 percent cut basically in their payments simply by virtue that one of the national chains -- if I misunderstood that, correct me, but those were my three questions.

DR. JOHNSON: So taking them in order, I guess, I think the motivation for the rural adjustment is somewhat unclear. There was some mention of MedPAC's rural payment adjustment policies in justifying the rural adjuster, but, you know, in our review of that, we don't think that MedPAC's principles on rural payments were followed as closely as they could have been, and that the joint consideration of isolation and low volume would be important and that the rural adjuster does not do that. So there's not a lot more we can say there, I don't think.

MS. RAY: Yeah, I mean, we can go back to the proposed rule when they announced their intent to implement it. The best I can recall, it addressed stakeholder concern about rural payment issues.

DR. DeBUSK: Along that same line, because I

don't have the March report in front of me, when we broke out rural versus urban dialysis centers, is there a margin differential or is the industry so consolidated we can't really look at it?

MS. RAY: There is a difference between urban and rural margins, which is directly linked to the number of treatments on average that rural facilities provide. They provide lower number of treatments than urban centers. That's not to say that there aren't rural facilities that provide, you know, 7,000, 8,000, 9,000, 10,000 treatments. But, on average, rural facilities, you have a lower average number of treatments than urban ones.

DR. DeBUSK: But if you control for volume, and I look at a rural -- say a cohort of rurals and a cohort of urbans, is there are margin difference once I control for volume? We do that in the March report, I'm pretty sure. Don't we?

MS. RAY: Well, but you said controlling for volume.

DR. DeBUSK: Yes.

MS. RAY: Right.

DR. DeBUSK: If I'm looking at a cohort of --

MS. RAY: Right. So what you're asking for is to compare the margin, let's just say, for example, for a rural facility that furnished 5,000 treatments and an urban facility that furnished 5,000 treatments. I'd have to come back to you with that answer.

DR. JOHNSON: On the second question about the continuous variable, it's certainly feasible. I'm not familiar with every other payment system to say whether or not -- how frequently a continuous variable is used in those payment systems. I think it is more common, at least in the Medicare Advantage risk adjustment model we discussed yesterday, for there to be mostly binary variables and the rest of the variables in the ESRD PPS are binary. But that doesn't mean it's not possible. It is, and we modeled that out as an example.

The final question was about consolidation, and I think, you know, the scenario you proposed was that if a new facility set up shop right next to an existing low-volume facility within five miles, that would mean that the low-volume facility would low their low-volume adjustment. However, for a facility to decide to move within five miles of another facility, they wouldn't receive the low-volume

adjuster for at least three years. As a new facility, they would have to establish three years of low volume in order for them to be eligible for a low-volume adjustment. So there's some disincentive to that type of competition where you're taking a hit for a period of time in order to force somebody out of business, I think is the way to look at that.

DR. DeBUSK: I was just thinking through a scenario if you had someone, say a local or a smaller chain, and I was, say, one of the larger companies, and I said, well, either you're going to sell out to me or I'm going to put a place next door to you and you're going to lose 23 percent of your revenue overnight, I was just trying to play that scenario out and see if that was possible. Thank you.

DR. CROSSON: Amol?

DR. JOHNSON: Using that 23 percent low-volume adjustment, right?

DR. DeBUSK: Yes.

DR. JOHNSON: Yes. It seems like that would be possible if such a strategy was so aggressively pursued, I guess, to take the hit for so many years.

DR. CROSSON: Sorry. Go ahead.

DR. NAVATHE: So one quick thing. On Table 2 in a reading on page 10, I think it might be just a typo, but are the column headings switched between the -- are in an existing ESRD-related functional category and are not in an existing ESRD-related functional category?

DR. JAFFERY: That was my --

DR. JOHNSON: Sorry?

DR. JAFFERY: I had the same.

DR. NAVATHE: Okay, yeah. Because it doesn't line up with the text or the table you showed.

DR. JOHNSON: I think that's right. Let me go back to --

DR. JAFFERY: It's correct here.

DR. NAVATHE: Yeah. It was correct here.

DR. JOHNSON: And the main difference is that last column, whether or not it basically is updated.

DR. NAVATHE: I think the entire -- the column headings are just switched, but anyways --

DR. JOHNSON: Yeah.

DR. NAVATHE: If you could just correct that typo, that would be great.

DR. JOHNSON: Right.

DR. NAVATHE: Just minor.

The other question I had is on the rural facility piece. Have we looked at -- I guess this is a two-part question. One, are there, quote, "validated" or good measures of access, and have we looked at them in the context of -- it seems somewhat -- understanding some of the history here, but the 25 miles, 5 miles, all of that seems somewhat arbitrary, and at the end of the day, what we care less about, is there another facility close by and we care more about if there is an ESRD beneficiary in that locality, can they find a center bed. And in other cases, we might use something -- we should be able to know the number of beneficiaries in a particular area. So could we not do something like a beneficiary to bed ratio or something like that?

DR. JOHNSON: That's something we could look at.

DR. NAVATHE: Okay. Thanks.

DR. CROSSON: Okay. Jonathan?

DR. JAFFERY: So Brian did actually ask my question this time, but it was about the continuous. So I think you answered it, although I guess I'm still not

totally clear about -- I understand it could be done, and it would be administratively more complex. But can you give us a sense of how much better, if at all, you think it would be? I'm trying to understand whether it would be worth the squeeze for the administrative complexity.

DR. JOHNSON: In theory, it should more accurately account for the costs of all of the amounts of treatment volume for those that are eligible. There is a first step, which I think is determining what exactly the right level is to determine who's eligible. We chose 7,000 because it roughly lined up with our other policy, but there's probably an empirical analysis that could be done to determine that.

One concern is about the accuracy of the cost data that is used to estimate this model, and there's a longstanding MedPAC recommendation to audit the cost report data. And there has been an audit going on for a number of years, which we haven't heard the results form yet. So I think the ability to come up with a very specific adjustment, I think, in some ways relies on a valid and accurate set of underlying data in order to correctly specify that, and I think that there is some concern among

us and, I think, people in the industry about that level of data qualities.

DR. CROSSON: Thank you.

Kathy?

MS. BUTO: So my questions are around TDAPA, Nancy. The question about what we know about sort of the motivation behind this change to allow drugs that are already where there are already functional categories to get the TDAPA kind of passthrough payment, whether that's driven by biosimilars, number one.

Number two, when they're folded in, even when the totally new drugs are folded in, how is that done? What kind of adjustment is made that we know about to the base rate, the bundled payment within -- or that payment bundle?

And then I guess I'm also wondering what other categories -- if they're not in the functional categories that exist in the bundle, what other categories are there that you know of? So I guess I'm asking about what drugs got the TDAPA before this other change was made. Do you know anything about that?

MS. RAY: Okay. Good questions.

The motivation of the TDAPA as described in the

agency's rulemaking process, I think it was to promote innovation, simple as that, and --

MS. BUTO: But that's even for the expanded category where there's already a functional category and there are drugs in that category?

MS. RAY: Yeah. Looking at this same again, so recall that -- let's focus on the middle category for a moment. The agency implemented the TDAPA for drugs not in an existing functional category, and that was based on a statutory mandate.

Statute essentially said, you know, "Agency, come up with a way to fold in new drugs into the bundle," and so through the rulemaking process, the agency said, "Drugs not an existing functional category will get a TDAPA for at least two years. During that two-year period, we'll collect the necessary utilization and pricing data to then when we put the drug in the bundle, we'll evaluate whether or not there needs to be a change to the base rate, and we'll add a new functional category." So that's what was implemented in 2016 in the middle category.

MS. BUTO: And are there any drugs that met --

MS. RAY: No.

MS. BUTO: So there's been nothing?

MS. RAY: Nothing.

MS. BUTO: Okay. And that's even totally new, no functional --

MS. RAY: That's correct. Nothing.

MS. BUTO: Okay, got it.

MS. RAY: So then in the 2019 rulemaking process -- so a couple years later in the 2019 year of rulemaking process, agencies said, "We want to promote innovation in ESRD space, and so we want to promote innovation even for existing -- for new drugs in existing functional categories. So what we'll do is we'll pay for these new drugs in an existing functional category for two years. This is our way of promoting the drugs, and then thereafter, they're folded into the bundle, no change to the base rate."

MS. BUTO: Again, totally theoretical. Nothing has happened in this category?

MS. RAY: Not yet.

MS. BUTO: Yeah.

MS. RAY: Not yet.

MS. BUTO: Do you know of any drugs that are in

line to the considered for this and kind of what is your sense of the pipeline? Has it spurred a pipeline of existing functional category drugs or --

MS. RAY: Well, given that this policy -- that the right-hand policy was only -- it first implemented in 2019. I mean, these drugs would have had to have been in the pipeline before that. So I can't answer the question of did it spur innovation.

Again, I'm not a -- I'm neither a pharmacist nor a physician, so I'm not an expert on this, but looking at the dialysis websites I go to --

MS. BUTO: So sorry.

[Laughter.]

MS. RAY: I kind of like them.

It does seem like there may be a couple of drugs that might qualify, but again might, you know.

MS. BUTO: Nancy, last question. So for the existing functional category drugs, the ones that again would start getting considered this year, I guess, was that added by CMS, or was that a statutory requirement as well?

MS. RAY: That was added by CMS.

MS. BUTO: I'm asking because, obviously, if we

recommended a change, is it something that CMS could do was my question.

MS. RAY: Oh, oh, oh. I'm sorry. You're talking about the draft recommendation?

MS. BUTO: Yes.

MS. RAY: Yes. The Secretary does have the discretion to eliminate it, yes.

DR. CROSSON: Andy, I thought I saw your light come on. Do you want to talk about your Web-browsing history or something else?

DR. JOHNSON: No, thanks.

[Laughter.]

DR. CROSSON: Okay. We've got Bruce.

MR. PYENSON: Thank you very much. It's a terrific report.

I want to pick up on some of the questions and line of questioning that Kathy had. I note on the bottom of page 11, towards the top of page 12, you discuss how several years ago, a new market entrant, an EPO beta, very quickly was taken up by one of the big organizations. I think it's public knowledge that the different organizations have long-term obligations to use particular

drugs in long-term contracts.

So I'm wondering. If you've looked at that impact with respect to TDAPA, so whether the situation, the example form 2015 might not apply today?

DR. JOHNSON: We haven't looked at the contracting policies, but I think that issue would arise with any new drug coming on the market, whether or not it is through a TDAPA policy or not, that if it is applicable to dialysis patients, facilities might find themselves in a situation of having to honor longstanding or long-term contracts or switching to a new drug.

MS. RAY: Yeah. The only other thing I would add to that is we are not privy to the contracting agreement. Those are confidential, and it's not clear. If they are long term, it's unclear to us whether there's provisions in that contract that says -- I'm making this up -- something to the effect that if a competitor comes out at a lower cost, then there has to be some change in either the payment arrangement or whatever.

MR. PYENSON: I was just thinking about that in the context. Kathy was, I think, asking about motivation, why TDAPA was expanded to existing categories and whether

that might explain part of the reason.

DR. JOHNSON: I don't think we know whether or not that was part of the reason. I think there was one other step in expanding to -- the TDAPA to existing functional categories, as in the first year, CMS established a criteria that it was only that a drug be new and did not exclude -- it included generics. It included biosimilars. It included classes of drugs that FDA considers new but are only new due to packaging differences or whether or not it has been changed to different statuses, and those criteria were added in the second round.

Given the history, it's not clear to me whether or not that is part of the motivation.

DR. CROSSON: Warner?

MR. THOMAS: So I guess with implementation of this policy, do you have any concerns that it would impact innovation, or what concerns would you have in putting this policy in place?

MS. RAY: I think what's important in implementing this policy is monitoring the adequacy of Medicare's payments over time. As new drugs and other

items are included in the bundle and practice patterns change, I think there needs to be the year-to-year monitoring of payment adequacy and of quality of care.

DR. CROSSON: Okay. Seeing no further questions, we'll move to the discussion period. If you could up the last slide? Just put up the last slide, the summary slide, because I want to take them both together.

I think I will, for the discussion purposes, take both together. We'll be looking for, as we've seen yesterday, relative levels of support for the recommendations. If not, why not? Suggestions. But we'll take both recommendations simultaneously for discussion purposes.

Kathy?

MS. BUTO: I support both recommendations, and I actually would add -- and I'm not sure. We don't have time in this cycle to do it, but it just strikes me that for the category of totally new drugs, not within current functional categories, we should consider looking at tightening the criteria for those. I don't actually know what the criteria are for those, and it's not all that clear. And it sounds like we don't have any examples. So

that makes it hard.

Looking to the next session on the outpatient criteria that we're looking at for trying to align it more with drugs that add some unique benefit, et cetera, et cetera -- and maybe there's a cost element to it too, but that for some cycle going forward, you look at that category because, at least for now, you have no candidates that I can tell in that category. Now would be the time to look at those criteria and considering tightening them. So that would be my only add to the first recommendation.

DR. CROSSON: Jim?

DR. MATHEWS: Kathy, you have actually hit on one of the implications of the next session, which is while we're talking about the OPPS in particular, looking at passthrough drugs and separately payable non-passthrough drugs, if the Commission embraces the algorithm or this is entry that we talk through, there is potentially much broader implication or application of that concept to other sectors, where you need to make a determination of separately payable.

DR. CROSSON: Thank you.

Jonathan, Brian, David.

DR. JAFFERY: Thanks. I also am in support of both of these recommendations, and I just want to emphasize, I think, the points that both Kathy and Jim just made. And even thinking about this in the second column, I mean, I think one of the challenges here is trying to define innovation a little bit.

If there's a new drug that really brings something new, even if it's an existing functional category, it may have a significant clinical or otherwise significant benefit to beneficiaries. Maybe it would be worthy of trying to spread that innovation.

I think one of the big concerns I have -- and maybe hear this from others -- is that there's a "me too" drug possibility, and that may be the likelier thing that happens.

Again, very supportive of this, and maybe these other discussions, the next discussion helps us think through that. But if we can get to these ideas of how do we define clinical innovation, that that becomes a significant criteria as part of the proposal as well, the recommendations.

DR. CROSSON: Thank you.

Brian?

DR. DeBUSK: First of all, I think your TDAPA treatment is excellent. I think it's a good idea. It fixes a badly needed or badly -- could be abused hole in the system.

I do want to talk a little bit about that second recommendation, and if no one else feels this way, then I'm completely on board. So this is not stick in the mud.

I am a little concerned in that this does create the ability to drive more consolidation. I mean, we're in a highly, highly consolidated market, anyway, and it really wouldn't be hard, because we're changing the definition of "isolated." We're fundamentally changing because it's not just isolated. It's isolated with respect to all of your competitors too.

And it wouldn't be hard for someone with, say, a large footprint to just look at where these outposts are, these non-corporate dialysis centers, and can the 23 percent pricing decrease just simply by locating next to them?

The rural thing concerns me a little bit too because we fully adjust the payments for these dialysis

centers by the Hospital Wage Index, but then we don't really capture some of the costs that are associated with being in a rural location. I mean, I'm sure it's a little harder to get service for equipment. I'm sure it's a little harder to fill positions. So it almost seems like they take the full rural hit but don't really enjoy any of the rural benefit.

Again, if I'm the only one that feels this way, then I'm going to vote yes next month, but I just didn't know. And I really wanted to draw on Kathy and some of her experiences too in this area, and Jaewon.

MS. RAY: If I can just add one other issue, though. I mean, so in order to open up a new ESRD facility, CMS requires a medical director, and that's typically a nephrologist. And if you're located in an isolated area, I mean, that's going to be an issue in finding a qualified physician, a nephrologist, most likely, to be the medical director. So in addition, as Andy said, that a new facility that's going to open up next door and try to furnish 3,000 treatments, they're not going to get any payment adjustment for three years. That's the first issue.

And then the second issue is trying to recruit that medical director out there. In terms of business decision --

DR. DeBUSK: If we're comfortable with the level of consolidation and don't think this is going to be a policy that drives even more consolidation then I'm on board.

DR. CROSSON: I think we've got -- did you want to come in on this?

DR. MATHEWS: Just a clarifying question and then say one thing. So the two large dialysis organizations together currently represent 80 percent of the sector, or thereabouts?

MS. RAY: 75 percent.

DR. MATHEWS: Okay. And is it the case that when we've looked at this in close detail it is volume that is the largest driver of cost per case. Is that also correct?

MS. RAY: Yes.

DR. MATHEWS: So, you know, we think that this combined adjustment does indeed capture the higher per-unit costs that the targeted facilities are incurring, and we think that the volume effect probably swamps any other of

the lesser inputs into cost. So I think, at least from the analytic perspective that we've conducted, I think we are okay.

DR. CROSSON: Hold on. Paul wanted to come in on this. Marge, on this point?

MS. MARJORIE GINSBURG: No.

DR. PAUL GINSBURG: Yeah, I was on the list but this is what I want to talk about. What I was going to say is that, you know, given that there are very important scale economies at the facility level, it seems as though the current policy on LVPA is a very dangerous policy. I say even if there are scale economies, if you're small we're going to pay you more, indefinitely. And in a sense, you know, I think getting rid of that incentive, so that we'd say, you know, we'll pay you more, if you're in a situation where higher volume isn't feasible, and that's where we get the isolated situation. If they're at low volume and they're isolated, we figure that's really the best volume they can do, so we need to subsidize that for access.

So I don't know if this is the best strategic thing for a large company that wants to expand in these

isolated areas. I'm not sure why they would. But in a sense, as Nancy has mentioned a couple of times, they're going to have to have this way underscaled facility for three years before they can start getting the subsidies that they're going to drive out their competitor.

DR. CROSSON: Hold on now. We've got Marge on this topic, Warner, and Jonathan on this topic as well? Okay. Marge.

MS. MARJORIE GINSBURG: Definitely related to this topic. What do we know about the individuals who need dialysis, and whether, in fact, there is any way of knowing whether there's a problem with access, that people in rural areas able to access dialysis when they need it? So I don't think any part of this actually discussed are needs currently being met by the location and availability of the dialysis centers.

MS. RAY: So we look at access to care in our payment adequacy analysis, and we do this on an annual basis, and we have not found any systematic problems, issues in beneficiaries' access to rural facilities.

DR. CROSSON: Warner.

MR. THOMAS: So just a question, getting back to

Brian's point. On the LVPA, do we have an idea of how many facilities the two large nationals have that receive that type of subsidy payment? I mean, my impression is that they are targeted more in urban areas, but that's just an impression.

MS. RAY: Yeah. I do, back at the office.

MR. THOMAS: Okay.

MS. RAY: So we can include that in the next go-around.

MR. THOMAS: I mean, I think it gets to Brian's question.

MS. RAY: Yes.

MR. THOMAS: I mean, is this -- I mean, I see where Brian is going with this. I think we don't want to drive more consolidation. But it also comes back to, you know, is that a big number? Are they pretty prevalent in rural areas? You know, I just don't know if that would be something to -- where has growth been over the past few years. I mean, do they saturate urban? Are they going into more rural areas?

DR. CROSSON: Jonathan, on this?

DR. JAFFERY: Yeah. So I think what I'm hearing

from Brian also is this notion that the LDOs would be able to -- despite the fact that they wouldn't get the payment adjustment for a few years, they could eat it. And so that said, I think these protection that we talked about, they need a medical director, I think the other thing to think about, and it maybe gets back a little bit to Amol's question about beneficiary-to-bed ratio is that if you've got a small unit that's doing 3,000 session a year, there's not going to suddenly be another cohort of patients there, in that area.

And so I think that there are a number of things that make some of the risks -- mitigate some of the risks in some of the other payment policies around pushing towards home dialysis also is a big direction that things are happening in the industry. That said, I think it is really worth monitoring the impact, particularly on consolidation. I mean, that's come up several times this cycle, is that we've got a very unique situation in this sector, with the degree of consolidation, that I know has been concerning for all of us. And so that may be something we want to revisit a little bit in the next year.

DR. DeBUSK: And to that point, you know, one of

the large operators, 75 percent of the industry, is in urban area. Let's go find a place on the fringe of this urban area that does 3,000 treatments per year. If it's one of the large operators, I can simply call them and say you're either going to sell your business to me or I'm going to build one next door to you, and if I do, you're going to take a 23 percent price cut. So I want to buy your business at an impaired rate. I mean, this is kind of how M&A is done. I mean, this would not be that hard to do.

DR. JOHNSON: I think one other issue is that the facilities with 3,000 treatments are not majorly profitable. These are not the facilities that somebody is going to want to swoop in and "I want to take over your zero or slightly negative margin."

[Laughter.]

MS. RAY: Yeah.

DR. DeBUSK: Well, until I can make sure and use all of my equipment and drugs that come from my subsidiary, you know --

DR. CROSSON: Okay. Paul wants to come in and then Bruce, do you want to come in on this point as well.

DR. PAUL GINSBURG: I had a thought that might help that might help out a little bit on this, which is if you have a situation where someone is getting the subsidy under our scheme, and is all of a sudden no longer isolated, you could delay their losing the subsidy, which would make it that much more expensive for predatory type behavior, and make it really much cheaper for the large entrant to just buy the small facility.

DR. CROSSON: Bruce.

MR. PYENSON: Yeah. I liked the solution that Paul has proposed. I point out the profitability issue changes with consolidation, and likely the underlying financial dynamics of larger organizations. And don't forget that when you have large organizations that need to grow, that's sometimes when they expand into the areas that might not be as profitable as the core one. So it's not uncommon to see that happening in the business world, or bad choices sometimes, expansion.

So I think considering those effects would be important, so I agree with Brian that there ought to be a solution to this.

DR. CROSSON: So here's my suggestion, that in

the next draft, the final draft that we see next month, we insert this issue, this concern, and call on CMS to monitor this. And, in fact, I don't want to give you more work but I think perhaps inserting an example or two, like Paul described, what kind of consideration might come into play if this pattern of behavior manifests itself.

Okay. Let's continue with David.

DR. GRABOWSKI: Great. Thanks. I'm very supportive of both of the draft recommendations. You didn't speak about it today, just in the interest of time, but you focused on the categorical adjustment, the low volume and isolated. I really like the continuous. Like a good MedPAC Commissioner I've gotten very suspicious of cliffs and bunching around those cliffs.

So I really like the continuous, not just on the number of treatments, but Amol really pushed it a little bit in the first round about the five miles, and thinking about whether or not that's just an arbitrary threshold. And so I'd also want to think about how meaningful that threshold is, and I think, Amol, you offered a very good check for that. But is there a way to think a little bit more about what's the right distance, and do we present any

incentives if we have sort of a threshold or cliff there as well?

But overall very supportive. Thanks.

DR. CROSSON: Let me just -- I'll just say something, and I think maybe you were going to say the same thing. I think in terms of -- and we deal with these issues of distance between facilities in a number of areas. There is, at least in my thinking, a clinical and beneficiary issue that comes in, depending upon the nature of what treatment or what condition is under play, but also the frequency. So, you know, I think perhaps one justification for the five miles is the fact that we know that the majority of patients seeking dialysis may have to make this trip three times a week, on average, and therefore that might be different from somebody seeking care in an acute care hospital once in a year or once every other year or something like that.

DR. GRABOWSKI: And I wasn't disagreeing with that, only to say that could we do some empirical work to kind of establish that five miles is the right. Maybe it's three miles. Maybe it's seven miles. I just -- why five miles? And I don't know if there's any empirical

justification but it would be nice to sort of push that a little bit.

DR. CROSSON: Yeah. I don't want to be argumentative either but one of the problems that we've wrestled with over time is whether the criteria should be miles or travel time. And so five miles in Los Angeles at rush hour is one thing, and five miles in a rural area is quite something else. We've talked about travel time and finally pulled our hair out and given up. So there is a certain arbitrariness to this, I agree.

DR. MATHEWS: If I could also just point out that the recommendation as currently drafted is not specific or somewhat agnostic on each of these points, the distance threshold and how the low volume element would be implemented. But we can enhance the supporting language that say, you know, you could do it this way, you could do it that way. We're talking five miles but it could be three, it could be seven. We can add some of that nuance if that helps.

DR. CROSSON: Did I steal your thunder?

DR. JAFFERY: Yeah, pretty much. But, I mean, even to just add a little bit more flavor to how complex I

think you can get, because even the time for travel will change. You know, going through the mountains in winter is different than in summer. So there is a level of arbitrary nature to it. That will be tricky.

DR. CROSSON: Yes, Bruce.

MR. PYENSON: I would like to see some mention using public sources, credible sources of the supply contract issue that I mentioned, that I'd asked about in the question session. I know among Commissioners, and in MedPAC, we sometimes go into that and sometimes don't, but I think in this case, since the contractual issues are very close to the content that we're examining, just some mention of that as best we can, as a consideration and background for the reader.

DR. PAUL GINSBURG: Is it on the TDAPA, Bruce?

MR. PYENSON: Yes. On the TDAPA and the supply chain issue.

DR. CROSSON: Okay. Good discussion. We will revisit these recommendations again, as we said, in April, for a vote, and we'll have the opportunity to enjoy in the revised chapter some of the good ideas that have been brought forward.

Thanks very much, Andy and Nancy, and we'll move on to the next presentation.

[Pause.]

DR. CROSSON: Okay. We're going to proceed with the final presentation for our March meeting. Dan is back with us. It seems like he didn't have enough yesterday, so he's back again all by himself.

As Jim mentioned, we're going to return to the issue of separately payable drugs, this time with respect to the hospital outpatient environment, and, Dan, you're on.

* DR. ZABINSKI: Okay. I was just realizing yesterday I had a presentation, and it was a mountain of data. Now I have no data.

[Laughter.]

DR. ZABINSKI: But I always feel more comfortable with data, so we'll see how this goes.

Anyway, today we're going to talk about how drugs are paid in the hospital outpatient prospective payment system, or the OPPS, and then discuss how that system could be improved.

In the session you just listened to, Nancy and

Andy discussed separately paid drugs in the ESRD system, and their presentation and this presentation are the start of an effort to develop a consistent approach of paying for drugs.

If you're like me, you'll find what we're about to talk about pretty complicated, so I think it will be helpful to provide an overview of what we'll be discussing.

We'll start by talking about the unit of payment in the OPPS, and that will be followed by an explanation of how drugs are paid in the OPPS.

In the OPPS, most drugs are packaged into the payment system of the related service, but some are paid separately, and we'll talk about the programs for separately payable drugs and the problems we see with those programs.

Then we'll discuss the system for separately payable drugs in the OPPS and how it can be improved. And then we'll finish with alternatives to the current system for separately payable drugs.

Even though the focus of this presentation is drugs, we think it will be helpful to first talk about the payment bundles in the OPPS.

In the OPPS, most payments are for a primary service, which is usually the reason for an HOPD visit. And then the OPPS uses bundled payments in which the cost of ancillary items are packaged with the primary service into a single payment unit.

A real simple example is something like say a patient is coughing and wheezing, they're congested and whatnot. So they go to an outpatient clinic, and the doctor orders an X-ray to check for pneumonia. In this case, the visit is the reason the patient is there, so it's the primary service and it's paid separately, while the chest X-ray is an ancillary item, and the cost of it is packaged into the payment rate of the clinic visit.

It's really important to remember that when an item is packaged in the OPPS, that does not mean there is no reimbursement for that item. Instead, the cost of the item is reflected in the payment rate of the related service with which it's used.

The payment bundles in the OPPS contrast with a fee schedule, in which everything has its own separate payment, including ancillary items.

The benefit of using payment bundles rather than

a fee schedule is that payment bundles provide powerful incentives for providers to seek the lowest-cost, most efficient way to furnish a primary service.

Now we'll finally turn our discussion to drugs.

Now, in the OPPS, most, but not all, drugs are ancillary to a service. Like other ancillary items, packaging drugs encourages hospitals to us them efficiently. However, packaging of drugs can be taken too far, and effective packaging of drugs would balance incentives for efficiency with limiting providers' exposure to financial loss, as well as providing incentive to use the right drug at the right time.

That is, we have to be careful with packaging because packaging drugs that are expensive or that are rarely used with the related primary service can make providers reluctant to use those drugs because the exposure to potential financial loss may be very high.

Before leaving this slide, I want to be clear that while most drugs are ancillary items, some are not. In particular, some drugs are very expensive, and receiving the drug is the reason for the visit. Many chemotherapy drugs fit in that category. And because of their very high

cost and because they are not ancillary, we believe that these drugs should be paid separately and not packaged.

By volume, most drugs in the OPPS are packaged because they have low cost, at least relative to the service that they're provided with. However, a minority of drugs are separately payable, and these drugs are usually expensive, but actually some aren't.

Over time, the importance of separately paid drugs has increased, with program spending in the OPPS increasing from $5.1 billion in 2011 to $12.9 billion in 2018.

Like most features of the OPPS, the programs for separately payable drugs in the OPPS were developed on somewhat of an ad hoc basis. The OPPS has two programs for separately payable drugs: there is the pass-through drugs, and there's the separately payable non-pass-through drugs.

The reason that the program for the pass-through drugs exists is that during the development of the OPPS, there was consideration for actually packaging all drugs. But there were also concerns that for new drugs the needed cost and use data would not be available to include them in the payment rates for the related services.

So, in response, the Congress created the pass-through program, and payments for pass-through drugs began when the OPPS was launched in August 2000. This program provides separate payments for new drugs, which mitigates providers' financial risk. Also, some stakeholders argue that these payments help maintain incentives for drug innovation by manufacturers.

The program for separately payable non-pass-through drugs began in 2004, and the focus for this program is established drugs. The intent is to provide adequate payment for relatively costly drugs to ensure their use, which, again, mitigates providers' financial risk.

These two programs for separately payable drugs have different criteria for eligibility and to some degree serve different purposes.

For a drug to be eligible for the pass-through program, it must be new to the market and also have a cost that exceeds three thresholds that are related to the payment rate of the applicable primary service.

Having pass-through status has a definite time limit as drugs can have this status for only two to three years. But for a drug to be eligible for the separately

payable non-pass-through program, it must, first, not be a pass-through drug because this program is for established drugs, not new drugs; and it also must have a cost per day that exceeds a threshold, which is set at $130 for 2020, but CMS updates that threshold for drug price inflation every year.

Then, finally, there is no specified time limit for separately payable non-pass-through drugs. They can hold this status as long as their cost per day exceeds the required cost threshold.

Now, our goal for drug payment in the OPPS is to balance the benefit of packaging, which is that it provides efficiency, while recognizing that some drugs should be separately payable drugs to avoid excessive risk on providers and create incentives for clinical improvements, as well as incentives to use the right drug at the right time. That is, we want to have packaging, but we don't want to go too far.

So we analyzed criteria for separately payable items in other payment systems to get ideas about criteria for an effective separately payable system for drugs. These payment systems we reviewed are pass-through devices

in the OPPS, the new technology add-on payments in the inpatient prospective payment system, and the ambulatory patient group system developed by 3M Health Information Systems, which was the blueprint for the OPPS.

Taken together, these systems use four criteria to identify separately payable items: their cost per day, the cost of the item relative to the related service, whether the item is new to the market, and the items must show clinical superiority over competing items.

On this table, we compare the four criteria that are used in these other systems to determine separately payable status to the criteria that are used in the two programs for separately payable drugs in the OPPS.

A concern that we have is that the criteria that drugs must meet to be eligible for either the pass-through program or the separately payable non-pass-through program can allow drugs to have separately payable status even though, in our opinion, could be packaged without putting providers under excessive risk or adversely affecting incentives for innovation.

For example, for pass-through drugs, there is no cost per day threshold that drugs have to exceed.

Therefore, low-cost drugs can be eligible for this program and be paid separately, and this does occur.

For separately payable non-pass-through drugs, there is no requirement that the cost of a drug be high in relation to the payment rate of the related service. Therefore, drugs that are low cost in relation to the related service can be eligible for this program and be paid separately.

And, finally, neither of these programs requires drugs to show clinical improvement over competing drugs. Without a requirement for clinical superiority, incentives for innovation could be mitigated.

Finally, we really only want to pay separately for a drug if there is a clear reason to do so, and we question somewhat whether either of these programs accomplishes that. In particular, showing clinical improvement over other drugs is a strong reason to pay separately, and neither of the OPPS programs require it.

On this schematic, we show how decisions on making drugs packaged or separately payable would work in the OPPS if we implemented all four criteria that are used in the other systems for separately payable items discussed

on the previous slide.

Now, using all of this criteria would require a drug to meet all four criteria to earn separately payable status. So if a drug does not meet any one of the criteria, the drug would be packaged.

There are two big questions that would need to be addressed.

First, should we require a drug to meet all four of these criteria to have separately payable status?

And, second, what should be the specific features of each criterion? On this slide we have concepts, but how would these concepts work in practice?

Over the next few slides, we'll discuss details of a new program for separately payable drugs in the OPPS, including answering these two questions.

One thing we want to be clear about is that not all drugs are ancillary items. Rather than being ancillary, some drugs are the reason for a visit. They have a very high cost; they dominate the cost of the visit; and these drugs are usually infused. Once again, chemotherapy drugs are in this group.

Because these drugs aren't ancillary, we believe

they should be paid separately without being subject to any other separately payable criteria.

We have a concern, however, about the lack of price competition for some of these drugs. Many are single-source drugs with therapeutic alternatives, and usually, these drugs have their own billing code and payment rate.

Price competition could be increased for these drugs using policies that the Commission has discussed in the past, including: consolidated billing, where drugs in the same therapeutic class are in the same billing code and have the same payment rate; or reference pricing, where a reference price is established for drugs that are in the same therapeutic class. And for drugs that are above the reference price, the patient is responsible for the additional cost.

Now, all other drugs are considered ancillary, specifically those that function as supplies in a procedure or a service or are not costly enough to dominate the cost of a visit, such as an analgesic for surgical pain or an injection of a corticosteroid. Typically, these drugs are administered by simple injection, and the drug

administration is not the purpose of the visit.

For these ancillary drugs, it would be beneficial to replace the criteria in the current programs for separately payable drugs in the OPPS with a new system of criteria for identifying which should be packaged and which should be separately paid.

The four criteria on the previous slide can serve as a starting point for what this new system would look like, but we need to answer questions about which criteria to include and what the criterion would look like.

One potential criterion for separately payable status for ancillary drugs is that it has to be new to the market. The benefit of this requirement is that it would help maintain incentives for drug innovation.

But it also leaves a big question: What to do about the established drugs that are already on the market?

One, you could grandfather them and let them keep their current status, either separately payable or packaged based on their cost per day. Another alternative is to package them, either immediately or let them keep their current status for a while and then package them; or you could simply just drop the "new" requirement and subject

established drugs to the other criteria, including clinical improvement. but that also raises the question of how to apply a clinical improvement requirement to established drugs.

Another possible criterion for separately payable status is that a drug must have high costs per day.

The idea is to require separately payable drugs to have a cost per day that exceeds a threshold, which is a reasonable requirement.

Separately payable non-pass-through drugs have to cost per day of at least $130, and this may or may not be a reasonable threshold. We do have a concern about it because it's not based on empirical evidence. So we need to determine what an appropriate threshold would be.

A third potential criterion for separately payable status is that the cost of the drug is high in relation to the payment rate of the related service.

This is a useful criterion because if the cost of a drug is high in relation to the payment rate of the related service, use of the drug may expose providers to financial loss.

This criterion is used in the pass-through drug

program, which actually requires drugs to meet three variations of this measure. And I've concluded that any formula applicable to this measure is going to be pretty complicated, but one possibility is in your paper: that the cost of a drug is at a level such that the difference between the cost of the drug and how much of that drug's cost would be in the payment rate of the related service if the drug were packaged has to exceed some percentage of the payment rate of the related service.

An obvious question here, though, is: What should that percentage be? In the paper I've suggested 10 percent, but that's definitely up for debate.

The final criterion to consider for separately payable status is that the drug must show clinical improvement over competing drugs.

Specifically, the clinical performance of a drug would be compared to that of drugs that have similar therapeutic uses. If the drug is clinically better in some way, such as faster resolution of the disease process, then the drug can be separately payable; otherwise, it would be packaged.

Some systems require clinical improvement for

ancillary items to have separately payable status, including new technology add-on payments in the IPPS and pass-through drugs in the OPPS.

For our purposes, the new technology add-on payment requirements for clinical improvement is a viable option.

Finally, two other issues to consider are:

First, should there be a time limit on how long a drug can be separately payable? For example, the pass-through program has a limit of two to three years.

Second, should separately payable status be limited to one time and you're done? Or should drugs be evaluated periodically and, if they pass the criteria for separately payable status, they can maintain that status indefinitely?

Now I want to go full circle and explain why we're doing this analysis.

One thing we know is that spending on separately payable drugs in the OPPS has been rising rapidly. And we also know that packaging and payment bundles can help rein in that spending because they are powerful tools for encouraging efficient use of resources.

But the criteria in the two programs for separately payable drugs in the OPPS allow separate payments for drugs that could reasonably be packaged.

So to close the presentation, we would like to know the Commissioners' thoughts on several issues.

First, is it okay to exclude the costly, non-ancillary drugs such as chemotherapy drugs that are the focus of visits from the criteria for deciding whether a drug is packaged or separately paid?

Second, should being a new drug be a criterion for separately payable status, or should established drugs be allowed?

Third, if established drugs can be separately payable, how would we apply criteria for clinical improvement?

We'd like to discuss the structure of each criterion, such as the cost thresholds and how to determine clinical improvement.

And, lastly, should there be a limit on how long a drug can be separately payable?

I turn things over to the Commission.

DR. CROSSON: Dan, thank you very much for a very

clear and logically constructed analysis and presentation of a complex issue.

So we'll start now with clarifying questions. I see Kathy, Jonathan, Bruce, Jaewon.

MS. BUTO: Thanks, Dan. You did well with that, having a lot of data in front of you. A really complicated issue, and I would even describe it as a thicket of policymaking.

But I have a few questions in Round 1. One, can you tell us what happens to passthrough drugs after the two to three years, even if they are dominating the rate of the affiliated service? So that would be question one.

Two, can you tell us what the split is between the $13 billion between passthrough drugs and the separately payable non-passthrough drugs?

Thirdly, I think there is, but I could not remember what the NTAP cost threshold was in addition to the clinical improvement criteria. So there's some kind of a cost test that has to be met, and it's not like $130. It was a lot more complicated than that.

If you could, just those three?

DR. ZABINSKI: Remind me. The first question

was?

MS. BUTO: What happens to the passthrough drugs after two to three years, especially if they're expensive, they dominate the service?

DR. ZABINSKI: Yeah. They can become separately payable non-passthrough drugs. Their time ends on passthrough status, and there's a consideration.

Okay. We'll get down in the weeds a little bit here. If they're basically a supply in a service or a procedure, they're a "policy package." That's the term. They basically are automatically then packaged. If they're contrast agents in imaging or like a pain reliever in a surgical procedure, they become automatically packaged. Otherwise, they just run into the test of do they cost more than $130 per day.

MS. BUTO: So you could be a passthrough drug and then just go right over to the non-passthrough category?

DR. ZABINSKI: Definitely happens.

MS. BUTO: Which has no time limit?

DR. ZABINSKI: That has no time limit, and that happens. That's the most common case for passthrough drugs.

MS. BUTO: So a lot of infusion drugs would be in that category, would you say?

DR. ZABINSKI: Yes.

MS. BUTO: Okay.

DR. ZABINSKI: Then on the $13 billion, the real strong majority is on the separately payable non-passthrough.

The passthrough drugs, it bounces around a little bit, but it has really increased in recent years to around about $2 billion or so. Then the rest is the separately payable non-passthrough.

On the NTAP cost threshold, I don't remember the exact numbers, but it's kind of similar to the way the cost criteria worked for passthrough drugs, where they compare the cost of the drug in relation to the payment rate of the applicable, in this case, DRG. At least I think that's right. Anybody, does that sound -- yeah.

MS. BUTO: I was just going to say it would be really helpful to know that because, obviously, as you point out, $130 threshold is pretty meager. If we could figure out what that one is, especially if you're pointing toward the clinical criteria.

DR. ZABINSKI: Right.

DR. CROSSON: Great. Thank you, Kathy.

Jonathan?

DR. JAFFERY: Yeah. Thanks.

Thanks, Dan. It is, along with what has been said, a great presentation on a really complex and important issue.

Could you go to Slide 14 for a second? Thinking about this question about the cost of the drug, how you would calculate this, are there situations that you thought about where a drug might be used with different multiple services? If so, how frequent is that, and how would we think about that?

DR. ZABINSKI: I don't know how frequent it is -- well, back up. Yes, I thought about it. I'm not sure how frequent it is. It's got to happen, definitely.

I will say that I keep on falling back when I think about a lot of these issues to the ambulatory patient groups, the APGs, which is like the blueprint for the OPPS, and it's actually used in a lot of state Medicaid programs.

I think they thought about this a lot when they were developing it, and they are kind of like -- and I

think it's that type of issue that you're asking about that sort of said it gets real dicey. Sometimes a drug is packaged, and sometimes it's not. So they just said, "Never mind. We'll go something simpler."

So it's an issue, but I'm not sure how frequently it happens.

DR. JAFFERY: So would you imagine that if it was related with the different services that the calculation, sometimes it might be part of a package and sometimes it might not be based on that?

DR. ZABINSKI: Yes.

DR. CROSSON: Okay. Bruce?

MR. PYENSON: Yeah. Thank you very much, Dan.

Some of the treatments for sure are available to patients in sites other than hospital outpatient, such as physician office, which in fact compete with hospital outpatient. Then there's discussion of consolidation, a vertical consolidation of the hospitals. Do you have a perspective on the split for these drugs, what portion of the relevant treatments are physician office administered versus hospital outpatient administered?

DR. ZABINSKI: No. I'll tell you what I do know.

In particular, chemotherapy is really shifting from the community-based oncology to some sort of hospital-owned infusion centers, and I'm not sure what the split is right now. But it used to be very -- most of it in the community oncology centers, physician owned, and a lot of it has shifted over. But I'm not sure what the split is right now.

MR. PYENSON: So, evidently, if reimbursement is inadequate for hospital outpatient, that hasn't hindered that consolidation, apparently?

DR. ZABINSKI: Apparently not, no.

MR. PYENSON: I think there's other sites of service that might be relevant. For example, some of these treatments are used in SNFs --

DR. ZABINSKI: Perhaps.

MR. PYENSON: -- and other settings. It seems there's no add-on for reimbursement in a SNF.

DR. ZABINSKI: Right.

MR. PYENSON: I have asked the same question for these treatments whether we see what portion is in those other service areas.

I note some interesting language in the text that

I was curious why it was presented this way, that basically, inadequate reimbursement may cause hospitals to avoid using some treatments which can adversely affect incentives for drug innovation. Is there any evidence that reimbursement is inadequate or drug innovation is hindered or that hospitals are stinting on drugs?

DR. ZABINSKI: I'm not aware of it.

MR. PYENSON: Okay.

DR. ZABINSKI: Because I'm not aware of it doesn't mean it's not true.

Let's see. That was really the argument in particular for the passthrough system. Like I said, when they were developing the OPPS, they really thought about, okay, we're going to package all drugs, and then there was concern, though, for new drugs that the cost and the use data wouldn't be available to incorporate the cost of those new drugs into the payment rate of the related services. The reimbursement might not be adequate enough or the hospitals to consider using those new drugs, so they developed this additional system. That's a theoretical argument.

I don't know if there's any empirical evidence

one way or the other.

MR. PYENSON: Thanks.

You mentioned in the text, 340B reimbursement.

DR. ZABINSKI: Yeah.

MR. PYENSON: Though I'm not sure that was in the -- did that flow through to recommendation or a policy alternative? That is, in terms of setting what Medicare pays, would that consider whether the institution was a 340B or not?

DR. ZABINSKI: No. It would not consider that.

The gist of this exercise is to really think about how to set the criteria for what's set in the table and what's not.

The level of payment, that's a good question. I guess we'll have to consider it along the way, but I hadn't really thought about exactly how the 340B hospitals would be dealt with.

MR. PYENSON: Okay. Another question on an analogue, I think there's some imaging procedures that might have a situation where the professional component is small relative to the technical component, which would seem to be an analogue to some of the issues we're raising here.

DR. ZABINSKI: Okay.

MR. PYENSON: Meaning the technical drug is bigger than the administration.

Does this issue that we're raising here ever come up in that circumstance?

DR. ZABINSKI: I don't know. I'm not sure.

MR. PYENSON: Okay.

MS. BUTO: Bruce, you're pointing to the fact that those are bundled together in the payment system, the technical and the -- I think they are, but I'm just --

MR. PYENSON: Yeah, yeah. They are, and like it or not, we've made decisions about supply-chain issues in some circumstances and seemed to avoid them in others and analogues.

DR. CROSSON: Jim, did you have a comment?

DR. MATHEWS: Yeah. Just one, to put a marker down, as this discussion unfolds.

This is our first foray into this issue in quite a while, and a lot of the work that we are doing here is developmental. And what we are looking for from the Commission are these kinds of things that we may not have completely and comprehensively scoped out as we're putting

this in front of you, but if you buy into the concept, if the idea seems feasible, something you want to pursue, these are the things that we would look to do over the next cycle.

DR. CROSSON: Okay, good. Jaewon?

DR. RYU: Yeah. Thanks, Dan

I had two questions. The first, what are the implications, if any, on beneficiary cost share? I'm just not clear how that works in this space.

Then the second, this general payment mechanism, does this carry over to the MA world? Do we have any insight or line of sight into how that works? And any changes, would those also presumably then carry over?

DR. ZABINSKI: Okay. Implications on beneficiary cost sharing. My guess is the way it would work, I think beneficiary cost sharing would probably go down, but that is really hard to say definitively ahead of time because the way the package -- if you increase packaging of items, it's going to increase the payment rate of the related service, if you take a drug that used to be paid separately and then you package it, but typically only a fraction of the drug cost is going to be reflected in the payment of a

related service, because the drug typically isn't used every time a service is provided. So there's going to be probably some savings on the beneficiary cost sharing, but it gets really complicated.

Then carryover to MA, I immediately start thinking about the base rate. I guess it's going to filter over to the base rates in MA.

DR. RYU: I was just curious. Do most MA carriers? I'm guessing how they pay for these services and drugs, but I don't know that. I was just wondering is this --

DR. ZABINSKI: I'm not sure. I would guess a lot of them just follow fee-for-service Medicare, in a sense.

Jeff is nodding yes. So, yeah, I guess so.

DR. ZABINSKI: Paul and Jim both wanted to come in.

DR. PAUL GINSBURG: Actually, I was going to say as far as MA, probably, depending on the contract with the provider, the MA plan could either be following Medicare policy or what's the norm in commercial. So I don't think it's an obvious thing.

DR. CROSSON: Okay. Jaewon, are you done?

DR. RYU: Thank you.

DR. CROSSON: Oh, okay. So then we have Dana and then Marge.

DR. SAFRAN: Thanks. I agree with all the comments of praise about the importance and the nice clarity you've provided on this.

My questions have to do with the likely cost impacts here. As I think about your question to us about how we would establish drugs, how we would do the clinical improvement piece, I think that's really, for me, part of the heart of the matter because I think without that clinical improvement piece, I'd be very worried about the inflationary aspects of this, but with that, I really like it.

So I wonder if you could just talk a little bit about for the new drugs. Since clinical improvement isn't part of what Medicare currently evaluates, how would that get evaluated? How would we go about that? And then we can think about the established.

DR. ZABINSKI: Well, I'll just read off like in the NTAP. They consider things like it offers a new treatment option for the patient population unresponsive to

or ineligible for currently available treatments, or the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable. It reduces at least one clinically significant adverse event, including a reduction in mortality or clinically significant complication or a decreased rate of at least one subsequent diagnostic or therapeutic intervention. It's a long list. It covers a lot of items such as that.

My personal feeling, I think this would be a very useful starting point.

DR. CROSSON: Paul?

DR. PAUL GINSBURG: I think since there is experience, of course, with the inpatient program, NTAP, I think a lot of it might come down to the fact that how much in the way of resources has CMS or the carriers does it take to make a judgment for one drug, because I think a lot of the inpatient ones are very experience things, really worth spending a lot of time.

It could come up that if we are talking about $100 or $200 drugs on the outpatient, unless the volume is high, that maybe this would be kind of overwhelming to CMS

and the carriers.

So it really comes down to what kind of resources does it take to make these judgments in a way that the public will have confidence that they had been made carefully.

DR. CROSSON: Marge?

MS. MARJORIE GINSBURG: I just wanted to verify my thinking on this. These are all Part B costs to clients, so if they are paying separately under Part B for the drug, plus they're paying their share of the bundled service, if we put the drug within the bundled service you're dropping the cost altogether, and taking them separately the whole idea is to fold a more expensive drug into bundled service so that the sum total of the costs are actually going to be less, and going to be less for the beneficiary. Is that right?

DR. ZABINSKI: Some degree, yeah. Think of it in terms of you've got a service, say, without the drug bundled in, costs $100, and a drug is used with it that costs $20. And the drug is used half the time the service is provided. So what would happen is you take 50 percent times 20, and $10 would be folded into the payment rate.

MS. MARJORIE GINSBURG: [Off microphone.]

DR. ZABINSKI: Typically, yes.

DR. CROSSON: Well, wouldn't it be lower for some beneficiaries and higher for others, depending upon whether or not they had the drug?

MS. MARJORIE GINSBURG: Whether or not they what?

DR. CROSSON: Whether or not they actually were given the drug.

DR. PAUL GINSBURG: Yeah. I mean, I think there's -- you know, so for the half beneficiaries that get the drug I think for the system the savings come when the drug is used less frequently, because it's in the bundle.

MS. MARJORIE GINSBURG: So going forward, I'd be very interested in seeing how this plays out, at least theoretically, on terms of the beneficiary cost-sharing.

DR. CROSSON: Okay. Amol and Warner.

DR. NAVATHE: So I think, you know, I sort of echo the comments around the importance of the topic. One of the things I was struck by is just if we look at the last slide where you have the different dimensions that we need to consider, I think in some sense it would be helpful as we pursue this work to have examples or use cases of the

variation that we have along with these dimensions, to the extent that we have them, for drugs that are meeting the current separable payment criteria.

Because I think in some sense, like Jonathan's question earlier about are there other drugs that would sometimes meet this or used in different clinical settings, it's hard to envision an abstract, to some extent, where we might have unintended effects, and I think having a couple of examples where the variation exists along these dimensions might help us sink our teeth into this a little bit more concretely.

DR. CROSSON: Warner.

MR. THOMAS: Just a couple of quick questions. I mean, I think, number one, this will probably continue to escalate, just given the growing number of drugs, especially specialty drugs. But I guess the question I had is, in the chapter you talk about things that have been identified previously and/or recommended. I mean, did we think about kind of a cap, an inflator cap, things like that? Because I know when you said before, you know, Medicare doesn't really directly buy drugs, but here you're pretty close to pretty directly buying the drug. So did we

think about inflator caps, things like that?

DR. ZABINSKI: No. Nothing like that. I mean, in this particular sector, on the drugs, it's been a long time since we've done anything on that. I think, in fact, I was the last one to do it, and that was like in 2002, or something like that. So it's been a while.

DR. CROSSON: But, I mean, you did list some potential approaches to drug cost control, and in the context of other work that we've done on drug cost control, some of those ideas, like you mentioned, would be relevant to this, as well as everything else.

Okay. Seeing no further questions we'll go on to the discussion. We've got the suggested discussion topics here, and Kathy is going to begin.

MS. BUTO: Yeah. So let me start out by saying thank you for starting this work, and I'm sorry I won't be around to see it completed. But I will say this. I think we should package as much of these drugs, as many of these drugs as possible into the rate. I haven't heard compelling reasons why that can't be done. So I'd start there.

I also think back to something Dana said, that

while we need to obviously look at the costliness of any drug that we allow to be paid separately, that there ought to be that threshold, but then the next step should really be applying clinical improvement criteria. In other words, let's get a little simpler about the universe of drugs that qualify for separate payment, and for everything else we should do what we can to package those into the rate.

I think it's difficult as I compare inpatient PPS to OPPS, in inpatient PPS you are dealing with a diagnosis-related bundle. Here it's a service-related bundle, so that makes it a little more difficult, because when you're talking about infusion drugs they end up being infusion related to a service rather than infusion related to treating a condition. So it's a little different, and I think it's not entirely parallel using NTAP and using those criteria in OPPS. But I think that's a really good starting point.

I think we all recognize that the cost of drugs is driving a big cost in Medicare, and we wonder how can we do something about that. Well, the separately payable drug category on the passthrough drugs were specifically put in there so that new drugs could get a leg up, and without

any, you know, new evidence per se, except the FDA approval. So I think we can add a lot more discipline to looking at that.

The other thing I think we have to consider is the time frame. I know in the paper, Dan, we talked about let's just collapse these categories, do away with the passthrough potentially, make them all -- just decide what the set of separately payables should be. But I think we have to think about a time frame even for those. And then the question becomes, well, what do you do if they're high-cost drugs that dominate the service? There has to be a set of alternatives for dealing with those.

And I am not a fan of either reference pricing or the consolidated coding approach, because they become ways to sort of assign a price to a drug based on other drugs. There's a process involved. I would rather see those drugs bundled, and like we just did in the ESRD example in the functional categories, let the chips fall where they may. Let the best drug win, if you will, in that circumstance, but let that bundle be sufficient along with the service, whatever it is, to allow choices to be made.

But if you pick winners and losers with a

passthrough system, and then if you have a high-cost drug approach that really, in a sense, picks winners and losers, using reference pricing, that has never been -- I don't feel comfortable with that. I think we ought to let that decision be made clinically, and if we can come up with other ways to create a bundle that allows those decisions to be made, a la what we just did in ESRD, I think that's a better approach.

And the last comment I would make is I think we should look at doctor's offices. So let's say we go down the road of bundling or packaging more drugs into the service. If there is a similar service provided in a physician's office with those drugs, we should look at packaging drugs in the physician's office. In other words, let's try to align these policies across both settings.

But back to my original point, I think we really need to try very hard to package as many drugs as possible and not get into the separately payable, because that really does pick winners and losers.

DR. CROSSON: Thank you, Kathy. Further discussion, input for Dan? Jaewon, Warner, Sue.

DR. RYU: Yeah. It gets back to the beneficiary

cost-share question from earlier. I think as we go down this analysis it would be important to just understand deeper what would that impact be, or maybe there's no impact. I think the more things that are packaged -- I agree with Kathy. I think there is a cleanliness and a simplicity there, in particular, how it pertains to beneficiary cost share, to the extent you're pulling things out, you know, is it Part B, is it Part D, is it a separately administered cost share for that service, because, you know, they got this facility. I think understanding all of those moving pieces for the beneficiaries, you know, through the beneficiaries' perspective, would be helpful.

DR. CROSSON: Warner.

MR. THOMAS: So I think this is a great topic. I think it is going to be continued cost escalation for the program. I do think that we should be looking at other -- you know, using this idea we've used in other components of the Medicare program around blunting the escalation of drug costs. I think the idea of having -- we've used inflators. I mean, we've made that recommendation and used an inflation cap.

I mean, I think we can look at complicated ways that we think about how much the drug is as part of the payment, or we can basically just say we're going to go to the drug cost and have an impact on what that drug cost is and blunt it over time, which is, you know, going to be a main part of what this overall cost is. So I'm encouraged just to look at those drug caps, or inflator caps.

And I agree with Kathy that I do think looking in a broader way to physician offices makes a lot of sense as well. But I get concerned that we're going to make this so complicated that it's going to be hard to administer. I would really challenge us to think about simplicity, and I think something like an inflation cap is understandable. It's more simple, and I think it's easier to implement, versus some of the calculations and ideas that are kind of outlined in the paper.

DR. CROSSON: Thank you, Warner. Sue.

MS. THOMPSON: I just want to echo how well you did in the chapter, Dan. I thought it was very, very clear in how important this topic is. And I want to second the motion to keep this simple. You know, I'm attracted to the idea of examples for every one of these discussion items,

but we will get into a very complicated discussion of anticipating what the provider responses will be. So I just think before we begin the work let's decide, do we need to get so complicated or can we keep this simple, with the goal of some expediency to a pretty big problem for the Medicare program.

And secondly, I also want to support Kathy's thoughts about let's have a level playing field here in all area that deliver this outpatient service, and so we're not setting up a system where we're just going to be moving the problem to another sector.

DR. CROSSON: Thank you, Sue. Kathy and Dana.

MS. BUTO: Sorry. I remember that I forgot to mention one thing, which is for those really expensive drugs that are part of a less-expensive service, I think one way to consider that is if there's a case to be made for some sort of separate payment -- again, going back to the criteria that it has to be made clinically -- so just to put that idea of using more proactively criteria, where the burden of proof is on whoever is proposing that add-on or that separate consideration for cost to bring forth the evidence of that clinical distinction.

DR. CROSSON: Thank you, Kathy. Dana.

DR. SAFRAN: Yeah. So I think I fully agree with the comments and issues that have been raised. The thing that I guess I'll add in is just to say that I think that we'd be well served to have the chapter create some connections over to what we're seeing in the revamping of the Part D chapter, because, you know, understandably, we consider these two different parts of the benefits, but to a manufacturer these are just drugs for Medicare beneficiaries, and if one window has closed, another one has opened for high-priced drugs.

So I think we need to be very clear in that, and to the point that Warner and others have raised, that inflationary effect this could have, and I do think, as my question intimated and as Kathy picked up on too, that clinical criteria are going to be extremely important here. So I'd like to see us really put some good thought and muscle behind those, and some of the comments already around the table, I think, gave us some good ideas on that. Thanks.

DR. CROSSON: Thank you, Dana. Paul.

DR. PAUL GINSBURG: Kathy had really wise

comments on this, as did others. I wanted to reinforce her point is that the core of that bundling, you know, the core of our payment approach in fee-for-service Medicare is bundling wherever we can. You know, hospital outpatients is an area that we converted to bundled, so guiding principle would be support the bundling, you know, put it into the bundle unless there's a compelling reason why not to.

I think there will be some drugs -- these will be Part B drugs, particularly -- that will be -- you can't fit into a bundle because often they're the dominant reason for the visits. And in that case, I think this general thing is that as we evolve in tools to address Part B drug prices, we will want to automatically apply them to the passthrough drugs as well. And I'm not getting us into a debate about, you know, whether inflation caps or reference prices or something else are the best way, but in a sense whatever we come up with, or whatever anyone else comes up with for Part B drugs, ought to be the criteria.

Kathy mentioned something really interesting about physicians' offices, and what occurred to me is that, you know, we have bundling in outpatient payments. We have

no bundling in physicians' offices. So in a sense it brings up a big topic, as to the degree that we should start introducing some bundling of ancillary services into physician visits. I don't know if that's feasible. We only have five visits going to three or four, so I don't know if we can do that.

But in a sense I guess that's a caution, and it's always going to be a problem having a completely different approach to physician offices versus hospital outpatient departments, is we're going to be continuing to create incentives to move things one way or the other, likely to the detriment of the program, and just something always have to be very careful about.

One thought I have, that Dan might be able to find for existing information, is the attempt to quantify, you know, what portion of the dollars are we talking about as far as, say, drugs that are clearly ancillary and not that expensive, versus one that are, you know, the opposite, very expensive, often the reason for the visits. And to get a sense of, you know, where are the dollars? You know, where should we pay the greatest attention to?

DR. CROSSON: Thank you, Paul. Very good

discussion again. Dan, thanks for the clarity here, and I think you've had some good input, so we look forward to your future work in this area and potential expansion of it. Sorry about that.

So that concludes our presentation and discussion for the March meeting. We now have time for a public comment period. If there are any of our guests who wish to address the Commission, please come forward to the microphone. I will give you some instructions in a second.

I'm just looking to see. Okay. So we would ask you, if you would, to identify yourself and any organization that you are representing and to confine your remarks to about two minutes. When this light in front of me comes back on, that time will have expired. Thank you.

* MS. LESTER: Hi. I'm Kathy Lester. I'm here on behalf of the Kidney Care Council. I think most of you know that organization is more than 30 members, patient advocates, dialysis facilities, the health care providers, nurses, physicians, others, and the manufacturers.

I very much appreciate the dialogue today. As many of you know, we do support addressing the low-volume issue. We think money is leaking out of the system

inappropriately and not really getting to the patients in rural areas who need it. And the proposal that is before you does really seem to target those dollars appropriately.

In terms of the TDAPA payment, we, too, think that it needs to be refined, but I would encourage you to keep the patients first here. There has not been innovation in this area other than in the anemia management category, and the examples you've highlighted are in that category. There are a few, and very few, other functional category drugs that came into development when the PPS started because there was an excitement that the new system would allow for innovation and evolution over time.

The whole premise of the problem with the ESRD PPS is it has been really in this lockdown mode. There aren't additional dollars. As the Chairman recognized in the last meeting, we're going to see this roller coaster because of the way TDAPA is functioning, but it doesn't mean the underlying bundle is appropriately priced. So if you try to add a new drug into a category -- and there are some, for example, that could be viewed as in the antipruritic category -- an unmet need, the current treatments do not work for patients. They're

antihistamines, and that's not what pruritus is. But that drug is going to compete at less than a dollar? It just isn't possible.

So I would encourage you, as you continue to think about the recommendation, to take a nuanced approach and to really take some of the ideas that were in the outpatient discussion around substantial clinical improvement and really think about ways to incrementally adjust the bundle as needed and using a TDAPA period to help that. We think TDAPA can be further narrowed, but we also think there needs to be a pathway for innovation that's sustainable.

So encourage continued dialogue, and thanks for giving me a chance to make comments today.

DR. CROSSON: Thank you very much.

I think you heard the instructions, so please proceed.

MS. BUNNING: Hi. My name is Sue Bunning. I'm with the Medical Imaging and Technology Alliance, or MITA. I'm going to reference one of the questions earlier today relating to diagnostics. MITA represents the precision diagnostic, medical imaging diagnostic drug companies. We

have done extensive work in this area recently, and in our particular instance, the nuclear medicine bundles, these newer precision diagnostics can't even hope to affect the average of the APC. And we have done research on the data demonstrating fall-off, what happens when they come off pass-through.

So we want to serve as a reference as you proceed on this topic, and we're happy to answer any questions. We know that it is impacting patient access, and we're happy to share with you anything that you might need.

DR. CROSSON: Thank you for your input.

Seeing no further people at the microphone, then we are adjourned until the April meeting. Thanks to the Commissioners, thanks to the staff.

[Whereupon, at 10:29 a.m., the Commission meeting was adjourned.]