MEDICARE PAYMENT ADVISORY COMMISSION

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AGENDA PAGE

P R O C E E D I N G S

[11:16 a.m.]

DR. CHERNEW: Hello, everybody, and welcome to the October, unfortunately, virtual MedPAC meeting. This is our West Coast-friendly schedule, which has been appreciated by all of our West Coast Commissioners and, frankly, some of our East Coast Commissioners. In any case, I think we have a very exciting agenda for today and for tomorrow, and I'm not going to take any more time.

I think I am going to turn it over to -- I think, Nancy, you might be starting -- maybe it's going to be Kim -- to talk about what is obviously a really important issue for the country and for the Medicare program, which is how do address the high prices of pharmaceutical products and, as noted, other technologies.

So, Nancy, are you up?

MS. RAY: I am up. Thank you, Mike.

Good morning. The audience can download a PDF version of the slides on the right-hand side of the screen.

An important driver of growth in Medicare spending is the use of new technologies, particularly drugs and biologics. Manufacturers set launch prices based on

what they believe the U.S. health care market in part will bear and historically have set high prices for many new drugs, whether or not there is evidence that it is comparatively more effective than existing standards of care. Price growth for existing drugs is also a concern.

Today's session examines approaches for Medicare to address high launch prices of first-in-class drugs and high prices and price growth of new and existing drugs with therapeutic alternatives.

Our goal is to get your feedback on policy options that we should pursue during this cycle.

There is a lot of background material in your paper on how FDA approves drugs and on how Medicare covers and pays for drugs. In the interest of time, today's presentation focuses on the drug spending issues that Medicare faces and approaches to address them. While we are focusing on Part B drugs, some of the issues may be applicable more broadly to Part D drugs and to other new technologies.

During this morning's session, we will start with some background about trends in drug spending and pricing. Then we will move to approaches that Commissioners

expressed general interest in pursuing. First, we will review an option to address high launch prices of new Part B drugs with limited clinical evidence. Second, we will consider an option to address high and growing prices for Part B drugs with therapeutic alternatives. Third, we will discuss an option to counter potential financial incentives under Medicare's payment method for Part B drugs.

So let's discuss the issues. On the Part B side, 2019 spending was $39 billion, with spending increasing at nearly 10 percent per year since 2009. Higher price is the largest driver of cost growth. Spending is highly concentrated in cancer, rheumatoid arthritis, and eye drugs. Ten products, all biologics, accounted for 41 percent of the total spend.

On the Part D side, 2019 spending was about $105 billion, with spending increasing at 6 percent per year since 2009. Program spending is increasingly driven by reinsurance costs incurred by less than 10 percent of beneficiaries, with reinsurance costs growing by nearly 16 percent per year during the same period. For those enrollees, higher prices account for nearly all of the cost growth. Part D spending is also concentrated, with just

two classes, cancer and diabetes, accounting for over one-third of spending.

The concerns about drug prices listed on this slide are not new. Estimates suggest that U.S. drug prices are roughly double the prices in OECD countries. Higher prices in the U.S. reflect higher launch price and more post-launch price growth. According to some researchers, high launch prices is not always related to the value of the product. For example, researchers found that for cancer drugs, drug launch prices have been increasing, unrelated to the value of the products.

Prices have grown rapidly for certain existing drugs without any evidence of a change in the product's effectiveness.

Products approved under FDA's accelerated approval pathways are launching at high prices with limited and sometimes unclear evidence about their clinical effectiveness.

The newly approved Alzheimer's drug is a case study that demonstrates Medicare's lack of tools in covering and paying for a new very costly first-in-class drug.

It was approved under the FDA's accelerated

pathway with unclear clinical benefit. With the manufacturer setting the drug's price at $56,000 per year, there is the potential for very large effect on Part B spending, although it is too soon to know what the drug's take-up will be.

Currently, about 6 million individuals have Alzheimer's dementia. If even 500,000 were to be treated with this drug, the annual cost of the medication alone would total $29 billion. That's nearly 75 percent of the total spend on Part B drugs in 2019, and this estimate does not include other related costs, such as brain scans. Spending of that magnitude could have a noticeable impact on Part B premium and Medigap premiums for beneficiaries with supplemental coverage.

This figure shows the spectrum of potential policy options to address high drug prices.

On the left are policy changes that are within the current Medicare payment system. Some of the changes to the ASP payment system included in our 2017 recommendation on Part B drugs would be an example of this type of policy option. Policy changes in this category tend to have limited or no direct impact on how prices are

set.

On the other end, on the right, are policy changes beyond the scope of Medicare; for example, reducing the length of a drug's market exclusivity.

Most of today's discussion discusses policy options that fall in the middle, changes that would move Medicare to consider clinical value when covering and setting payment rates for drugs. The options we discuss today are Part B-oriented, but there could be ways to extend some of the policies to certain Part D drugs.

So these policy options aim to better align what the program and beneficiaries pay for drugs with the value of those products, spur price competition among drugs, and limit beneficiaries' and taxpayers' financial risk for products with limited evidence on clinical effectiveness.

These policy options are designed to address concerns about the overall price Medicare Part B pays for drugs and the lack of price competition among drugs with similar health effects.

Potential outcome of these policy goals include generating savings for beneficiaries and taxpayers and improving the financial sustainability of the Medicare

program.

For first-in-class products with limited clinical evidence, we discuss the policy option of introducing value into the payment for Part B drugs by setting payment using cost-effective analysis and using coverage with evidence development to collect clinical evidence.

For existing drugs and new drugs with therapeutic alternatives, we focus on applying reference pricing to spur competition among drugs with similar health effects.

Lastly, for all Part B drugs, we discuss modifying the add-on to the average sales price, that is, Medicare's payment rate for most Part B drugs, to address concerns that the add-on might influence providers' prescribing patterns.

The first two options, introducing value into the payment process and using reference pricing, aims to affect manufacturers' pricing behavior for certain drugs, while the third option, modifying the ASP add-on, targets providers' prescribing behavior.

Medicare has few tools to address a product's coverage or payment Statutory and regulatory language appear to require fee-for-service coverage of Part B drugs

for their FDA-labeled indications. And with Medicare generally paying 106 percent of ASP for Part B sole-source drugs, the manufacturer effectively determines Medicare's payment rate for these product. Medicare's payment policies generally do not consider whether a new service results in better outcomes than its alternatives.

A combined approach of setting payment based on cost-effectiveness analysis and applying coverage with evidence development, CED, has the potential to increase the value of Medicare spending and improve post-market evidence development.

This policy option, which we call a "value-based approach," would focus on first-in-class Part B drugs that the FDA approves based only on surrogate or intermediate clinical endpoints under it accelerated approval pathway. We seek guidance from Commissioners about your interest in applying this policy to other new drugs approved based on surrogate or intermediate clinical endpoints.

Under this approach, Medicare could set a value-based price based on an assessment of the comparative clinical effectiveness and cost effectiveness of a new product compared to the standard of care. Cost-

effectiveness analysis compares the incremental cost in dollars of one intervention with another in creating one unit of health outcome.

Also, under this approach, Medicare would also apply coverage with evidence development to generate clinical evidence on, for example, a new drug's risk and safety profile and impact on patients' functional status and quality of life. Medicare implements coverage with evidence development in the national coverage determination process. This combined process of pairing cost-effectiveness analysis with coverage with evidence development reflects the uncertainty of the effect of accelerated approval drugs on health outcomes when these products are first approved by the FDA.

So now I am going to turn it over to Kim who will review two more policy options that Commissioners have expressed interest in pursuing, using reference pricing and modifying the add-on to the Part B drug payment rate.

MS. NEUMAN: Shifting gears, we now turn to an option that could address concerns about pricing for drugs with therapeutic alternatives.

Because Part B pays each single-source product

based on its own ASP, it does not promote price competition among therapeutically similar products,

In 2017, the Commission recommended a combined billing code policy for biosimilars and originator biologics, which is a type of reference pricing that would pay these products the same average rate to spur price competition.

Building on that, reference pricing approaches could be considered more broadly for products with similar health effects as a way to promote competition and value.

So here's how an internal reference pricing policy for Part B products with similar health effects might work. CMS could set a maximum payment rate for a group of single source drugs or biologics with similar health effects based on, for example, the minimum, median, or average ASP across the products.

So, to be clear, what we are talking about is a step beyond paying the same rate for a brand drug and its generic equivalent or for biosimilars and the originator biologic. This would involve the Medicare program paying the same rate for therapeutically similar products; for example, products in the same therapeutic class with

similar health effects.

If the patient and his or her provider selected a higher-priced treatment, the patient would pay the difference in higher cost sharing, and there would be an exceptions process if a beneficiary had medical need for a particular product.

The idea here is that this structure would create an incentive for the patient and physician to choose the lower-priced alternative, but access to higher-cost products would be maintained

To implement reference pricing for drugs, CMS would need a transparent process to identify groups of products with similar health effects, establish a reference price, and update this over time as new products or evidence become available and prices change.

In addition to internal reference pricing, another approach that could be explored is a one-time rebasing of Part B payment rates informed by, for example, international pricing data. Although structured differently, Medicare has implemented rebasing in other sectors like ESRD and home health.

Next, we'll discuss an option to address

financial incentives under the ASP payment system. Medicare generally pays providers 106 percent of ASP for Part B drugs. Six percent is often thought of as the provider's margin, but a provider's margin on a drug may actually be higher or lower than 6 percent due to factors like price variation across purchasers and the two-quarter lag in ASP payment rates.

Concern exists that the 6 percent add-on may create incentives for providers to choose higher-priced drugs in situations where differently priced therapeutic alternatives are available to treat a particular patient, and providers can profit more from the more costly product than the less costly one.

The literature is limited on the effect of the 6 percent add-on on prescribing behavior. A few studies that have focused on selected products suggest some effect of 6 percent add-on on prescribing, but the size and scope of the effect across Part B drugs is unknown.

To reduce the potential for financial incentives, various approaches could be considered to modify the 6 percent add-on. For example, the size of the percentage add-on could be reduced. For example, in 2017, the

Commission recommended reducing the add-on from 6 percent to 3 percent as part of the Commission's recommendation to develop and encourage enrollment in a voluntary alternative to ASP payment system, which we referred to as the "drug value program."

Another approach could be to convert some or all of the 6 percent add-on to a fixed fee. Determining how much of the percentage add-on to convert to a fixed fee involves tradeoffs. Fully eliminating the percentage add-on would eliminate any potential financial incentives, while maintaining a small percentage add-on may help ensure providers can obtain drugs at Medicare payment rates, since a provider's acquisition costs is not necessarily ASP.

A third approach could be to place a dollar cap on the percentage add-on payment so that there's a limit on the size of the add-on for very expensive drugs.

In modifying the ASP add-on, it would be important to consider its effects on providers' ability to purchase drugs within the Medicare payment amount and how any change would affect providers' incentives.

So, reflecting on the various policy options we've discussed today, it's important to recognize that

there would be complexities and challenges.

In terms of implementation of value-based pricing, coverage with evidence development, and reference pricing, there would be technical complexities specific to each option. With value-based pricing, there are technical complexities associated with designing cost-effectiveness studies. With coverage with evidence development, some researchers contend that there's a need for clearer statutory authority so the process is more predictable and a need for a more systematic, routine approach to funding CED.

With reference pricing, there are technical complexities with determining which products have similar health effects.

A well-defined, transparent, and consistent approach would be key to success of any of these options.

Another challenge is that any coverage or payment decision that affects patient access to a product or drug payment rates may result in patient, clinician, or manufacturer dissatisfaction. For example, CMS has faced stakeholder pressure when it tried to implement coverage with evidence development for CAR-T therapies. CMS also

faced stakeholder pressure a number of years ago when seeking to implement a functional equivalence payment policy for erythropoiesis-stimulating agents for outpatient hospitals.

Last but not least, there are issues to consider related to the implications of Medicare policy on drug research and development. Manufacturers maintain that policies that constrain Medicare drug spending would lower their research and development investment and the pace of innovation.

On the other hand, others counter that the current aggregate level of payment is not necessarily the right level, and that it is possible to reduce some payment rates without hurting innovation by shifting incentives toward development of products with higher value.

In addition, some point out that there are a number of ways to encourage innovation that are beyond the scope of Medicare, such as federal investment in research and development, for example.

So this brings us to the end of the presentation. The four of us are happy to answer your questions and look forward to your discussion. Our goal is to get your

feedback on the issues and policy options we've discussed and an additional ideas you have to help guide our work going forward. We plan to come back in the spring to discuss in more detail how these policy options could be designed and implemented.

DR. CHERNEW: Great. Thanks. We are about to jump into the Round 1 questions. I will just, as a precursor, lay out what I think the fundamental conundrum here is, that I think we certainly acknowledge the value that a lot of prescription drugs provide, certainly in the sphere of [audio distortion].

MS. KELLEY: Mike? I'm sorry. We're having --

DR. CHERNEW: And also have concerns about how much we pay [audio distortion].

DR. PAUL GINSBURG: Mike, you're really breaking up.

DR. CHERNEW: -- and how to balance sort of those concerns --

MS. KELLEY: Mike, we're having difficulty hearing you. I'm sorry.

DR. CHERNEW: -- and making sure that people are [audio distortion] -- actually provide that.

I'm sorry. Dana --

MS. KELLEY: I'm going to go ahead to Round 1. Paul, you're up first.

DR. PAUL GINSBURG: Thanks. I had a question about the approaches on drugs that have been approved under an accelerated basis, meaning that there's less evidence of their clinical effectiveness than there normally would be. I found myself very puzzled by your singling out cost effectiveness analysis for those drugs, because those are the drugs that we don't have much information about.

So I was wondering, you know, I certainly would support, you know, paying attention to them and changing payment for them, but it seems as though they're not the candidates to use, you know, effectiveness evidence, because that's kind of what distinguishes them, that we don't have very much.

MS. RAY: Okay. Let me take a shot at trying to address the question, and then I'd also look to my colleagues for a little bit of assistance.

Certainly we would, you know, encourage Commissioners to discuss the use of a value-based approach for other drugs, in addition to drugs approved under the

accelerated approval pathway. I think based on prior Commissioner discussion, we focused on this value-based approach on drugs where, yes, you are correct, you don't have health outcomes like overall survival, but they are approved with surrogate outcomes, and those surrogate outcomes, of course, can be used in any assessment of cost-effectiveness analysis. And I think we've provided an example of that in the paper.

And I think given the manufacturers essentially determining the price of the drug, which may or may not reflect its value, we thought that using cost effectiveness for these drugs would be one place to start.

DR. CHERNEW: Can I emphasize the point "one place to start"? The economics does not suggest that prices should always be set at value. In general, I may be able to defer to Paul later, we need to understand that value, when we're talking about it here, is a starting point. It is not the notion that we're going to set the prices equal to value, even if we could measure value, which I think was the framing of the question.

DR. PAUL GINSBURG: Yeah, Mike, I have a lot of things to say in that, and I was holding it for Round 2.

DR. CHERNEW: Thank you, Paul. I'm sorry for jumping in. I know we have discussed this.

MS. KELLEY: All right. Jaewon is next.

DR. RYU: Yeah. Thanks. I just had a question about ASP+6, and I think you may even have referenced it in the slide. I think it was Slide 13. And I think it's referenced in the chapter as well, that the margin that the provider realizes can be greater or less than the 6 percent. I was wondering if we just have a sense of the distribution of what is typical and how does that distribution curve look like as far as what kinds of margins and where providers fall on that, and are there even providers that lose money even with the ASP+6?

MS. NEUMAN: So that is an issue that has always been a challenge. We, in general, do not have distributional data on sort of across providers what prices are being paid by different entities.

Now one small thing that we do have is an analysis that we did back in the 2015 report. We had some IMS health data for 34 high-expenditure, Part B drugs. And so we looked at invoice prices for those products, compared to the ASP that was in effect for payment at that time, and

distinguished prices didn't reflect off-invoice discounts, so they would be on the higher end.

And what we found in that analysis, which is back five-ish years ago, is that for about two-thirds of the products, 75 percent of the volume was at 102 percent of ASP or below. But that was two-thirds of the products. So we had some data that broke out, for some of the other products, the 75 percent market would have been a bit higher than that.

But this is sort of the heart of the question that comes up whenever we talk about the 6 percent add-on.

DR. MATHEWS: And, Kim, we're going to talk about this issue specifically in the next session, in light of the new ASP data. Correct?

MS. NEUMAN: We will talk about it. It will get us a little bit of the way there, but we still won't have it at the provider level.

DR. MATHEWS: Yes.

MS. RAY: You know, if I could just add, the HHS OIG has compared providers' acquisition costs to ASP for certain providers, including back in the day ESRD providers, and I think -- and I'm looking to Kim for the

eye drugs, and we can get back to you with more information about that.

MS. KELLEY: Dana.

DR. SAFRAN: Thank you. Just two questions. One is, I am sure I must be wrong, but I thought that the Medicare Modernization Act made it not possible for the Medicare program to use cost effectiveness analysis in setting prices. Am I wrong about that?

MS. RAY: So there has been statutory language about the program not using QALYs. Cost effectiveness analysis, of course, doesn't necessary have to use QALYs. But to be clear, right now the statute requires that for sole-source drugs that Medicare pay according to each product's average sales price. So a statutory change would have to be made to use cost effectiveness.

DR. SAFRAN: Okay. Thanks, Nancy.

And then my other question is, you know, it would be extremely valuable as we think about reference-based pricing and a potential change to the 6 percent add-on to have some modeling of, you know, what kind of results that might achieve and what it might look like for beneficiary out-of-pocket, et cetera. Is that something that spills

over to our next conversation about, you know, the data, or is that something I should ask -- do we have any access to, you know, information that lets us model some of that out, or should that spill over to how we might use the data that we now have access to?

MS. NEUMAN: So I'll start. On changing the ASP add-on, we would have the potential to do some modeling, and so we could bring that back to you. As far as reference pricing, Nancy?

MS. RAY: As far as reference pricing goes, sure, I mean, we can come back to you and show you examples of groups that reference pricing could be applied to. We could also discuss items that CBO and, I believe, GAO have published on using least costly alternative, which is a type of reference pricing. And we can take a stab -- we could try to take a stab at modeling the effects.

DR. SAFRAN: Okay. Thanks. I think that would be very, very helpful. Thanks.

MS. KELLEY: Jonathan Jaffery?

DR. JAFFERY: Actually, Dana's second question on modeling was my question, so we're good.

DR. CHERNEW: And Dana, I think Larry had a

comment on one of these points. Am I right, Larry?

DR. CASALINO: Yeah, but I think I had a question about one of the questions that was asked. But I think at this point, you know, the thread has changed and I can just wait my turn.

DR. CHERNEW: Okay. Sorry. Back to you, Dana.

MS. KELLEY: Bruce.

MR. PYENSON: Thank you. My compliments to the team that put this together. I've got two Round 1 questions, and I think one is for Nancy and one is for Kim.

Nancy, as you know, CMS reviews Part D formularies, and with some frequency rejects them or to get to revisions in particular plans' formularies. To what extent is that authority able to be used to reject formularies that encourage originator drugs versus biosimilars or biogenerics? That is in the interest of perhaps patient cost-sharing. That's one question.

And for Kim, the proposal that you have would have the patient pay for more costly drugs, but I'm wondering why an alternative is not for the patient just to pay the cost-sharing on more expensive drugs, since it's both a provider and a -- probably mostly a provider

decision?

So two questions. Thank you.

DR. SCHMIDT: So I know you said the first one was for Nancy, Bruce, but I think we'd like you to kind of expand a bit more. Under Part D there is, you know, a whole process by which CMS has to a approve the formularies of these private plans that are providing the benefit. Are you suggesting that there should be a similar kind of formulary situation for providers with respect to biosimilars?

MR. PYENSON: I'm sorry. I was addressing Part D and biosimilars in a Part D context.

DR. SCHMIDT: Okay.

MR. PYENSON: For example, the self-injectables.

DR. SCHMIDT: So at this point there aren't biosimilars available on the market for Part D drugs.

MR. PYENSON: Well, there are for insulins and there are for the erythropoietin stimulating agents, self-injectables. And I think there might be some other classes where biosimilars are available.

DR. SCHMIDT: So CMS would somehow involve itself in the decision of that, what should be on the plan's

formulary?

MR. PYENSON: I'm asking about authority, whether they would have the authority to do that in order to protect -- to perhaps protect the beneficiary's interest in lower cost-sharing.

DR. SCHMIDT: I think they have, thus far, interpreted their authority as being more limited in nature, that that might involve getting involved in price negotiation and that type of thing, where they feel that under law Part D is not allowed, through CMS, not allowed to at this point. That's my understanding.

MR. PYENSON: Thank you.

DR. CHERNEW: Okay.

MS. RAY: So Bruce, to address your question about cost-sharing under reference pricing. So this is an item, a design feature that I think we would value Commissioner input on. I think what we were thinking is when there was a medical exception provided that the physician could attest to that the patient would not be required to pay the highest cost share. If there was no medical exception then one option could be is that the patient would pay the additional -- well, the Medicare

program would not pay the additional cost-sharing.

But we would like your input on this.

DR. CHERNEW: -- in Round 2.

MS. KELLEY: Okay. Amol.

DR. NAVATHE: I had a follow-up to Dana's first question. This is another Round 1 question. So Dana had asked about sort of quality used in cost effectiveness, and I was curious -- I have kind of a two-part question, just seeking clarification on what's included or what's in the statute. So is there any distinction between using cost effectiveness for coverage versus for reimbursement or pricing, or are they tied directly together?

And secondly, so in terms of the change in statute that would be required, I just want to confirm that that would apply to using any sort of cost effectiveness or comparative effectiveness in the context of CED coverage as well, the CED process.

MS. RAY: Okay. That's a really good question. So on the payment side, there would be a statutory change required to use cost effectiveness in paying for Part B drugs. As I said earlier, the Secretary is mandated to, for most drugs, to base payment based on an average sales

price.

Now, with respect to coverage, that's sort of a different story in a way. So what the statute gives the Secretary authority to do is to cover all services that fall into a Medicare benefit category that are reasonable and necessary for the treatment of an illness or injury. Now, a long, long time ago, the Secretary tried to, in the rulemaking process, tried to adopt either introducing cost effectiveness analysis or the service's comparative clinical effectiveness into the coverage process. Those proposed regulations were never adopted, in part based on pushback from stakeholders. And I can follow up in our next paper and provide you with more detail about this.

So we talked about cost effectiveness now and using cost effectiveness in the payment and cover. So now let's talk about coverage with evidence development. So the Secretary has applied coverage with evidence development first using its authority to cover services that are reasonable and necessary for the treatment of illness and injury, and later on, more recently, since I think roughly 2006, under AHRQ's authority, to conduct research studies for Medicare.

And so some researchers contend that, well, if the Secretary had more explicit authority to do CED then it would improve the whole process of selecting which services to apply CED and having the infrastructure to deal with creating the study protocols, et cetera.

But to be clear, right now the Secretary does implement coverage with evidence development, and CED is applied in the national coverage determination process.

DR. NAVATHE: Thank you.

MS. KELLEY: Pat, you had a Round 1 question?

MS. WANG: This has to do with reference pricing, and as you summarized it in the slide you have described how reference pricing might work, and then in a separate bullet one-time rebasing using international reference pricing. You know, the one-time rebasing thing, all of it you raised the questions in the chapter, so what happens then.

Is there any consideration, or does it even make sense to think about including the international reference price in an internal reference pricing process?

Why keep them separate? You know, and that could take a lot of different forms, but could it be helpful to

inform any kind of internal reference pricing process?

MS. RAY: So I'll take a stab at that question, and then, Kim, if you want to add on. So there's concern that continuous use of pricing information from overseas and over time that the price will be harder and harder to obtain, for example, in trying to get information on prices net of rebates. And so that's why we thought, well, it may be feasible to do it for a one-time rebasing, but over time there may be a concern about the availability of the data sources.

[Pause.]

MS. KELLEY: Mike, we can't hear you. You're on mute.

DR. CHERNEW: That's because I was on mute. I was just going to jump in. I think I want to give a clarifying answer to a clarifying question. I think here the frame reference pricing is being used in slightly different ways, and so there's a big-picture question about whether or not we should use international price indices in how we manage prices just writ large in the Medicare program. That has a lot of complexity, as Nancy just mentioned.

The reference pricing type of activities we talked before I view really as more like efficient internal pricing for the things that we buy, and I think they're very different issues. So I don't think one is simply an extension of the other despite us using the same word for them.

I will just say now, while I have the floor, I personally am very concerned about one-time rebasing because I think it creates a very challenging policy precedent about what does it mean to invest in innovation and get a patent if later things can be rebased. But that's for a Round 2 discussion about how people feel about that particular option.

I think for now, to answer your question, Pat, it is a legitimate question about how one might do that, and there has been a lot of debate about the role of the international price index in a whole bunch of negotiation things. But it's not really analogous to reference pricing, the actual things that we were talking about when we use the term "reference pricing" in the chapter. And if I'm following the chat right, Bruce might want to say something about this, or someone else might, too. Yes,

Bruce.

MS. KELLEY: Bruce, on reference pricing?

MR. PYENSON: Just my question was -- the discussion was around an international price index, but there's also the same considerations, would Nancy's response be different if the VA schedule were the price index?

MS. RAY: I'm sorry. I didn't follow that.

MR. PYENSON: There's discussion about setting prices to international as a reference. There's also proposals to use the Veterans Administration acquisition set as a reference. And would the same considerations, concerns about availability of that, would there be other concerns with that?

MS. RAY: I think I'd like to think about that a little bit more, but I think that's an option that Commissioners should discuss.

MS. NEUMAN: And this is Kim. Just to add one thing to that, I do know that CBO has written a little bit about the idea of applying Medicaid prices or VA prices in Medicare and said that, if that were to happen, those prices may change. So that would just be something you'd

have to think about in that kind of policy option.

DR. CHERNEW: Yeah, so let me try and give another version of this. Some of these reference pricing models are you take the price for Product X and you use it as a price for what should be paid for Product X in a different setting. That is different than looking at the price for Product Y and using that as a reference price for Product X. Those are different things, because if you make the price for Product X in Medicare a function of the price for Product X in, say, the VA or internationally, you change the incentives for the maker of Product X when they're negotiating with the VA or other countries. And that has been, I think, what the CBO has been worried about. The difference is when you're going to a different product or bundling two biosimilars together, for example, it's a different type of reference pricing than if you're picking a different customer's price for the same product because it affects the dynamics of what the price is for that -- the way that the manufacturer of that product sets the price to the other customer. And that's just an economic distinction I think differs between using international/VA versus using the reference price for, say,

a least costly alternative model where you're looking across product as opposed to within product.

That was a mouthful, and I think -- I'm sorry. If I'm right, Larry's next. If not, Dana is going to correct me and tell me I need to pay more attention. Dana, am I right?

MS. KELLEY: I have Larry as the last Round 1 question.

DR. CASALINO: All right. I think Kim actually addressed this earlier, but I want to ask it explicitly. Is there any evidence one way or another about -- I'm talking now about Part B ASP plus 6 percent and whether some providers make or lose money on that. What kind of evidence is there about the ability or the differential ability of providers to negotiate Part B prices? So, you know, could a large hospital system, for example, that employs physicians negotiate lower prices for their Part B drugs than a solo practice oncologist, say? That was the question I had. Since then, I have another Round 1 question. I'll just ask them both at the same time. So that was about negotiating leverage and whether it exists, whether it works for distribution of Part B drugs.

The second was in terms of reference pricing. This is still not clear to me. Maybe it should be. It sounds like what the recommendation is is if the reference price is $1,000 and the manufacturer's charging $2,000, the beneficiary would pay the difference. So I guess the question is: Is that -- do I understand you correctly? And then a corollary question, if I do understand you correctly, so the provider in that case still has an incentive to prescribe higher-cost drugs, but the reference pricing makes no -- with your recommendation, does the reference pricing have any impact on what the provider actually gets paid or is responsible for above the reference price? Two separate questions.

MS. NEUMAN: So on the first question, as far as different negotiating leverage across different size purchasers, so we don't have great data on what the distribution of purchase prices look like across purchasers. ASP is an average, but how big a variation there is around it, we don't have that data to know.

When people talk about this issue anecdotally, you know, there's perceptions that high-volume purchasers probably have more leverage. But there are buying groups

and so forth, GPOs, that smaller entities can participate in. And so there's a question of how much does that level the playing field. So that's the first question.

MS. RAY: Okay. I can take a stab at the second question. So let's use the example of erythropoietin-stimulating agents, and if -- well, let's say, for example, the payment was set based on the least costly alternative. What we described in the paper is that if the doctor thought, attested to that the patient required the more costly product, then the patient would not incur any additional cost sharing. They would be charged the cost sharing under the LCA policy.

If, however, after the patient and doctor met they both wanted the more costly drug, there was not a clinical necessity for it, then the program would not pick up the additional cost sharing. But this is, of course, a point that Commissioners could discuss.

DR. CASALINO: But the additional question, part of that in effect goes to the manufacturer or whoever's selling the drug and part of it goes to the physician. Is that correct? Or this doesn't change the physician's incentives except insofar as they care about the patient?

Do I understand that correctly?

MS. RAY: Well, I mean, you know, this policy is motivated to spur price competition among clinically similar drugs, and that once, you know, Manufacturer A sees that Manufacturer B is lowering the price, that will stimulate that manufacturer to take appropriate action in the next -- you know, over the future.

I would anticipate that the provider and the patient would talk together about the choices of different medications and the differences in out-of-pocket costs as well.

DR. CASALINO: Thanks, Nancy, and I'm not trying to make a point that it should be one way or the other. I would just say in the chapter it probably could be more explicit than it is, who's responsible for the extra payment, you know, above the reference price. I'm not making an argument who it should be or how it should be, but just I think what the staff intends could be more explicit, I think.

DR. PAUL GINSBURG: I'd like to follow on what Larry has been asking, which is when say under 6 percent of ASP, if the percentage was lowered and meant that some

physician practices would lose money to administer on some drugs, is it administratively feasible for manufacturers to then cut the prices to those practices that -- to keep them whole, to avoid them losing money?

MS. NEUMAN: So manufacturers can lower the price to any purchaser. If they do, what would happen is that that would feed into the ASP a couple quarters later. But another approach or response that might happen is if the percentage add-on was reduced, there's a possibility that manufacturers would reduce the variation in prices across purchasers. So even if we know what it is today, which we don't, but if we did, that's not necessarily what it would be in response to the policy.

MS. KELLEY: Did you want to get in here, Mike?

DR. CHERNEW: No. I was just going to say I'm glad we left the amount of time we left for this session, because we have now about an hour for Round 2 questions, and I think the tension here -- I just want to emphasize what I was trying to say before when you couldn't hear me, which is the real tension here is the tension between managing the price and the overall spend on these products, acknowledging that they do add a lot of value, and that we

want to, therefore, also incent their development in the future. That's the core challenge here. So we want to buy efficiently. We want to spend less. We want to maintain the incentive to innovate.

I think as we talk through these options, I'm really interested in thinking about not just how to get prices low -- I think that's easier -- it's how to get prices low and make sure that the purchasing is more efficient and we don't really have too deleterious a consequence on innovation.

Again, I don't think -- we have to be careful not to use innovation as an argument for why manufacturers should have a blank check. I think that's completely wrong. But I do think we have to recognize that trade-off, and we want to purchase efficiently not only cheaply. And efficiency in this context is dynamic, not just at a point in time.

That being said, I'm now going to listen to all of the Round 2 questions. I'm going to let Dana manage the queue, but I think I'll kick it off because I think if I'm right, Brian is first. Is that right, Dana?

MS. KELLEY: Yes, that's right.

DR. CHERNEW: Okay. Brian, go ahead, and then, Dana, you can manage the rest.

DR. DeBUSK: Thank you, and thanks to the staff for an excellent report. What I actually have are two borderline Round 1/Round 2 comments, but I wanted to push it into Round 2. But it is a question and a statement for the staff.

First of all, I do see the value of a reference price, whether it be, to Bruce's point, Medicaid, VA, or even an international price. It seems like very useful information. But I also see the problem -- and I think Amol and others pointed this out -- about using it in a formulaic way, hard coupling into payment. It creates all these issues of what is the correct payment amount, how do you address cost sharing.

So I want to ask a question, and it's a little bit rhetorical but not entirely. Have we looked at using a reference price or some type of international, even, reference price as a way to set a threshold or a trigger? So, for example, if a drug reached 150 percent or 200 percent of the reference price, so say to a median price in G20 countries, could we from there trigger, say, the

restructuring of the ASP? Or could we, for example, trigger the consolidation of the billing code?

So I'm just wondering if we could use that exogenous price in a beneficial way but use it more as a threshold and give the Secretary a little bit more latitude so that you don't have this hard coupling into the system where, you know, if A, we have to multiply it by this factor and turn it into B. So I guess that's my first comment and question, on the use of an exogenous or reference price as a threshold for some subsequent action. And I do, by the way, very much favor modifying the ASP add-on payment, especially, you know, to someone who, say, is potentially a bad actor.

My second comment is around launch prices. The dominant strategy clearly is to launch high and then walk down a rebate, because there's really -- in a rebate environment, there's really no penalty for launching too high because, you know, as you step up the rebate, they're enjoying the ASP benefit. I mean the price of the drug is actually shrinking. And you see the difference between that versus trying to walk the ASP back up from a drug because, you know, with the two-quarter lag in the ASP

calculations, providers are always staying behind the curve.

So here's my question, and I'd really, really appreciate some Commissioner feedback on this, too. Is there any reason that a newly launched drug should have a large rebate attached to it? I realize that there might be a rebate attached to formulary placement or some type of preferential access to the drug. But I don't see a 30, 40, 60 percent rebate. So I guess this is the second question or policy option, is when we focus on new drugs and launch prices, if we restricted the amount of rebate or put some type of guardrails on that, would it get us closer to discovering the true launch price of a drug? Would it give manufacturers less latitude and actually add an individual to guess correctly with a launch price?

And with that, those were my two questions/comments, and, again, thank you for an excellent chapter.

MS. RAY: So just one item about the trigger that you had suggested early on. So I think there might be some implementation issues to consider, number one, the availability if you were to base it on international data;

and then, number two, so, again, this -- you know, our option to use what we call "internal reference pricing" on a therapeutic class of drugs, you could have some variation in prices already under the current ASP plus 6, and so this trigger could trigger, let's say, Drug A but not Drug B. And I think we would have to think a little bit more about how that would play out.

DR. DeBUSK: Thank you.

MS. KELLEY: Stacie?

DR. DUSETZINA: Thanks to the group for the excellent presentation and report.

I have a few comments just to make it in general on the suggestions and the recommendations that we're hopefully working towards.

One is that I fully agree with the idea of using some sort of value-based payment limit for new drugs and especially thinking about maybe a starting place for that being drugs with less evidence available at the time of approval. So, for me, the accelerated approval is a very good example of that, where we might want to think also about overall budget impact in addition to the information available at the time the drug comes on the market.

I also think this is -- I am very supportive of the internal reference pricing, and just to be clear, the concept especially of thinking about putting therapeutic alternatives together under the same billing code in Part B, I think, is incredibly attractive.

From one of the Round 1 comments and thoughts about evidence generation, it could be worth thinking about how Medicare Advantage is currently handling these Part B drugs and trying to steer people to lower-cost alternatives when higher-cost alternatives exist as one way of kind of gathering a little bit of information about where we might target this kind of bundled therapeutic substitutes for reference pricing in Part B.

I think very much like a couple of the other comments that have come up about this thought about who pays more, and I think it was Larry's point about kind of trying to get clarity around the patient paying more when they have a drug that is selective that is not the preferred or referenced product. When reading that part of the chapter, I kind of reacted fairly strongly that I don't think that we should necessarily put the patient on the hook or the beneficiary on the hook for all of that

additional spending, and part of the comments made in Round 1 about this is often a physician-driven decision -- and especially in Part b, the patient doesn't see that price before they get the bill later, after they've received the service.

So I guess I'm a little bit more inclined in the Part D setting of reference pricing and co-pays and cost sharing for beneficiaries. At least they see the price before making a decision to fill the drug. So I think we want to be cautious about that component and how the cost sharing affects beneficiaries.

Just two more quick points. One is the average sales price change and that lack of information about the distribution of some potential physicians who are losing money on the average sales price versus making that margin. It seems there is an opportunity to think about offering -- some sort of vendor model, I know, has been proposed in the past, the idea of having a place where those smaller practices could get the drug without having that financial penalty of having a purchase price that is above the average sales price, in which case, we wouldn't be double penalizing them. But I really am supportive of the idea of

changing how we reimburse for these drugs and leveling the playing field for low-cost items.

And I think for the rebasing question, less enthusiastic on that very broad approach, although I am enthusiastic about us being really cognizant about trying to get to a place where we're rewarding innovation that provides additional value to patients and trying to get rid of the overpaying for low-value treatment.

Again, thank you so, so much for this excellent chapter.

MS. KELLEY: Okay. Paul?

DR. PAUL GINSBURG: Thanks. Well, all four authors did a great job, both writing the materials we looked at and presenting, and gave me a lot of ideas about comments to make. I'm going to try to limit myself.

The first one I want to make is that as this progresses to potentially a chapter, I would like to see some framework discussion really addressing the fact that why do drug prices rise so much, because you had made the point accurately that this is a key driver in spending more, and when you think of a drug, a brand-name drug that has been launched already, much of the price is not for the

production costs, but it's really as compensation for the R&D that went into developing the drug.

So it's a very strange phenomenon normally to think, well, why would a drug raise its price. I mean, why would a manufacturer raise the drug price after launch? Because you would think that as time goes by and more new drugs come out that might be better than that, that means that the price would fall rather than increase. And I think the most likely explanation for this is that the domain conditions have changed.

We have, I think, fortunately, much better coverage for drugs. More people have coverage. Except for Medicare, most people with drug coverage have out-of-pocket limits that applies to drugs as well as spending on services. So, in a sense, I think a lot of the reason for the price increases is that we've done good in providing coverage and access and financial protection for patients, but one of the downsides has been that this has generated price increases. So I just want to say I think we should keep this in mind as a framework for our discussions.

The second issue I want to talk about is what Mike was trying to get into, which is what we mean by

value-based pricing. I realized recently, really, how loosely some of us speak, including myself, on this. In fact, I learned about myself speaking loosely the last paper I published at Brookings about drug pricing when it was going through internal review at Brookings. It was pointed out to me, and I fixed it. I want to, hopefully, help the Commission fix its loose use of value-based payment.

And it goes like this. Most of us, when we're thinking about value-based payments, we're thinking about services or drugs that have very low value for patients or even negative value, and we don't want the payments to be higher than the value that patients get from the treatment. That all makes sense.

But what happens when it comes to high-value drugs? Here's an example. Blood pressure medications, widely used, really valuable because people can control their blood pressure and the cardiovascular events are reduced as a result, but we pay very little because most of them are generic. We use the term "value-based payments" and apply it not as a cap, saying we should never pay more than value, but that we should pay value, then I think we

could be overpaying a great deal for the drugs that have high value.

In the economy outside of health, many goods and services that consumers buy have much higher value to them than the prices they pay, and how does this happen? It happens because competition drives prices down to the marginal cost of producing it, and you see this in a most extreme way when you think of water. Some units of water that people use are extremely valuable. They're essential to life. But most water that's used is for the lower-value uses, for watering lawns, for growing rice in deserts in California. So, in a sense, the market price that's usually fairly regulated of water tends to be a very low price because it is based on the lowest-value uses to which it is put, and the people that drink water to sustain life, well, they get a great bargain because they don't have to pay enormous amounts to survive with the water that they use.

So the key thing is that consumers often -- and as the way it should be -- don't pay as much as the value of goods and services they get.

Now, for medical care, we also have this issue

that for many treatments, we overuse them. Some of them are very valuable for some patients, but we tend often in this country, in particular, to apply them to additional patients where the value is lower. So, in a sense, I don't know how to operationalize that for medical care, but in a sense, again, the prices should be based on those patients where there is value but the value is lowest.

So, anyway, that's just a caution as to let's use the term "value-based payment," et cetera, more carefully, and let's not inadvertently say all of the value that comes from drugs should go to the manufacturers and the patients or the payers that pay for their drug should really pay that full amount up to that value.

The other thing I wanted to say something about is the 6 percent of ASP for Part B drugs. Just one thought to consider is that I'm somewhat concerned that this may be an area where, as they say, the juice isn't worth the squeeze. I'm somewhat concerned that some of the proposals that have been put up as suggested in the past just don't have that much potential and that we should be looking elsewhere to have bigger impacts.

I think one exception to this would be when it

comes to when we have very large differences in prices between drugs that are therapeutic substitutes for each other. Then it might be worth having distinctly higher payments for the less expensive drug, and for the drugs used for macular degeneration, we actually see this in commercial insurance more frequently where the much lower-priced drug, Avastin, that some payers will pay physicians a much higher markup in dollar terms for administering that than for administering the much more expensive drug.

So that's kind of a caution. Let's use this for strong incentives, but otherwise, the incentives that we're talking about, fiddling with ASP+6, say a combination of a dollar amount and a percentage, just might not be worth the bother because the previous, fairly timid proposals got so much opposition from physicians concerned they would lose money.

Final comment is that with drugs approved under the accelerated processes, without evidence of clinical effectiveness, maybe -- and this is the point I made at the beginning, but since we don't really have information on clinical effectiveness, maybe we should just pay for those drugs a much lower amount, perhaps based on production

costs to, in a sense, provide a strong incentive to accelerate the process of developing the clinical evidence that's really so important. Thanks.

MS. KELLEY: David?

DR. GRABOWSKI: Great. First, thanks to the team for this great work and presentation. Paul's comments provide a really nice launching point for my first point.

I wanted to also talk about value-based pricing. I think, Paul, you teed this up perfectly. We don't want to spend more by applying value-based pricing broadly, but I do think there's a role for it, as Stacie and others discussed, a very targeted value-based pricing, especially with the high launch prices.

Stacie raised the accelerated approval pathways where clinical benefits are still uncertain. I know Stacie has written about protected classes as well as being another place where you might apply this where public payers are required to cover particular drugs. So I do think there's areas where we could use value-based pricing.

I will, as an additional point here, suggest that we also need to invest in an infrastructure if we're going to use that, and I think we have very little of that

infrastructure currently in place. I think the chapter does a nice job right now of outlining what some of that infrastructure looks like in terms of data and methods and so forth, but I am supportive of using this in very selective ways. I do think there's a role for it.

But, Paul, I completely agree that that role is not shifting our system to complete value-based pricing.

Shifting gears, then, I did want to respond to the second bullet there about reference pricing. I'm also supportive of this in Part B where there's therapeutic alternatives. I think my fellow Commissioners have already raised some good points that I won't repeat about some of the potential pitfalls here, but I do think there's a role for it.

Finally, around the financial incentives for ASP plus 6 percent, it's not hard to see with that system what the incentives are, and we've certainly seen a lot of providers respond to those incentives. I like the idea of shifting to a fixed fee. That may not be popular with everyone, but I do think there's a role here fixed fee because if you continue to pay plus 6 percent, we all can guess what providers are going to do.

I'll stop there. Once again, I'm really supportive of this broad set of work and excited to see where we take this. Thanks.

MS. KELLEY: Bruce?

MR. PYENSON: Thank you very much. Again, I want to say again to the team, really terrific work.

I do have a couple of points. My first point is to amplify something that Mike said, that the issue is not just about new drugs, though it's much of the focus of the chapter. In particular, when I look at Table 1, which totals many billions of dollars in Part D spending, the leading spending on drugs, of the 20 drugs listed there, it seemed to me about half of them were drugs that either should have been off patent for which there are biosimilars available or drugs for which there are much cheaper alternatives. I think the potential of looking at the ways to address the existing portfolios of drugs, there could be huge value there.

I do want to state my opposition to general value-based -- keeping in mind Paul's comment that I might not quite know what I'm saying about value-based, but I'll say that the issue of value is often defined on a

willingness-to-pay basis, and that's part of the framework that the federal government often uses in economic decisions. On that basis, the Medicare program country would be very quickly bankrupt.

I'm also opposed to the use of QALYs. There's a number of methodological flaws and even arithmetic limitations in the use of QALYs. However, as an alternative, I'd like to suggest that our expectation for drugs should be deflation for the reasons that Paul mentioned and to build that into our outlook that the expectation is that drugs will deflate over time as opposed to talking about a CPI inflater or as a limit. It should be quite a bit less than that.

A couple of comments on the concern about innovation. In stock pricing valuation, there's a concept of certain things already being discounted. I would say that health care reform and limiting prices, price controls on pharmaceuticals is nothing new. It's been talked about for decades, and so I'd say the valuations probably have that already discounted.

I'd also say, as a cautionary note, that when some economists talk about innovation and the valuation of

that, that would include innovations such as OxyContin. I will say looking at the mortality improvements from drugs that treat late-stage cancers are emphatically modest for most of them. So, while there are emphatically terrific innovations being made, the term has lost some of its meaning because of the very limited benefits that are seen.

In terms of the expedited approval, there was just a paper out on how much Medicare program spent on a drug or two whose indications were withdrawn, and I would suggest an option for our consideration is that Medicare program gets a refund in exchange for covering expedited approval drugs, that if the drug is withdrawn, there is a refund made to the Medicare program.

And finally, back to value, I think the public has to own a good portion of the value. The improvement in the public good is something that we can quantify or something that we can identify as conceptually. Innovation occurs for a number of reasons. There are investments in particular companies. There are also investments made by federal research funds. There is also the infrastructure that society creates and the regulatory apparatus that allows markets to operate.

So a good portion of that value belongs to the public, and if we go down this route I think we need to separate the idea of value, the concept of value from who pays for it and who gets paid for it, rather than assuming that the value would go to the manufacturer. Thank you.

MS. KELLEY: Lynn.

MS. BARR: Thank you. Great work by the staff. As a new Commissioner I'm in awe of your staff, Jim. You are so lucky. I really appreciate the comments from the other Commissioners.

I think one of the things I've been looking at a lot lately is access to drugs and health equity. And I'm seeing very large differences in access to these drugs in safety net patients versus non-safety net patients. And I would really appreciate it if the staff could look at this, because, you know, Medicare is kind of the only place where there really isn't drug coverage for a large portion of the population, people above 150 percent of the federal poverty limit and then, you know, down below maybe 300 or 400. I'm not sure exactly where that number is but I can see huge disparities in our data.

So I'm very in favor of doing these policies.

I'm also a practical person and understand the difficulty of getting anything past the pharmaceutical lobby.

I'd like to propose that maybe we could think about this in a different way, and if we think about a voluntary program for the manufacturers that if they agree to reference pricing, CED, whatever it is -- and this really applies particularly to Part D drugs, following Stacie's comment -- that we could waive the cost-sharing on those drugs. And is there an economic middle ground here, where we actually reduce the cost of drugs, because the competition is to get all of those patients in that aren't accessing these drugs today. And if we can somehow divert some of that cost to the patient and allow them to be like tiered, like generics, if they voluntarily submit we might create competition without having legislation.

MS. KELLEY: All right. Dana.

DR. SAFRAN: Thanks. I'll be brief. Just also adding my appreciation for this outstanding chapter. A lot of the ideas in here are really exciting, and I like how it's coming together.

I'll add my support to much of what's been said, to not consensus I can hear in this group, for value-based

payment models for new therapeutics. I understand, from Nancy's response, that the cost effectiveness component of that would require legislative change. I still think that this is something definitely worth pursuing, in conjunction with the coverage with evidence development. I like that pairing that you proposed.

In terms of reference pricing, as my Round 1 question indicated, I would want to have more data from modeling before weighing in on the merits of that, but I agree that on its face it does seem to apply here.

And then finally two items. I definitely support, you know, continued emphasis by MedPAC that CMS should act to either reduce or eliminate and replace the 6 percent. You know, I was struck by your say that the rationale for the 6 percent was to provide a "fair margin." You know, 6 percent, it's stunning as a number selected for that purpose, if that was, in fact, the sole reason for selecting that number. Times have changed.

Finally, I really like the point -- I think it was Paul started the conversation about you know, why are medication prices not deflating. It's compelling given the nature of this good and its difference from other health

care services, where there are human wages to be considered. I know that's a topic for later in the meeting.

So it is compelling, but I do wonder, as I do that thought exercise, how that kind of policy change, if were implemented, could affect drug innovation and the uptake of new, potentially more expensive drugs, whether, you know, the way that that dynamic would play out would actually cause us to be shooting ourselves in the foot if we build in deflation on existing medications. So just something I'd want us to consider, but again, on its face I thought that had a lot of merit and something we should be thinking about.

So thanks for the great work and the opportunity to comment on it.

MS. KELLEY: Betty.

DR. RAMBUR: I think Marge had a comment on Stacie's comment, if you want to go to her first.

MS. KELLEY: All right. Marge?

MS. MARJORIE GINSBURG: Great. Thank you. Lynn, I really liked your comment. I'm not sure I understood it completely but I think what you were saying is let's

encourage drug manufacturers to follow the rules for more efficient pricing by basically eliminating the copays that beneficiaries would have if, in fact, the drugs are following our rules for efficient drug pricing. The love the idea, if I understood that correctly. And I think maybe sometimes we haven't paid enough attention to how can we use beneficiary cost-sharing to help move forward more effective pricing mechanisms. So anyway, great idea.

MS. KELLEY: Stacie, did you have a reaction to Marge?

DR. DUSETZINA: Yeah. I just wanted to say that, you know, historically I think that the literature on reference pricing for patients has tried to shift in that direction of the preferred drug being free for patients and then the other products that are less preferred by the plans being a higher copay or the difference in the price. But I think that really would provide a nice benefit for people in Part D, in particular, is make that preferred drug very low cost or no cost, would be great.

MS. MARJORIE GINSBURG: Let me just say one more thing. If I recall from years ago, information about reference pricing, is that sometimes patients value

something more when it costs them something, and this often can also be a bit of a danger if they think, well gee, if it's free it must not be as good as something else.

So I recognize that we may have that element to deal with, but notwithstanding that I still think it's worth a try.

MS. KELLEY: Okay. Betty.

DR. RAMBUR: Thank you so much, and staff, thank you for an absolutely fascinating chapter, and Commissioners, I really appreciate your input.

I'm very happy with the overall direction of value-based initiatives that we're talking about, and I just wanted to underscore and amplify a point that was previously made about physician incentives or provider incentives for using more expensive drugs and removing those incentives, and not putting it on the beneficiaries.

There is literature out there about the difficulty providers have in talking to patients about cost, and shared decision-making that is inclusive of cost has not been found to be a very workable model. And as you all know, it is a vulnerable purchase for individuals, and for a provider it is just so easy to say, "Well, we can

always try X, Y, or Z." So I think it's really important to take away the financial, overly generous financial incentive to say we could just try X, Y, or Z.

The only other thing, I wanted to support the idea of there should be deflation, and I'm not hearing a lot of enthusiasm for rebasing as part of that, or there hasn't been much conversation on that. And just to put on the board that I'm not sure that rebasing, one-time rebasing, is a bad idea. So I look forward to hearing more about what others of you think about that.

MS. KELLEY: Larry.

DR. CASALINO: Yeah. I mean, first of all, really fantastic chapter. So informative and nicely laid out.

I'm very supportive of reference pricing. I think it's been shown to work well in other areas, for example, for some surgery-based episodes. And by reference pricing, there has been a little discussion of why, I guess, what we mean by that. I mean, you take the lowest-price drug that has comparable clinical effects to the other drugs in the class and set the reference price there.

I am concerned, though, that we're talking about

Part B drugs. We're not talking about prescription drugs. And so it wouldn't really be great for someone to inject something in a patient and a month later have the patient get a bill, based on the reference price for a large amount of money that they were completely of this. So I think for reference pricing for Part B drugs there would need to be some kind of mandate for providers to discuss the additional cost with the patients and some evidence that that has been done.

Obviously, we don't do that for prescription drugs. The providers would spend their whole day having those discussions. But we're talking about Part B drugs here. We're talking about things that are injected, usually repeatedly, in many cases repeatedly, and not necessarily that often. So cancer chemotherapy, you know, intravitreal injections for macular degeneration. And the providers who are doing that again and again on the same patients, I don't think it's too much of a burden to ask them to discuss possible cost-sharing if there is reference pricing. So I am in favor of reference pricing, as things stand out.

I also am in favor of doing something about the

ASP+6 percent add-on. You know, I'm mindful of Paul's comments about is the juice worth the squeeze. I think it is. It's a terrible distortion of standards to have physicians in some specialties, like oncology or ophthalmology, make most of their profit from choosing expensive drugs to inject as opposed to for work that they actually do. I mean, if you were a Martian and you came here and somebody told you that, you'd say, "That's absolutely insane."

So something should be done about that. I like all three of the alternatives the staff presented, about possibly the most workable, and there are people here, I'm sure, who know a lot more about this than I did, would be maybe changing the percentage and then setting a dollar cap so that you couldn't make just outrageous profits from a single injection or a single drug.

And then the last two things I have to say, one is, value-based pricing, you know, it sounds great. I think some Commissioners have raised some of the problems with it. The fact that there are problems with it or would be problems with it doesn't necessarily mean it shouldn't be done. But I think I'd like more discussion from

Commissioners, possibly from the staff when they come back to us, if not value-based pricing for first-in-class drugs, Part B drugs, then what? What are the alternatives? Because I don't have a sense of that but I suspect there are people who could suspect that.

And then my last point is just about innovation. You know, we don't want to kill innovation in the pharmaceutical industry. I mean, development of the COVID vaccines, development and treatments for HIV, for hepatitis C, there have just been marvelous things done in a short time. So I don't intend to bash pharma. But I do think we have some room to wiggle on innovation, and if the profit margins for pharmaceutical companies are left somehow extremely high, we do pay, you know, twice what other countries pay for drugs, and to me that does suggest that -- and the NIH, of course, contributes a lot to innovation.

So I think that we don't want to be too timid, I think. We don't want to kill innovation, but at the same time there is no reason why the current profitability in the industry, in my opinion, has to stay the same as it is to keep innovation the same as it is.

MS. KELLEY: Mike, did you want to get in here?

DR. CHERNEW: Yeah. I wanted to say something in response to reference pricing, that Larry said. This is really a question for Nancy and Kim. My understanding of what we mean when we say reference pricing here is much closer to a least-costly alternative price that Medicare would pay as opposed to a reference price for a knee surgery, line in the benefit design literature, you know, Jamie Robinson, Chris Whaley, Tim Brown's work on reference pricing. So again -- now I see Nancy.

I think we're struggling with some of the terms. We don't mean set a price and then the beneficiary has to pay more. This is not really a benefit design discussion, I think. My understanding, Nancy, is this is a payment discussion about what Medicare would pay, and what you mean by a lot of this is things like let's lump biosimilars in the same code, which is a recommendation we already have, by the way, and analogous things, where the difference is not picked up by the beneficiary. Nancy, can you speak to that for a second, before we go to, I think Amol is next?

MS. RAY: So under least-costly alternative policy, for example, let's just make it very easy. Three clinically similar drugs, one is priced at $5, another is

priced at $10, and the third is priced at $15. So Medicare would set the price of all of those drugs at $5, and then the beneficiary co-insurance would be based off of the price of the least-costly alternative, and in this example it would be $5.

DR. CHERNEW: And the difference -- I'm sorry. Go on, Nancy.

MS. RAY: No, no. You go.

DR. CHERNEW: The difference there is not a reference price or the person pays the difference in the 10. The difference is Medicare just said if you are pricing 10, there's another drug that we think it's the same drug and we're paying 5 for it, we're giving you $5 for your drug. That's just the price you get. It's the manufacturer -- in what Nancy is describing, the manufacturer is just getting paid the reference price. There's not a balanced billing version of this or some other version, Larry.

Again, I'm just trying to interpret what's on the table here, in terms of what's meant by reference pricing. In a reference pricing in a benefit design sense you would use the term in a completely different context, where the

insurer would pay for the reference price and the beneficiary would have to pay the difference. And again, I don't think -- my read of the materials and my discussions with you, Nancy, suggest that you're not suggesting that type of reference pricing. You're suggesting much more of a price-setting the lowest-price alternative drug, in that example.

MS. RAY: Right. So Kim, if you could provide a little assistance here. So to be clear, it's the physician who purchases the drugs, and Medicare pays the physician, not the manufacturers for Part B drugs. Now, so there's the instance in which, let's just say that the patient tried the less-costly drug, for some reason the patient had a side effect, and the provider wants to try the more costly drug, the $10 drug, for example. So the question is, what to do in that instance, with the 20 percent cost-sharing.

Kim, maybe you can help me explain this a little bit better.

MS. NEUMAN: So I think you're talking about the exceptions process?

DR. CASALINO: Yeah, and if I can -- and I don't

think the exceptions process is what we're talking about. I think that, in general, I really like reference pricing, but we are now an hour and a half into this discussion. It's pretty clear that at least some of us still don't understand what we mean in this context. I'm not talking about exceptions. But is the reference price what the provider gets paid, and that's it, or does the provider get paid their usual ASP+6 percent, or whatever, and the patient is somehow responsible for the difference, or there could be a way to split it between the patient and the provider, for example, some percentage less.

MS. RAY: So using a least-costly alternative payment policy, the payment would be based on the least-costly amount -- in my example that would be $5 -- and patient co-insurance would be based on the $5 least-costly payment.

DR. CASALINO: Okay. So the patient would not be responsible, as they are, for example, for an episode of surgery.

DR. CHERNEW: Right.

DR. CASALINO: The difference between the reference price and what the provider was charging. Is

that correct?

MS. RAY: Right.

DR. CHERNEW: Right. That's what I was trying to say. We're not using the term "reference price" here in the context that you might see it in a benefit design discussion. We're using reference price here much more closely as the way you would see it in a least-costly alternative discussion, which is about the price that Medicare pays.

And so, again, I think the point you're making, Larry -- and I think this is true and I'll say this in my summary, right after Amol talks -- is we use certain terms in different ways, and it generates confusion because some of those terms are used in other contexts for other things, and so people are not always sure what's going on. Again, I'll say something about that, but at least for the purposes of this discussion, Larry, is it clearer now what we're talking about when we talk about this particular thing?

DR. CASALINO: Clearer, but I still think if we went around the room and asked each Commissioner to say what they understand we might not get the same statements.

So I would just encourage the chapter to be very explicit about what gets paid to the provider, what, if any, responsibility the patient has, what implications this has for the manufacturer. Just spell it out, and with a dollar example it would not be a bad way to do it.

DR. CHERNEW: And what the provider has to pay, if they decided just who gets the exception process, if they decided to use the higher-priced drug or some other thing.

This really must be a clarifying thing, and I think we needed some clarity. We may not have gotten there yet. But if I'm right here Amol is next, and last. Is that right, Dana?

MS. KELLEY: Yes, that is what I have.

DR. CHERNEW: Okay. Amol.

DR. NAVATHE: Thank you. So I also want to echo Commissioners. Congratulations to the staff. This was excellent. It's obviously very complicated, and you all have done a very nice job of making it clear and laying out the options in a very digestible fashion.

So I wanted to sort of voice support of several things that Commissioners have said and then bring a couple

of extra points, I guess, on the issues. On the topic of the reference pricing, I think in the context of the clarification, without the benefit design piece of it, I think I would also like to voice my support of the idea of using reference pricing here as a potential mechanism to address the short of high costs here.

A couple of other points. So I think there has been some debate about the use of cost effectiveness data, or comparative effectiveness data. I'm sympathetic to the points that using formulas as a standard basis to do things is potentially very risky in getting funky, you know, not optimal types of results. But I do think that there is a value in thinking about many of these factors. You know, take a cost effectiveness, comparative effectiveness evidence, external prices, reference prices, as potential inputs into a process of considering how, for example, FDA accelerated pathway approved drugs, for example, end up getting priced.

And so I think having to some extent a differentiated system that acknowledges the fact that there may be a need to bring these drugs to market very quickly at the same time they're coming with much less evidence,

and then bringing the multiple data points to help understand what that should be I think is something that seems reasonable and might be a very sensible pathway here.

I think there's also an important piece that we can do perhaps a better job in the chapter but also worth considering is the differences between using these data for coverage decisions and using these data for pricing decisions or reimbursement levels, which there seems per the earlier discussion to be some distinction around, and I think it's worth kind of highlighting that and how that might be effectively used.

Personally, I would say I'm not particularly enthusiastic about the idea of rebasing that you had asked about that, although I would also not say that I'm diametrically opposed to it. I think there could be some value in rebasing and it would be worth exploring what that could look like.

Similarly, I will say that I am -- I guess like many other Commissioners, I see Paul's points about the juice is worth the squeeze on the ASP plus 6 percent. At the same time, I think actually we have a complete dearth of data on what that variation looks like and what that

impact would be. And I think, in fact, in the report, the writeup said, you know, is there support for doing additional analytic exercises to better understand what a fixed fee or partially fixed fee could have in terms of impact. So I wanted to definitely voice support for moving in that direction. I think it would certainly be worth doing the analytic effort in that way.

Then, lastly, I think like Larry, I would just want to make sure or make the point that there's a lot of innovation that's happening. I think we want to support and understand the link between the policies that might be developed and the future development of drugs and devices and therapeutics, vaccines, et cetera, that might be important. I think this has been mentioned at times perhaps in other settings, but we should be mindful that oftentimes the price that we're paying for here is not necessarily related to the marginal cost of producing this particular drug, but it really is a reflection of the cost, if you will, of the innovation, the pace of innovation. And so we should be very mindful of that as we think about that sort of coverage and pricing policies going forward.

Thanks.

MS. KELLEY: Stacie, I think you wanted to add something.

DR. DUSETZINA: Yeah, I realized that I had neglected to respond to the question about coverage with evidence development, so I just wanted to make one final point about that. And part of it is based on the idea of having this somewhat coupled with the conversation around accelerated approval where we know the evidence that has been generated to do is maybe not as robust for clinical outcomes.

I guess in general I think coverage with evidence development, having more flexibility around that is good. But I also think it's important to not be redundant with requirements of the industry to produce this information. So not having it used as, you know, fill in the gap for trials not recruiting enough people who look like Medicare beneficiaries or who have these risk factors. So I think in general I wanted to say I'm supportive of it, but I think that when first reading the chapter, it came across a little bit as if we are going to set this value-based price or think about some sort of value assessment for pricing, that we would also do that in the context of coverage with

evidence development, and I think that they could be not necessarily always used together.

That's it.

DR. CHERNEW: Okay. Dana, I think that was the end of the queue. Are we right?

MS. KELLEY: Yes, that's all I have.

DR. CHERNEW: I'm going to pause for a second to see if anyone wants to say something else. Then I'm going to summarize. We're going to eat and come back -- to talk more about drugs, by the way.

Okay. Going once, twice, gone.

So here's what I heard. I have a lot of conversation to summarize, so you can grade me on my summary later. And, of course, I will take this back to Jim and the staff, and we'll discuss all of this, but at least so you know what I heard.

Point number one, there's a lot of support for a different pricing regime for drugs that got accelerated approval and maybe other places where competition isn't working out. We haven't talked a lot about protected classes, but I would think there's an analogy there. There's not necessarily a lot of support for what I'll call

"value alignment" because that essentially gives whatever assessment of value we have to the producers. But we may want to use information on effectiveness in whatever pricing regime gets put in there, and we have more work to do to figure out what that might be. So, you know, thinking about effectiveness is fine, but we wouldn't want to take a new drug and say, oh, this looks like there's a lot of value and just in general we're going to raise the prices and raise the price of everything up to some measure of value. So that's point one.

Point two, there's a lot of support -- this is going to be fun to say. There's a lot of support for reference pricing, but a lot of disagreement about what that term means. So let me say a few things about that.

There's one version of this, which is -- I call it the "same drug, different customer approach." In other words, you look at the VA, you look at international pricing for the same drug. And the concern with that is there's complex feedback issues about what that other price, the VA or the international price, would be. And that requires a lot of thinking about the merits of what I will call a "same drug, different customer reference

pricing model."

Then there is a different version, which is -- I'll call it the "different drug, same customer model," so basically within Medicare. So now you're looking at the example that Nancy gave. There's three drugs. They're pretty equivalent. One of them priced at 5, another is 10, another is 15. Let's set a reference price for that. Least costly alternative version would have been you set it at the lowest one. You could bundle them all together in the same code and set it at the average. But the point is it's really about taking different drugs that are similar and bundling them together, get a single price. It's almost -- I think, Bruce, you alluded to this at some point. It's almost like an episode payment for really similar drugs, basically. And Larry pointed out correctly we need to really think through who pays the difference if someone wants to use a different drug in that bundle per se. But just to be clear, this is very much in the spirit of existing MedPAC recommendations on biosimilars and other things. It's not clear if we want to keep the different code and just set a fixed price or put them all in the same code. There's some information issues. But I do believe I

heard a lot of support for some version of that, acknowledging the added clarity that's needed.

There seems a lot of interest in exploring further analysis to pick up on Amol's comment on ASP plus 6. I think there's an acknowledgment that we would like to see some changes there for a bunch of reasons. ASP plus 6 can be quite problematic. But, of course, there's pitfalls, and so that just means there's more work for us to do.

Let me emphasize -- and, of course, we're having a heat wave here, but it is nevertheless October. So we have a ways to go to do that extra work, and I'm sure the staff will do a wonderful job as always. But we will look at ASP plus 6.

One issue that I suspect everybody agrees with strongly but was only mentioned by Lynn is the equity issues and the access to some of these drugs, particularly with the value, for drugs that are high value. It is important that we have a system to make sure that there's equitable access to them. This is a very value-based insurance design. I know Shinobu spent a lot of time on. I'm not going to discuss it much more now, but I wanted to

make sure that Lynn and everybody listening knew that that comment didn't drop by the wayside.

And the last point I'm going to make -- and I say this as an economist somewhat sheepishly; I say it both in language and in substance sheepishly. There's a lot of worry about what I will call "general equilibrium effects," and, yes, I did say "general equilibrium" in the MedPAC meeting. For example, I'm going to name three. There's a lot of concern that I have on the impact on, I'll call it, "the external reference price drug" if we tie a different drug to it. So that means if we -- this is a summary of something I said before. If we make the price in Medicare the same as the price in the VA, we're worried about the general equilibrium effect on the price of the VA drug, and we need to think about the magnitude of that, and folks like CBO and others have.

There's a lot of concern about the general equilibrium effects of things we might do on the prices post launch on what the launch prices are. So we might do a lot to try and say, well, you can't -- you know, launch at what you want, but then you can't inflate. That may just increase the launch prices. So we have to think about

the general equilibrium effects of how that all plays out, and that's complex.

And, similarly, I will say in response to Betty my big concern was a one-time rebasing or any type of rebasing, in fact. The general equilibrium effects of that could be price -- you get a ton of money up front no doubt. But what you do to an organization deciding to innovate going forward knowing that at any point they could rebase you and set the price another way is something that I think needs to have a lot of consideration before we do that. We haven't talked about it a lot. But I'd put that under a general equilibrium concern. If you weren't worried about the general equilibrium, there's a lot of money on the table. But I am worried about the general equilibrium issue.

And lastly -- and I guess this is illustrated by that point -- all of this, launch prices, post launch price, ASP plus 6, all the things we do, we worry about the effects on it on innovation. That does not mean that we are unwilling or we should be unwilling to address high drug prices in general, and certainly address what I would call -- I'm trying to come up with a good term -- flaws in

the way in which the drug markets work; you know, product hopping -- there's a bunch of stuff that goes on that's just really problematic that we allow to happen that we really should think about doing. And I think -- I personally would support thinking about those things, and, again, I think the staff would. But as we do all of these things to try and make sure that we have a health care system that we can afford that includes access to some of the many very, very high value drugs, we do it in a way that promotes innovation, because, remember, these high prices are not to reward whatever innovation has already happened. The high price is to incent that future innovation that we want. And so that's just another broad general equilibrium effect that I think we have to keep front of mind when we do this. But I do think -- and I think it's clear from the chapter -- there are enough problems both in terms of what we're spending, what we're getting in inefficiencies and pricing, that this is an area that's going to require a lot more work. And I'll go with a four-staff-person team to work on this.

So I'm going to close with my appreciation for all the staff that worked on this, and Jim and everybody.

I think that's Rachel, Shinobu, Nancy, and Kim. I may have that wrong. I'm sorry. I've been talking a long time. But, really, thanks for the incredible amount of work that they have done, and we will come back and continue to push this issue forward.

So in my mind, I talked for one minute. By the look on your faces, I probably talked for ten. Are there any other closing comments anyone wants to make before we break for lunch?

DR. CASALINO: Mike, I liked that: "In my mind, I talked for one minute." We should make that kind of a motto for the Commissioners.

DR. CHERNEW: Yeah, exactly. Thanks. That will be my legacy: "He talked for ten. He thought it was" -- it's like the Hanukkah of speeches.

So, anyhow, nevertheless, okay. We're going to break for lunch, and it turns out in this base of prescription drugs, there's a huge problem with the information we have. I think the buzzword would be it's not very transparent. We are incredibly fortunate to now have access to new data. It's really exciting. And the topic that we're going to address immediately after lunch

is going to be basically what should we do with all that data, and I can tell there's going to be excitement. So please, everybody, join us after lunch. We'll do that. And then we'll talk about another crucial part, access to care, particularly in rural areas.

So, again, have a good lunch, and thanks for the discussion today -- oh, actually, I need to say one other thing. I'm sorry. The audience, please feel free to reach out to us. We encourage you to reach out to MedPAC and the staff with your comments, and you can reach them by email, go on the website. We do want to hear public comment on this topic. I am sure people have strong opinions, and I fear I'm going to look at Twitter and hear them all. But, nevertheless, thanks again. We will have lunch, and we'll be back soon.

[Whereupon, at 1:15 p.m., the meeting was recessed, to reconvene at 2:15 p.m. this same day.]

AFTERNOON SESSION

[2:16 p.m.]

DR. CHERNEW: Hello, everybody, and welcome to our afternoon session. We're going to continue our discussion of prescription drugs. This discussion is really going to focus on what we might do with some new data that we have.

So I'm not going to belabor the importance of data and analysis for all of MedPAC's work, but I think it's exciting to see what we have access to, and I am really looking forward to the discussion of how we might use it.

Shinobu, are you taking the lead no this?

MS. SHINOBU: Yes.

DR. CHERNEW: Thanks. Shinobu.

MS. SHINOBU: Good afternoon. In this session, we'll describe types of drug pricing data that the Congress recently made available to the Commission. Because the information is proprietary, our access is subject to certain disclosure limitations. Nevertheless, the data will allow us to examine pricing behavior that was previously unobservable and may help us better understand

the effects of potential policy changes to Medicare drug programs.

In this presentation, I will review our work plan for analyzing the new data. We'd like to hear what you think our priorities should be and any ideas you have for additional research that would be useful to the Commission's work.

This work will be a team effort with Rachel Schmidt, Kim Neuman, and Nancy Ray.

As a reminder to the audience, you can download a PDF version of these slides in the handouts section of the control panel at the right-hand side of your screen.

At the end of last year, the Consolidated Appropriations Act became law. It included a provision that grants MedPAC and MACPAC, the Medicaid and CHIP Payment and Access Commission, access to two categories of proprietary pricing data.

The first category is data on rebates and fees that Part D plan sponsors receive after the point of sale that reduces plans' costs of providing the drug benefits. CMS refers to those data as direct and indirect remuneration, or DIR.

The second category includes detailed pricing information relevant primarily for provider-administered drugs under Medicare Part B, average sales price, and drugs covered under Medicaid, average manufacturer price and best price. I'll explain these in more detail in a few slides.

For both types of data, the law lays out disclosure limitations that will affect the amount of detail we can disclose.

Now let's go into a little more background about each of these categories starting with DIR. This slide shows a simplified example of a pharmacy transaction. The key point to note is that the gross price for a prescription at the pharmacy does not reflect what a Part D plan ultimately pays because there are rebates and fees that are paid after the transaction.

When a beneficiary fills a prescription, she pays the pharmacy her required cost sharing, while her plan and its PBM pay the pharmacy an agreed-upon amount for the prescription. However, the gross price that the pharmacy collects from the beneficiary and plan isn't the final price.

After a prescription has been filled, if the plan

and PBM have a rebate contract with a manufacturer of that drug, they collect rebates. Those rebates account for most of the DIR dollars. The plan and PBM may also collect retroactive fees from network pharmacies based on quality and performance metrics or other contingent payments, referred to as pharmacy DIR. Historically, this has made up a smaller share of DIR than rebates, but it has been growing fast. Plan sponsors generally use DIR to make their benefit more generous or to lower their premiums.

Sponsors submit DIR information to CMS annually for each of their plans. This includes any price concession that directly or indirectly decreased costs of providing Part D benefits. CMS needs this information to ensure payments to plans reflect actual costs of providing benefits.

The aggregate amount of DIR has grown from less than 10 percent of total Part D drug spending in 2007 to 26.5 percent by 2019. So, over time, the growth in DIR has widened the gap between prices at the pharmacy and actual plan costs net of DIR.

Plan sponsors submit two types of DIR reports to CMS, summary and detailed. The summary report shows

information about the different categories of DIR, such as how much is manufacturer rebates or fees paid by pharmacies. The detailed report shows DIR amounts at the 11-digit NDC, National Drug Code level.

While the access to this data will expand the kinds of research we'll be able to conduct, there are a couple of things about the data, such as how it's collected, that may have implications for our analysis. We will be looking to better understand the limitations of the DIR data in our initial effort at data validation.

The CAA also gives MedPAC access to average sales price data. ASP is used to set Medicare Part B payment rates.

Each quarter, drug manufacturers report to CMS the ASP and number of units sold for each of their products at the 11-digit NDC level.

CMS then uses these data to set the payment rate at 106 percent of ASP for each Part B drug billing code.

To do this, CMS takes the manufacturer-reported ASP data for each NDC assigned to a billing code and calculates the volume weighted ASP associated with the code.

The ASP+6 payment rates for the billing codes are public, but the more granular, NDC-level ASP data are not. The CAA gives MedPAC access to this more granular NDC-level ASP data.

The CAA also gives MedPAC access to average manufacturer price and best price data. These data are used to administer the Medicaid drug rebate program.

Manufacturers report NDC-level AMP and best price data to CMS. The agency uses these data to calculate rebate amount that drug manufacturers are required to pay states for Medicaid-covered drugs.

AMP and the best price also have implications beyond Medicaid. AMP serves as a check on Medicare Part B's payment rates. By statute, if OIG finds ASP exceeded AMP by at least 5 percent for several quarters, CMS substitutes 103 percent of AMP for 106 percent of ASP.

Also, for providers that purchase outpatient drugs via the 340B program, the 340B ceiling price is equal to AMP minus the Medicaid unit rebate amount.

Increasingly, payers, particularly states, are calling for more transparency into rebates out of concerns about potential misalignment of financial incentives with

their PBMs. In Part D, where 100 percent of rebate is passed through by law, lawmakers were more concerned that broad release of this proprietary information could affect price negotiations, potentially leading to higher prices. The CAA that provided the Commission access to these confidential pricing data also placed restrictions on disclosure.

First, law prohibits disclosure of pricing and DIR data in a form that would reveal the identity of a specific manufacturer or wholesaler or the prices they charged.

In addition, for the DIR data, it also prohibits revealing plan-level dollar amounts or identities of sources of price concessions.

As we discuss potential research topics, it is important to keep in mind that there will be limits on the amount of detail we can provide in our analysis. To ensure we adhere to the law, we will aggregate our findings or limit the scope of our analyses as appropriate.

For Part D, we will initially focus on validating the accuracy of the DIR data; for example, by comparing it to external benchmarks. We will also examine whether and

how the flexibility given to plan sponsors in how they allocate DIR might affect the reliability of analysis at the plan level or NDC level.

Examples of potential Part D research topics include examining the effects of therapeutic competition on rebates, examining the relationship between rebates and point-of-sale prices, and we could also revisit the issue of rebates in the context of Part D's risk adjustment that we discussed last fall.

For provider-administered drugs, our initial analysis will focus on ensuring we understand the ASP, AMP, and best price data and can validate it relative to benchmarks.

For example, we plan to confirm we can use the ASP data to replicate the Part B payment rates. After that, a number of potential research topics could be considered such as modeling combined billing code policies, exploring the variation of ASP across products within a billing code, and examining drug pricing and utilization dynamics after generic entry.

Also, we plan to conduct analyses comparing Part B and Part D net price growth for similar types of

products.

Gaining access to pricing data may allow the Commission to examine pricing dynamics that were previously unobservable to us. In April, we plan to come back to you with preliminary information about the pricing data, including their strengths and limitations.

During your discussion, we would like to get your feedback on the general analytical plans discussed today and in your mailing material, the relative priority we should place among the projects, and any other research ideas for staff to pursue.

With that, I'll turn it over to Mike.

DR. CHERNEW: Great. And I'm going to turn it over to Dana in a second.

I did have some quick questions, just to make sure. Are we going to get this data on a regular basis, and what years do we have it for now?

MS. SHINOBU: For DIR, we have received 2010 through 2019, and it will be on an ongoing basis. As the data becomes available, we will submit a request to CMS and receive the updated information.

For ASP, I believe we have the most recent two

years of data, and we're in the process of requesting additional years.

For AMP and best price, I believe we have 2019, and this is something that we will continue to get for other years.

DR. CHERNEW: Great. All right.

I think, Dana, now we can go through to the queue.

MS. KELLEY: All right. I think Bruce had a Round 1 question.

MR. PYENSON: Thank you.

Recognizing that there's some data geeks among the Commissioners, I'd like to know if it's possible if the Commissioners can get file definitions of the data that you have. You're asking us for analysis but without knowing what the fields are. It's kind of hard to know what we could ask for. So would that be possible?

DR. MATHEWS: I can look into that for you, but my general inclination would be, at this point, if you can give us some ideas conceptually, policy-oriented, that kind of thing, we will evaluate the data and let you know what we can and can't do in response.

MR. PYENSON: Okay. So, for example, a question, it seems like you had the elements to cross-validate the rebate amounts with some of the reported plan totals. That's the sort of thing. It also seems like you have the elements to calculate 340B price. So there's a host of things like that, that I'd be curious about, that it's hard to know without seeing at least the list of variables.

DR. MATHEWS: Understood. I would simply say that there's probably a lot we can do, and so if you can put some ideas on the table, as Shinobu indicated, give us some sense of your priorities, where you think the most value would be, we will do what we can with it.

Again, part of the reason I'm hedging so much is that if anyone ends up wearing an orange jumpsuit as a result of violating our data use constraints here, it's going to be me.

COMMISSIONER CASALINO: We'll visit you frequently. We'll take turns.

[Laughter.]

MS. KELLEY: Lynn, did you have a Round 1 question?

MS. BARR: I do. I actually have two questions.

One of them is, can you look at the rebates and tie them to premiums? Is there a way that you can analyze the data? Because the question is, are all these rebates just reducing premiums for the beneficiary, or are they enriching the plans? So it would be interesting to me to look at rebates by plan versus premium and see if that is actually getting passed on to the consumer.

The other, I love the fact that you're going to be able to calculate 340B price. I have, I think, expressed concern. The 340B market has moved very quickly since the Commission looked at it last, and I think that the market is actually much bigger than what people think it is and, therefore, is a much bigger problem if things happen to it. So I would really love to see you do some analysis of 340B.

Our staff has done a lot of analysis on actually identifying patients that are 340B-eligible by building algorithms that look at claims data. So we'd be happy to pass that on to you, because there's two pieces of it, like what are the eligible patients and then what are the discounts and who's getting them. So, if there's anything we could do to help you try to suss that out, we'd love to

contribute.

Thank you.

MS. KELLEY: Pat.

MS. WANG: Thanks. This is more of a process question. Since MedPAC and MACPAC have access to this data, are you planning to coordinate your research studies?

DR. MATHEWS: I'll take a stab at that. So, on a standing basis, we do attempt to coordinate with MACPAC on issues of shared interest; most presently, dual eligible beneficiaries. In some instances, the coordination is closed. Sometimes it's indirect.

In advance of each of our public meetings, each of the agencies kind of walks through the agenda for the meeting ahead so that our counterparts have a sense of what we are doing so that no one is surprised, and as part of that general interaction, if there are specific projects of shared interests, we could possibly contemplate more direct interaction if warranted.

But, at the moment, kind of what we are focused on are Title XVIII-specific projects for our first run at this data.

MS. WANG: Okay. Thanks.

MS. KELLEY: Marge.

MS. MARJORIE GINSBURG: Okay, thank you. As I think the MedPAC staff know, I have long struggled with understanding this whole realm of -- drug pricing has been a gigantic mystery to me. I really appreciate the slide -- I don't know, Slide 2 or 3 -- that showed the diagram. That is the clearest diagram I think I have ever seen in the drug pricing world that really begins to at least help me understand the impact of these various components. So it's more of maybe a request not only to take that diagram and keep it, but whether it's even possible to use it with a real drug price or real examples or, in fact, even fictitious examples where what we end up seeing are the relative costs and prices of each of those components.

So it's both an observation and a request. I have no idea if it's possible to actually make that diagram come to life with real examples, because I think more than anything, it's helping me, and I'm sure others, understand how meaningful each of these pieces are when it comes to the cost of drugs for Medicare and for the public.

Thank you.

DR. CHERNEW: Was that it for Round 2, Dana --

Round 1, I mean?

MS. KELLEY: I think that is it for Round 1. Are we ready to go to Round 2? Did you want to say something first?

DR. CHERNEW: All I wanted to say was, Dana, I think we're ready for Round 2.

MS. KELLEY: Great. Then why don't we let Stacie start us off.

DR. DUSETZINA: Thank you. I think that Bruce might have been outing me as one of the data nerds. I was really excited to see this information being made available to the team, and thank you for a really well-organized chapter.

I will say that, you know, reviewing the list of validation items that you have, I don't see anything to take off of the table. And I don't even think I can apologize for it, but I have a couple of ideas for additional analyses, things that I would like to see, and especially things that I think would help the research community doing work knowing that we all still won't have access to the net price information, but we could have better informed analyses maybe through some of the public

work.

So I guess in order of how they read in the report, one of the things that I think would be really great to have is an understanding of the variation in the rebates across plans to get a little bit at this argument against transparency. So, you know, that's always the reason we know that we're not seeing the net prices or this kind of concern that some are winning, some are losing on these negotiations. But my gut reaction is that these markets are so consolidated that it would surprise me if anybody's getting a really great deal and somebody's getting a really bad deal. So it would be nice if there's some way to understand the variability so we can get at this root question that tends to stymie efforts to be more transparent here.

I think another thing that strikes me as an opportunity is to maybe think about an analysis that looks at the drugs that have the highest and the lowest rebates and pull out characteristics related to being in one of those categories. You know, again, I think that researchers have some general sense about what this is; you know, competition gives you better rebates and protected

classes give you lower rebates. But it would be really interesting to look at those outliers on either side.

I did want to say for the plan to look specifically at specialty drugs, I would also add to that list to see if there's a possibility to look at drugs under restricted distribution in particular. Those have very strict limits on who's allowed to dispense them, and so I think that would be really helpful.

And then my last two, for thinking about helping researchers to do a better job when dealing with pricing in the absence of this information, I wonder if it would be possible to add to our status of the Part B program chapters, maybe a drug cross level average rebate, something that's rolled up to a level that is still not too concerning for disclosure, but gives us a better sense of how this looks by class and have this be something that's routinely included so that it can be reliably used in the future.

And then the very last is, you know, researchers tend to have access to wholesale acquisition costs but not really other great measures, so knowing the relative price trends in measures like AMP and ASP would be helpful in

comparison to what's going on with the wholesale acquisition cost, for thinking about when you're looking at wholesale acquisition cost trends, like how should we adjust those trends to account for the fact that we're using the wrong base measure in a lot of analysis.

That's my wish list, but I imagine you all are going to have a lot of fun getting into this. Thank you.

MS. KELLEY: Jonathan Jaffery.

DR. JAFFERY: Thanks, Dana, and thanks, this was a great presentation. You know, echoing Marge's comments about the figure that was really helpful, so clearly it's very exciting to have all this data available now. Stacie had some great ideas that she just described.

Just a few things that I thought of as some priority issues based on the reading and the presentation. Again, starting sort of similar to Marge's suggestion about using the example in the diagram, I think maybe try to quantify the overall impact on beneficiary costs and premiums and program costs using that model could be helpful. Obviously, you've talked about that a lot, but really understanding it fully or quantifying it might be helpful.

Really ever since being on a commission that really wanted to understand better the impact of having the protected class policy, and so your suggestion in the chapter about understanding how these protected drug classes affect rebate negotiations I think would be a great opportunity here.

And then, finally, thinking about the different impacts on Part D's risk adjustment, I think as part of our broader discussion on some of the issues around risk adjustment methodologies throughout the Medicare program, that would be really great to have some more insight into that aspect of things.

Those were just some of the things that jumped out as some relative priorities among what will no doubt be a huge body of work going forward. Thank you.

MS. KELLEY: Bruce.

MR. PYENSON: Okay, thank you very much. I'm aware of the issue that MedPAC staff has had with the encounter data from MA plans, which, as we've discovered, doesn't tie with other kinds of data, even though we might expect it would. So I'd like to suggest that an early step be the reconciliation of plan-by-plan amounts to the

aggregate reports in the PRS files or other filings of the plans. And so I think that would be an important first step. Hopefully the data matches perfectly and we can move ahead with confidence in the analysis.

I have a wish list. I'm not going to elaborate on what I think the value of these is, but I can. One of them is to compare a DIR within drugs by NDC to understand how differences may exist by channel; for example, 90-day supply, house brands, and other similar variations give a hint of channel.

Another comment is I'd like to see some analysis that reflects differences among wholesalers. The prohibition of identifying wholesalers was interesting because I didn't expect to get wholesaler data. So I think there's funds that are involved with wholesalers that don't count as rebates and, therefore, aren't passed through from the PBM to the Part D plan. That's important.

I'd like to compare DIR among contracts within the same plan -- for example, are the low-premium plans somehow being subsidized? -- and compare DIR by drug between stand-alone PDPs and MAPDs, similar issue.

Let's see. Compare DIR to the net plan liability

for different types of patients and conditions to understand how different conditions -- how patient profitability varies. Compare net plan liability for biosimilar and originator drugs when they're both present. And compare Part D net prices to Medicaid best price. And compare trends in net to manufacturer over time. I think we have two years of data, so that might be for the future.

There's a couple of things on Part B: again, examine whether certain channels are subsidizing others. This gets at some of the discussion we've had about whether -- who's paying more than ASP and who's paying less on the provider side. It could be that certain NDCs are associated with certain channels, and that's how differentials are being applied -- again, I'm not sure if we're getting NDC level data or HCPCS level data -- and examine drugs sold to ESRD buyers to understand whether the ESRD daily rate is reflective of current costs.

Thank you. A long wish list. You asked for it.

MS. KELLEY: Pat -- oh, I'm sorry, I think Jon Perlin had a reaction to Bruce.

DR. PERLIN: Thanks, real briefly on this point. First, great chapter and presentation. But this point that

Bruce is eliciting is that, you know, I can't get through without, you know, a Yogi Berra-ism, but the average doesn't betray the tails.

You know, this notion that we may be able to uncover practice patterns, the opportunity to associate with better or worse outcomes, the opportunity to associate with, you know, regional variations in practice that are associated with cost trends, et cetera, I think are another level of subtlety that these data may allow. You know, apropos of the comments about, you know, the availability of granularity, I don't know the level of specificity of the files, but if there are intra-plan variations, you may see some of the things that are more of the internecine mechanisms of this rebating process, including what Brian DeBusk has spoken eloquently about before, which is the bundling of certain loss leaders in order to generate uptake on things that are more value to, you know, different members of the supply chain.

Thanks.

MS. KELLEY: Okay. Pat?

MS. WANG: Oh, thank you. I wanted to agree with Jon Jaffery's emphasis on the importance of continuing to

refine risk adjustment. I'm not a data geek, so I'm not really sure exactly whether the specific approaches that you described in the papers, you know, are meaningful for that. But if you think they are, then I think they are. So whatever you can do in your analysis to try to refine those.

I wanted to suggest also an addition, and I think Bruce mentioned this, in comparing across plan types, specifically looking at MAPD and stand-alone Part D plans with respect to the LIS benchmark. In the previous session, Eric pointed out that it was in the paper that the LIS benchmark, which is driven by, you know, around six PDPs -- it's very concentrated -- that many MAPD plans serving LIS, low-income beneficiaries, were spending Part C rebate dollars to spend down to hit the LIS benchmark, which suggests that their drug costs as proposed were higher. And if there was a way to use the data that you have to understand whether those higher costs are driven by worse pricing or other factors, you know, such as formulary placement because the goal is to achieve an overall total better medical cost pharmacy combined outcome, formulary placement to drive medication adherence, for example, for

stars results, it might be good to know. The PDP market is very concentrated. The MAPD market is not so concentrated. So I thought that that might be an interesting thing to try to pull a thread through if you could, could have implications for how people think about how the LIS benchmark should be set going forward. And related to that, potentially understanding whether the implications of the data that you have for more accurate risk adjustment for Part D is different for stand-alone PDPs and MAPDs.

Thanks.

MS. KELLEY: Amol.

DR. NAVATHE: Thank you. I just wanted to echo support for a few different areas in terms of priorities. First off, I definitely agree that this was fantastically laid out and organized already from you folks, so it's very easy to follow and add on some thoughts.

The first thing I wanted to quickly just emphasize is I think it would be actually very helpful and I think this has been said in a few different ways, but I just want to tie it all together, which is understanding the characteristics of drugs, characteristics of plans, and how they relate to the rebates, and, in particular, if we

can understand what kind of variation we have in rebates that's within drug, across drug, within plan, across plan. In fact, I can imagine that we could do this somewhat jointly and decompose the variation for a variety of different classes of drugs, for example, that would be very meaningful. And I saw Stacie nodding her head, so I'm going to take that as a good thing.

The second thing is I wanted to echo Lynn's point about understanding how the rebates actually flow into premium reductions and cost-sharing reductions for beneficiaries. I think that's, you know, strongly described in a variety of ways, descriptively, certainly from the plans themselves and some literature, et cetera. I think here we have an opportunity to actually study that much like we study the way that premium reductions and other extra benefits in MA related to the benchmark policy. So this is an opportunity for us to do an analog, which I think will be particular important.

Really quick plugs. I definitely agree regarding what Pat was just saying about MAPD and looking specifically there. Risk adjustment, certainly very important.

Last point, I just want to put it another plug, which is there's -- because this information has not appeared in data regularly available to researchers and others, they're having a number of different estimates and empirical literature. I'm trying to understand what the dynamics are. So to the extent that we can even follow trends and report trends at the class level or some aggregated ways, that would actually be very helpful to understand the literature in some sense on which we have been trying to base policy was actually close to right or not. I think that itself would be very helpful, especially as we start to think about now building upon a lot of that concept and structure that has informed much of the Part B work that the Commission has already been working on for many, many years.

Thank you.

MS. KELLEY: Brian?

DR. DeBUSK: Yes, thank you. First of all, I'm really grateful to have this data. I know it's been a long time coming. There's been a real ask there, and I think it's an exciting opportunity for us now to be good stewards of that data and produce meaningful and actionable

information out of it.

I had sort of a question-combination-comment, and it's on page 7 of the reading material. I noticed that it speaks about PBMs receiving a combined rebate across several drugs, and it wasn't clear to me if those were, for example, different delivery formats of the same drug or if these were two entirely different drugs altogether. And I'd like to learn a little bit more about what kinds of drugs -- I mean, is this a branded drug in one therapeutic category, perhaps bundled or tied or attached to another drug that's in a completely different therapeutic category? Or are these just simply drugs that are in different doses or different delivery systems? So I'd really like, again, to learn more about when rebates are paid across several drugs, what does several mean and how does that all break out?

The other thing, too, as we do the analysis -- and this is just a request of staff -- I would be really interested in the allocation methods and the uncertainty that would be introduced in the allocation methods around how those rebates are allocated -- are distributed both at the plan level but also the methodology, because from what

I understand they can be -- the rebates can be dispensed, too, based on gross drug -- gross preferred or branded spending or on, say, preferred tier spending or on total drug spending. And it seems like those allocation methods might be very material to how we look at some of this data. So, you know, sort of a long-winded way of saying I think there are going to be a lot of footnotes on some of this analysis, particularly as it applies to the allocation. And I hope we can keep up with that.

Thank you.

MS. SUZUKI: Can I just--

MS. KELLEY: Go ahead.

MS. SUZUKI: So Brian, in regards to your question about the bundled drug rebates, it's not something that the data is going to actually tell us which drugs are bundled, if they were bundled, in the rebate contract. That's not something we'll have information about, so I just wanted to clarify that.

DR. DeBUSK: Well, how would we know, just as a follow-up to that, how would we know? I mean, if there was -- and I'm going to be egregious here -- if there was a blockbuster drug in a -- if the rebate were somehow bundled

or cross-linked to, say, participation in a generic formulary or purchasing, say, from another portfolio of generic drugs, all provided by the same manufacturer, if those were tied together would we have any way of seeing that in the data, or would we know that, or would we just simply see a distribution under the DIR category?

MS. SUZUKI: It would be the latter. We would actually see what the plan sponsor decided when they were recording this data. Sometimes they use the allocation, one of the allocation methods that you mentioned. Sometimes the rebates are tied to a specific NDC, and they may actually submit that information according to their contract. But they have some flexibility there.

DR. DeBUSK: Okay. Well, this is huge progress but what I'm gathering from this -- and please correct me if I'm wrong -- what we're going to see is the result of these rebate arrangements. I mean, we're going to see the shadow that they cast on the wall. We aren't going to necessarily see the structural arrangements that drove those payments.

DR. SCHMIDT: That's right, Brian. So what Shinobu was just describing is we're going to try and look

and see if there are patterns, just from what we observed, for how the data reported. That would give a sense of how much confidence we may or may not be able to have in those allocations. Or, you know, just to give us a sense of, you know, how to interpret the data.

DR. DeBUSK: Thank you. And by the way, again, as I started this comment, I'm very grateful for the data. I'm glad you guys have it. I hope it doesn't get Jim sent to prison. But, you know, I think it's wonderful progress, and I certainly don't want to question that. You know, good luck to the staff with all of that. Thank you.

DR. CASALINO: We want to know if Jim's going to have value-based bail, so he won't have to decide whether to get out or not.

DR. CHERNEW: That's a separate policy question. Okay.

MS. KELLEY: I think Bruce had a question on this point.

MR. PYENSON: Yeah, just really briefly, related to Brian's question. What information do you have on wholesalers?

MS. SUZUKI: That's another thing we should

probably have clarified earlier. As far as we can tell, there's no information about the specific wholesaler that a particular prescription was delivered through. I think the language that was in the disclosure limitations, I think that is sort of a broader just prohibition on disclosing certain entities and attributing certain discounts to entities. But as far as I can tell, DIR does not have any wholesaler information, and I believe that is true for other pricing information as well.

MR. PYENSON: So I believe certain NDCs have certain wholesaler routes, so maybe is that how -- what they might have been concerned about? I'm just speculating. Thank you.

MS. KELLEY: Pat.

MS. WANG: Oh, okay. Thanks. The thing that I asked about before about MACPAC, and you mentioned that, you know, the overlap where the interest would be in dual eligibles. Does it make sense to understand what Medicaid is paying for a particular drug, you know, under its special terms, and then what the Part D or MAPD dual SNP is paying for the same drug when that member ages into Medicare? I guess that was sort of -- I guess the idea,

when Part D was created, was, you know, that the states would turn over all of that drug purchasing or supplying to the Part D program.

I just would be interested. You know, the rebates go to different places, right? If it's Medicaid it's going to the states. If it's Medicare it's going to plan sponsors. But it would be interesting to know whether it's actually an equivalent deal for the taxpayer, I guess, when somebody in Medicaid ages into dual status.

DR. MATHEWS: That's a very intriguing question, and we'll definitely add it to the list.

MS. KELLEY: Stacie, did you have something you wanted to add?

DR. DUSETZINA: Yeah. I was just trying to think through how we might get at that issue of the multiple product rebate situation, where we don't know, like maybe there's a bigger rebate given for a package of products rather than tied to an individual drug, sort of what Brian and Bruce were talking about, these groupings.

And I guess I wanted to throw out, like the way I would maybe think about trying to get at that, if you did want to explore it, would be to look at drugs that have

preferred placement on formularies and also have a lower-than-expected rebate for the class. And then you could kind of back into, is that happening in situations where maybe the sponsor has multiple drugs for which they are negotiating.

So I think you could do a little bit of detective work. Of course, that's kind of a lot of work because you'd need to find these classes or categories. But it seems that you could maybe, maybe going back to the idea I had suggested about looking at these outliers on the low end, high ends of rebates, you know, if you have some drugs that don't seem to be following the pattern that you would expect maybe those could be in that situation where the plan sponsor isn't negotiating for just that drug but for a package of drugs, as one way to try to figure out some of those inner dealings.

DR. CHERNEW: Thank you, Stacie.

MS. KELLEY: That's the end of the queue, Mike.

DR. CHERNEW: Yeah, that was what I was -- you know, we kept having that extra person add, but I think now maybe we've gotten to the end.

So first of all, we are going to end a bit early.

That's obvious. So we're going to jump right into the access chapter in a minute.

I am going to give a summary of where we are. I'll start with a big thumbs-up, if we're being recorded. I think there is a lot of enthusiasm for continuing down this path, and I hope you found these ideas useful, given the ones that you gave. I'm going to try to characterize them into a set of different projects or types of analyses, and I'm going to actually add one at the end, and maybe a caveat.

So the first one is, there's a series of questions that I would put around, just checking the data. The data is new. We don't know if it's right, and we need to figure out what it replicates to, and this is a lot of work around understanding the data better. And I think there's widespread belief that you need to do that as a prerequisite to everything else. So I'm going to give a general thumbs-up, and I will add, for those listening, that's a lot of work. So we shouldn't assume you do that and then you're just done. There's going to be a lot of work there, and we very much appreciate you doing it.

The second set of questions, and I think we

probably spent much of our time on this set of questions, I'll put broadly into the category of shifting questions about variation in the DIR, across plans, between plans, across products, between products, how they span, you know, different types of products, and a whole slew of just general questions, that I would call broadly descriptive questions. I have nothing more to add to those descriptive questions. There were a lot. I will just say to the Commissioners, and frankly to the public, if you have ideas, meetingcomments@medpac.gov, let us know those interesting, descriptive questions to do.

The third set of questions I'll talk about, I'll call them essentially allocation kind of questions. Where does the money flow, how does it affect premiums, and who gets the money, and whole bunch of questions that I think I would put in the understanding where it goes. And given the discussion we had, those are the lion's share of the questions I heard, including some caveats about what to interpret from that, because of complicated things that Brian and others said, where you the rebate is due to a bundled set of products and it's hard to allocate them, and stuff like that.

I want to add one other point/caveat, and we can just leave it at this or people can react to this if they want. I think, in general, it's important to make a caveat that descriptive relationships aren't necessarily causal. And there are essentially three endogenous variables in this system. There is the gross price, the DIR, and the point-of-sale price. And if you were to find that, for example, the DIR was associated with a lower -- just descriptively a lower point-of-sale price, that doesn't mean increasing the DIR would affect the wholesale price. It could affect the gross price in various ways. There are different things that could be changed.

So I would put a pitch in for thinking about what I would call a little bit more -- I'm going to go with quasi-causal analyses, and I understand that's hard. I'll tell you some of the ones that I'm most interested in. What happens when there's an entry of new products in class? Do you see a change in not just the DIR -- that could happen. You know, you could see that change in the gross price and a whole slew of other things.

So the same would be true, as 340B has grown, some drugs might be more common in 340B. Do you see any

evidence of cost-shifting in how the gross price in the 340B rose? There are a series of causal questions that related policy not just to the DIR but to the components that make up the DIR, the net price and the gross price.

So I think thinking through some of those types of questions and how they vary across things, like is the drug primarily a Medicare drug, is it primarily a Medicaid drug, how close is it to patent expiration, what happens when the company is about to add a new product that might cannibalize itself? There are lot of very complicated pricing things that go on, and I think there is room to think through some of these things and do it in a way that might be more than just descriptive. That makes it more complicated, by the way, but since Shinobu mentioned we're going to be getting this data annually, we basically have it into the horizon.

And so this is not going to be the only bite at this apple. I just wanted to point out that we have to be careful about relating descriptive relationships and calling them causal. Otherwise you begin to bring them to policy.

So I think I will stop there. If I followed the

queue well enough, Larry might want to say something. Again, maybe not.

DR. CASALINO: No, just a quick addition, Mike. You said a few minutes ago that one of the many areas, if I understood you correctly, one of the main areas of analysis that people were asking for is where does the money go. I agree with that, of course.

And I might just add, I think for a lot of analyses it may be relevant, at some point as well, to think about what determines where the money goes. And I'm using causal language here, I realize that. What determines where the money goes? What are the factors that seem to affect where the money goes as far as rebates, the combination of how different factors interrelate with each other.

So knowing what the organization characteristics are, or maybe some other things that seem to be, and let's just say associated with where the money goes, I think would be useful at some point. I don't think that's the first thing that you should do, by any means, but as you're setting up your analysis and datasets, you may want to just keep that in mind.

DR. CHERNEW: Thanks, Larry. I see you all want me to quit using econ terms, so I will appreciate that as feedback. But I'm going to avoid that for now.

Okay. I'm going to pause for a second to see if anyone else wants to add to that. Let's see where we are. I want to, you know, make sure that the enthusiasm from all this work is sufficiently conveyed to everybody.

DR. NAVATHE: I have one quick comment, which is basically it seems like there, as you pointed out in your infinite number of interesting questions we could ask, I think one of the things that might be helpful as part of this, as we go forward, and this is probably actually a suggestion for Jim and Shinobu and the whole team, is I think if we are framing this first in terms of what are the key policy questions that we're working on as part of the Part D and Part B areas, and to some extent foreshadowing what is the direction of the policy work that perhaps we will jointly determine, I think that will be critical to having, as a superstructure, to inform the prioritization. Because otherwise, we could ask very interesting and important questions that don't necessarily directly serve the policy intent. So I think that's just worth putting

out there.

DR. CHERNEW: Yes, I agree, and thinking through how we will use the results of what we find for the policies that we deal with when we think about, you know, prescription drugs, pricing, et cetera. I haven't spent a lot of time tying the morning discussion to this, but you might imagine a version of trying to figure out if we were going to do something to change the prices in various ways, how would that play out to not only the gross but the net prices, and other types of things like that.

DR. RAMBUR: Michael, could I make --

DR. CHERNEW: Yes. Absolutely, Betty.

DR. RAMBUR: -- could I make one comment. I just wanted to say that I'm very enthusiastic about this. And apparently, you know, you've been working all this for a long time. Although this is, you know, my second year, this is my first year of having an opportunity to think about this in a deep way, and I think it's very exciting.

So I just wanted -- the lack of comment is really because I don't have a substantive suggestion about how you might use the data, other than, you know, enthusiasm for what my fellow Commissioners have said and this really

great opportunity that it brings to Medicare beneficiaries. So thank you.

DR. CHERNEW: That was thumbs-up.

Okay. We are now going to move on. I believe I saw, for a second, we were moving on to Jeff and Brian, but now I don't see that on my screen. There they go, Brian and Jeff.

So we have a congressional request to do a report on access to care, particular for vulnerable Medicare beneficiaries. A lot of this focuses on urban-rural distinctions. And this is an unbelievably important topic, one that we will both learn from today and keep in mind as we do a whole bunch of other policies. For the people listening, you will have some safety net work that we're doing. Obviously, this matters for updates. So we are both fulfilling a congressional request and educating ourselves on the facts as we think about a bunch of other policies.

So, Brian, are you going to start this?

MR. O'DONNELL: Yep. I am going to lead us off.

DR. CHERNEW: Great. Brian, take it away.

MR. O'DONNELL: Good afternoon. In this

presentation, we'll discuss our work towards fulfilling a congressional request to study rural and vulnerable beneficiaries' access to care. Before I begin, I'd like to thank my colleague, Lauren Stubbs, for her assistance with this work and remind the audience that they can download a PDF version of these slides in the handout section of the control panel on the right-hand side of the screen.

The House Committee on Ways and Means submitted a bipartisan request for the Commission to update its June 2012 report on rural access to care, to study emerging issues that could affect access to care, and to provide new information on beneficiaries with multiple chronic conditions, who are dually eligible for Medicare and Medicaid or reside in a medically underserved area.

The Commission covered the first two of these topics in its June 2021 report to the Congress, and we'll cover the last topic in today's presentation. This material will be included in our June 2022 report.

In addition, today's discussion will serve as a starting point for the Commission's broader work on safety net providers. We'll come back to you in November with more information on that body of work.

Before I get into new information, I'll briefly summarize our findings on rural beneficiary access to care that were included in the Commission's June 2021 report.

Survey and claims data from 2018 suggest that rural and urban beneficiaries had a similar ability to obtain care, although some small differences did exist. These results were similar to the Commission's findings included its 2012 report. Variations in service use across states were often large, but differences between rural and urban beneficiaries within states tended to be much smaller.

Rural hospital closures increased from 2013 to 2019, and have slowed since then. Closures were often preceded by large declines in inpatient use that were mostly attributed to beneficiaries bypassing local hospitals in favor of more distant ones. While rural hospital closures can disrupt access to care, Congress recently enacted legislation to maintain or improve access to ED and outpatient care in rural areas.

Now, moving on to new material, we will first discuss the service use of beneficiaries with multiple chronic conditions. We found that beneficiaries with more

reported chronic conditions had a higher average number of E&M encounters, inpatient admissions, HOPD claims, SNF days, and home health episodes in 2018.

For example, among urban beneficiaries, those with zero to one reported chronic conditions averaged .02 inpatient admissions per capita, while those with six or more conditions averaged .85 admissions per capita. The differences in service use between healthier and sicker beneficiaries were similar in rural and urban areas.

Also, as we discuss in your mailing materials, we believe that systematic coding differences complicates comparing rural and urban beneficiary service use by the number of chronic conditions. So the data we discuss today represent raw utilization numbers that are not risk-adjusted.

Next, we found that dual-eligible beneficiaries used substantially more care than other beneficiaries in 2018. These differences persisted across all types of services we examined.

For example, among rural micropolitan beneficiaries, dual-eligible beneficiaries averaged 5.2 SNF days per capita compared with 0.9 SNF days per capita among

non-dual-eligible beneficiaries.

The access implications of these finding are unclear. On the one hand, higher utilization is positive in that it suggests providers accepted and treated dual-eligible beneficiaries as patients. On the other hand, it's unclear whether dual-eligible beneficiaries' service use was sufficient, given their greater health care needs, which we discuss on the next slide.

The Commission has found that, compared with other Medicare beneficiaries, dual-eligible beneficiaries more frequently report being in poor health, have limitations in activities of daily living, and live in an institution.

In the future, the Commission's broader work on safety-net providers will examine dual-eligible beneficiaries' potential access issues in greater detail.

Next, I'll discuss medically underserved areas, or MUAs. I'll spend a few slides describing MUAs and comparing service use across them, and because better understanding MUAs may inform the Commission's future work on safety-net providers, I'll spend a few slides discussing some of the limitations of MUAs.

Areas are designated as MUAs based on four metrics: the number of primary care physicians per capita, the percent of the population with incomes at or below 100 percent of the federal poverty level, the percent of the population age 65 and over, and the infant mortality rate.

Once each of these metrics are calculated for an area, they are combined into a single score called the Index of Medical Underservice that ranges from zero to 100.

Areas with a combined score of 62 or lower are considered MUAs. This 62-point threshold was set in the 1970s based on the median IMU score of all counties, meaning that half the counties in the country had scores above 62 and half had scores at or below 62.

Different types of areas can be designated as MUAs. We analyze MUAs at the county level to align with our rural and urban classification system. We have three county-level MUA categories: full MUAs, where the entire county is designated as an MUA; partial MUAs, where the entire county has not been designated as an MUA but at least one area within the county has been; and non-MUAs, where neither the entire county nor any area within the county has been designated as an MUA.

Based on these definitions, as you can see in the first row of data in the table, we found that 18 percent of Medicare fee-for-service beneficiaries lived in full MUAs and about 60 percent lived in partial MUAs, meaning that more than three-fourths of beneficiaries lived in either full or partial MUAs in 2018.

The share of beneficiaries living in an MUA varied based on rurality. Beneficiaries who lived in rural counties were more likely to live in full MUAs, whereas urban beneficiaries were more likely to live in partial MUAs.

The fact that such a high percent of beneficiaries live in full or partial MUAs raises the question of whether MUAs are precise enough on their own to usefully identify vulnerable beneficiaries.

Next, we found that service use was similar for beneficiaries who lived in full, partial, and non-MUA counties in 2018. For example, urban beneficiaries in full, partial, or non-MUAs averaged 13.4, 13.4, and 13.3 E&M encounters with clinicians, respectively. This finding is consistent with past research on the topic and raises the question of why residents in an MUA might not be

associated with lower service use.

While we can't definitively answer that question, we'll discuss a few possible explanations. First, as we discussed in our June 2021 report, beneficiaries often travel several miles to access care. The granular nature of MUAs, which are often designated at the census tract level, means that beneficiaries residing in MUAs often don't have to travel far to access care.

Second, MUAs are not routinely updated to reflect changes in the demographics or supply of clinicians in an area. This means that many MUAs were designated decades ago and have not been reevaluated since.

Third, MUAs might be defined too broadly to identity the most vulnerable beneficiaries.

And, finally, the measure of primary care supply, primary care physicians per capita, excludes ARPNs and PAs. Because APRNs and PAs play an increasingly important role in maintaining access to care for Medicare beneficiaries, we next explore the impact of excluding these clinicians by measuring what share of all primary care clinicians they represent.

When APRNs and PAs enroll in Medicare, they don't

have to indicate the specialty in which they practice. We therefore used claims data to classify these clinicians as practicing in primary care or specialty care. An overview of the methodology we used to do this is included in your mailing materials, and we're happy to answer any questions about it on comment.

We found that a minority of APRNs and PAs practiced in primary care in 2018. Specifically, we found that 27 percent of PAs and 41 percent of NPs practiced in primary care.

Despite predominantly practicing in specialty care, APRNs and PAs still represented a substantial share of all primary care clinicians, as we discuss on the next slide.

Looking at the light blue row on the table, we found that in 2018, about 168,000 primary care physicians billed Medicare and 88,000 APRNs and PAs who practiced in primary care also billed the program, meaning that APRNs and PAs made up 34 percent of all primary care clinicians who billed Medicare.

In rural areas, they represented an even higher share of primary care clinicians. In 2018, APRNs and PAs

accounted for 44 percent of all primary care clinicians who billed Medicare in rural micropolitan areas and about half of primary care clinicians in rural adjacent, rural non-adjacent, and frontier areas.

These findings suggest that the measure of primary care supply that is used in the identification of MUAs likely fails to account for anywhere from a third to a half of all primary care clinicians.

In addition, the underestimate will continue to grow in magnitude in the future if the supply of APRNs and PAs continues to expand and the supply of primary care physicians continues to remain flat, as it has over the last several years.

Combined with other issues, these results suggest that MUAs by themselves might not be useful in the Commission's work to identify vulnerable populations and support safety-net providers.

The Commission anticipates exploring other measures to identify such populations in the future.

So, just to reiterate some of things we've discussed today, beneficiaries with multiple chronic conditions had substantially higher service use than

healthier beneficiaries.

Dual-eligible beneficiaries had higher service use than other beneficiaries, likely driven by their greater health care needs.

Beneficiaries who lived in full, partial, and non-MUA counties has similar service use.

While we found no clear indications of widespread access issues, our results do not signify that no access challenges exist.

Instead, our results suggest that more granular analyses are needed to better understand access challenges faced by vulnerable beneficiaries, such as dual-eligible beneficiaries.

In addition, our work suggests that some definitions of vulnerable beneficiaries, such as those living in MUAs, might be too imprecise, and that employing them to identify providers who merit additional support could lead to poor targeting of Medicare's scarce financial resources.

Consistent with the House Committee's request to examine service use among vulnerable beneficiaries, the Commission plans on undertaking a broader examination of

how to identify vulnerable Medicare populations and to evaluate Medicare's policies to support safety-net providers who care for them.

In terms of next steps, we're seeking Commissioner feedback on the materials we discussed today. The final results of this work will be included in the Commission's June 2022 report to the Congress.

In addition, as I've mentioned, we anticipate coming back to you in November with more information on safety-net providers

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

DR. CHERNEW: Brian, thank you. I'm having a hard time unmuting. That was terrific. I think there's a lot of information there ranging from problems with defining MUAs to substantive things we've learned about access and workforce issues.

In any case, I think we'll just go with the Round 1 questions, and then we'll move on through. So, Dana, you're in charge of the queue.

MS. KELLEY: All right. Lynn is first.

MS. BARR: Thank you so much for this report.

Actually, I found this particularly fascinating because this is a constant source of tension in that we know that there's disparities. We just can't prove it. How do we describe populations?

I've been doing a lot of work on this myself, and when I look at our population of patients, which are predominantly 75 percent safety-net patients, we have a much lower access to care. So I'm curious as to what you're counting and what you're not counting. My Round 1 questions are digging a little bit into your methodology.

I see the biggest difference in access between the two populations as drugs. Are you looking at drugs in terms of access, in terms of do they have access to -- are they insured for drugs? Do they have access to Part D? Then, if they do have Part D, I'm seeing a huge disparity between the actual drugs they buy under Part D and the fills that the actually can afford to make. So I think that might be an interesting way to look at access.

A couple of other comments. For some reasons, 2018 was a rather bizarre year in rural, and we saw a lot of anomalies in our data we never understood.

Bruce, if you ever have a chance to tell me what

happened in 2018, but I'm just whether 2018 is a good year to look at, just based on our own experience. Do you have any more current data? Could you look at 2019, for example? You might get a different story, and I don't know why, but there was something weird in 2018 in our half million lives.

We saw a big drop in access in 2020, and everyone did, but we measure our ratio of access from our patients to the broader MSSP population. Prior to 2020, we had 89 percent of E&M visits compared to the rest of the country, and in 2020, it went down to 83 percent compared to all other MSSP lives. So I see something very, very significant happening that I don't know if you can get at in your data, but 2020, we took a big, big hit in access in those rural communities, and it might help inform other things.

I'm curious as to whether, as you recall the chapter on telehealth -- and it talks about the disparities in access to telehealth versus urban populations in rural, and I think that that would be very important to include in this chapter in terms of referring to access.

Then, finally, in our rural communities, they

frequently do not have a PCP, and there is no access to care after hours. So about 50 percent of our ED visits are primary care. I don't know how you -- so my question is, how do you incorporate that into the whole access question as well?

My last comment is for Round 2.

MR. O'DONNELL: Sure. So, Jeff, I can take a staff at some of these, and feel free to jump in.

In terms of whether we looked at drugs or Part D, we did not in this report, but going forward in terms of safety network, we're not starting with Part D. But I think there will be a Commission decision on kind of what products and service lines they want to look at in terms of access to, whether it's hospital, physician. You're mentioning Part D. So that's one thing.

Go ahead, Jeff.

DR. STENSLAND: I'll just add on Part D. We didn't do it this time, but we did look at Part D in our last rural report, looking at rural and urban prescriptions per capita, and they were almost exactly the same, where you saw wide variation in drug use. Like in New Jersey, for whatever reason, they took a lot of drugs. So there

was the regional variation but not that much within the state between the rural and urban areas.

MS. BARR: Jeff, I wonder if that's changed because of the shift to brand. When so many drugs were generic, it was affordable, and I'm seeing a huge difference in safety-net patients and what they're filling in Part D, if they have it. You know, there's also a huge difference of them having access to it at all, but this is really being driven by what we were talking about earlier about the shift to brand drugs, which are not affordable. So there's these great life-saving drugs. Revlimid is a great example of it, and if you are attributed to a safety-net health system, you have a 40-percent lower chance of actually getting Revlimid than if you're not, if you're attributed to an urban health system. They can't afford it.

So I think that it's a good way of sort of -- you know, like the problem with health care data is it's so noisy, you can't see anything. That's why the MUAs are all kind of -- you know, everything looks mealy-mouthed, but when you start looking at drugs, it's striking.

DR. STENSLAND: One thing we're going to talk

about in the future, Lynn, is what do we mean by safety net? So just to get a handle on what you mean, what do you mean by safety net? Is it taking a provider, safety-net person? How is it defined?

MS. BARR: So this is my Round 2 question, so you can take me out of Round 2.

So I've been defining it as patients that are attributed to attributable to a safety-net hospital health system, and you can expand that to -- and I'm using 340B ID. If they have a 340B ID, then I say that's a safety-net organization. If not 340B ID, it's not. Then I'm analyzing the data that way, and I was thinking about in your struggle to define MUAs, the differences are very striking in those two populations. Under us, we've got like 175,000 in one bucket, 350,000 patients in the other bucket. I can see real differences by looking at it that way, and maybe you could use that methodology to then back into what to do with the MUAs. First, identify the differences, distinctly different populations, and then try to find some characteristics that describe them from a geographic point of view.

DR. STENSLAND: All right. We'll probably follow

up with an email so we can get precisely what your method is.

DR. CHERNEW: Yeah. I was going to say I think there's a set of comments that I think fundamentally involve what I would call inferences from data analysis from people that have access to data and then the MedPAC folks have access to data, and I think it's certainly valuable to have those things raised. But there's a point at which we're going to have to have some of that back-and-forth offline because it's too hard to hash out here.

Jeff, that was a great answer. Lynn, that was an amazing nod.

I think we're still on the Round 1 questions. Let me emphasize clarifying questions, and who's next, Dana?

MS. KELLEY: Larry.

DR. CASALINO: Yeah, I think this will be quick. Great job, in particular with MUAs, that's really -- that should have impact, what you guys found.

I have two Round 1 questions. Could you go back to Slide 4?

[Pause.]

MS. KELLEY: Sorry. We'll get there. It takes a few minutes for it to trickle down through the system here, but, yes, we'll get there.

[Pause.]

DR. CASALINO: Great, thanks. So in this second big bullet, "Differences in services between healthier and sicker beneficiaries were similar in rural and urban areas," how did you define healthier and sicker for that analysis?

MR. O'DONNELL: So for that, all that's saying is that we looked at those folks based on a number of chronic conditions, and then we looked at where they lived in terms of whether they lived in urban or rural areas. And what we're looking for is that if you're sicker in an urban area or a rural area, does it look like you have a differentially harder time accessing services? And it wasn't the case. The differences in terms of folks with, let's say, zero to one chronic conditions versus six-plus were relatively similar within urban-rural categories.

DR. CASALINO: Okay. The differences between healthier and sicker, it's like in the two bullets ahead, the zero to one and six-plus, you counted chronic

conditions and didn't see differences in service use. So there were differences in service use between healthier and sicker in rural versus urban, but the differences were similar. Is that what you're saying?

MR. O'DONNELL: Right. So, for example, if you're in an urban area, sicker folks might have used 50 percent more E&M visits, and in rural areas, that 50 percent was very similar. So sicker folks within, let's say, rural micropolitan, they also used 50 percent more services compared to the healthy folks within that given rural designation.

DR. CASALINO: Great, okay. And the other question, if we could go to Slide 5. Actually, can I ask one more -- just a follow-up question to what we just talked about. What do you think would be the pros and cons of, instead of counting kind of crude categories of number of chronic conditions, if you looked at in some way differences in service use by HCC scores?

MR. O'DONNELL: So this, I think, gets -- and Jeff can jump in here, but this gets to at least part of our concern with coding differentials. So I think we're stuck comparing within urban and rural categories, and so a

lot -- so within an urban and rural category, we could do what you're asking. I think it's a measure of how much time the Commission wants us kind of to devote to this.

DR. CASALINO: Got it. And the occurring differences would hold for -- okay, got it. Yeah, Slide 4. Can we go to Slide 5, please? I'm sorry. Jeff, were you going to say something?

DR. STENSLAND: No. I was just going to elaborate that, in general, the HCC scores are lower for rural, which would imply they're healthier, and we really don't believe that, because when they self-describe their health, they describe it generally as worse. And so if we use the HCC scores and adjusted the service use, it would look like rural people are using more care on an HCC-adjusted basis.

DR. CASALINO: Got it. That makes sense. You know, I got the slide number here wrong. Can we just go to the concluding slide? I'm sorry. The conclusions slide. The last slide. Yeah, go back one. Sorry. Okay. I'm not sure where it is, but one of these slides, you talk about using more granular measures to look at access. And Lynn was kind of calling for that in her remarks. I'll have

something to say about that briefly. But when you talk about more granular analysis, maybe you can make some of the comments that I would make, for example, unnecessary. What were you thinking about in terms of more granular measures for measuring access?

MR. O'DONNELL: Yes, so I think there's a couple things. One is that, you know, even within kind of, let's say, dual eligible beneficiaries, so I think right here what we have is kind of the forest view in the sense that they are sicker, they are getting more care. In general, that's positive, right? But a more granular look at it would be to say, okay, let's look at some survey data, for example, which we do every year, or the MCBS to see whether, you know, maybe the difference between duals and non-duals is present, but maybe it's too small to detect on a service use basis. So one kind of aspect is sticking with these same types of beneficiaries, but then kind of digging deeper into different sources of data. And then another kind of perspective is to say, you know, the MUAs, for example, is an area-based designation, but maybe that's not how we want to define vulnerable beneficiaries. Maybe it's things like are you a physician practice or a hospital

that serves poor people? So that would mean kind of just shifting the paradigm in terms of what we're thinking about in terms of vulnerable populations and safety net providers.

DR. CASALINO: Great. Thanks.

MS. KELLEY: Betty?

DR. RAMBUR: Thank you. I'll certainly have more for Round 2, but one quick Round 1 question. Table 13 in the materials, I'm curious how incident-to billing shows up on that. Does that show up in the nurse practitioner mode or that's showing up as physician work?

MR. O'DONNELL: So it would not show up -- incident-to would not be accounted for. So if an NP is billing under a physician's NPI, in our data it would appear as the physician.

DR. RAMBUR: I mean, we all know that incident-to is a problem. Many nurse practitioners in rural areas are seeing, you know, their own patients. So that's one gap.

And then, obviously, this is claims data, so it doesn't include non-claims data. But I'm curious about if the data is able to capture some of the barriers that have been in place. So, for example, when Vermont started its

all-payer ACO, nurse practitioners were not able to be designated as attributed providers in that because of technical issues. Do we know if those have been unwound? And we don't have to answer that now. I just am curious because we know that the majority of nurse practitioners are prepared in primary care, even though many do work in specialty areas. But just those two questions about the data, and I don't know the situation as well for PAs, but -- so any clarity on that would be helpful.

MR. O'DONNELL: Yeah, and that's a good point. And so, you know, we're aware of the limitations of claims data, and so we took kind of a three-part approach to validating our results with the help of one of our research assistants. One is that our estimates we compared to national averages. So for the PAs, we're pretty comfortable in terms of the national estimate that the PA Association makes. But about 27 percent of PAs work in primary care, and our number was pretty close to that. Or they said 26 and we said 27. So that's one approach.

The second approach, which I kind of call the "smell test," is that we ran our algorithm, and then we just manually looked up about 100 NPs and PAs that we

categorized as primary care or specialty care to see how accurate we were. It came out that our metric was very accurate.

And then I think third was that we purchased some outside data, IQVIA data, which collects information on clinician specialty, and we calculated whether an NP or PA practices in primary or specialty care based on the IQVIA data, which is non-claims data. And we compared that to our claims-based algorithm, and, again, they matched at a really high rate.

So we understand that our claims-based kind of analyses are limited, but we did take a pretty robust kind of approach to validating it.

DR. RAMBUR: Thank you very much. Appreciate that.

MS. KELLEY: Jaewon.

DR. RYU: Thanks. I just have two questions. One of them was on the coding discrepancy that you referenced -- I think it was Slide 4, and it was in the materials as well -- between rural and urban. I was just trying to figure out why that would be. I think in the materials you referenced that there are fewer incentives in

the rural environment to capture the chronic diseases, and maybe that's a function of MA penetration, but do we have insights into exactly what is driving that? Because I'm not -- I don't know, but I wouldn't have guessed that there's that much of a difference in MA penetration between rural and urban but, you know, was curious to hear more about that.

DR. STENSLAND: I think it's a combination of effects, and one I think is the MA penetration. There could be some coding spillover from MA. But there's also just a lot more critical access hospitals in rural areas, and they get paid based on cost as opposed to based on the number of conditions that they code for their DRGs. So there just is not the incentive to do the coding there, and, also, if you are a physician that might be in an ACO, you might have a bigger incentive to code things also, and there's going to be some discrepancy there in rural-urban ACOs. And you also may have less incentive to code to defend the level of your visit if you're a rural health clinic because you're just getting a fixed payment for that rural health clinic visit as opposed to some categorized level as you would in the physician fee schedule. And each

one of these things may be a small piece, but the thing is they all lean in the same direction of coding less in rural.

DR. RYU: That makes sense. Thank you. And then the other question I had was: In this past June chapter, I know we had produced the chapter about the rural in particular. And in the materials there was reference to the hospital closures, and in the time period preceding those closures, more people were traveling further to go elsewhere for their care, and it was fewer inpatient admissions, I think is what you reference.

Do we have any line of sight into what might be driving that? Was it programs that were discontinued? Was it capabilities that were retired? Was it -- I'm just trying to figure out, because I think consumer use patterns tend to shift only because -- it's in response to something, right? It's in response to a program no longer being available or something. But I don't know if we have any insight into what precipitated those shifts.

DR. STENSLAND: I think it may in large part be the consumer preference to get their care elsewhere, because for the hospitals that closed and saw these big

drops in inpatient use, sometimes on the order of 50 percent, if you look at the top DRGs, in the beginning years they were basically the same top DRGs that they were right prior to closure. So it's like they just had kind of a similar decline in their share of pneumonia cases in the market that went to them, a similar decline in the share of congestive heart failure cases that went to them, a similar decline in the UTI cases that went to them. For some reason they were generally bypassing that market. And I think, you know, this bypass that occurred, it's not going to be indicative of overall rural bypass, because we're saying these are hospitals that closed and we're looking backward then to say what happened when you closed. So you could say that the causation could go the other way around, where if you're in a community and the people decide they would rather not use you and go to a different hospital 30 miles away, then you may be more likely to close. And then when we look at the closures, sure enough we find that those are places where people stopped using the facility.

MS. KELLEY: Lynn, did you have something on this?

MS. BARR: Just I would love it if you could get

a little bit down -- a little bit more information about why people are driving by, because one of my concerns is that rural people are poorer than the rest of the country, and they pay higher co-pays in that rural community than they do elsewhere. And so how -- and this is one of my concerns about price transparency. Is price transparency going to create a downward spiral? So if we found out that a good reason that they were driving by was because of cost, we might want to really think about addressing the disparities in co-pays paid by rural communities sooner rather than later.

MS. KELLEY: Okay. Pat?

MS. WANG: Thank you. It's very, very interesting work and obviously raises a lot of questions. My questions are -- kind of reflect, I guess, the perspective that especially today when we talk about access, we should be talking about access 13 in codes, but it's also the type of access, right? I mean, we're talking about health equity. So I like that you're going to go deeper in this.

My question is sort of around the types of data that you might have considered using. A lot of this is

sort of the MUA, all of those concepts are describing a geographic area. Do you have access to information that would tell you things like emergency visits per 1,000 in different geographic units, admissions through the emergency room per 1,000 for the same geographic unit? I don't know if you have access to PQI. I don't know if AHRQ does that or somebody does that, because that is -- you know, I think it's a pretty commonly used indicator of adequacy of primary care. Regardless of the number of counts of primary care, if there's a very high level of PQI admissions, avoidable admissions. You know, it might have -- it might give some insight into whether the delivery system's actually organized in the right way to provide the right kind of access.

I was wondering about also the pharmacy question that Lynn raised. I don't know if you can do things like avoidable readmissions. I think these are indicators of -- it's not to say providers are bad or neutral. It's just sort of what is the delivery system like in that region when you add it to all of those other indicators.

I also wondered whether you consider, are going to consider using current, like very robust databases, like

the area deprivation index or social vulnerable index to layer on top of this to give more understanding, I guess. You know, I'm spilling over, I think, into Round 2, but sort of -- the other thing I guess I wanted to ask you about, so there's more data sources, I think, that can maybe get more at the question of, okay, there may be a count of what we call primary care, but can we go a little bit deeper to understand whether people are having the right kind of access and, therefore, the right kinds of outcomes?

The other thing is that the focus of the chapter -- and I guess this is the question about sort of what the analysis is for -- is the important task of identifying and appropriately supporting safety net providers, but is it also for the purpose of deciding where there might be new investments in different kinds of providers or new investments in different kinds of modalities that could inform, you know, delivery system reform beyond looking at specific providers and the payment policy for those providers, which is very, very important.

The chapter sort of talks about it in terms of the analysis in order to drive safety net provider payment

policy, and I guess I was just curious whether that's the context of the congressional request. Is that what it's for? Or is it possible that you could go beyond that?

DR. MATHEWS: So, Pat, I'll take a stab at answering this question, if I might. What we have done here in the material that we presented both in our June 2020 report on rural as well as MUA, duals, multiple chronic conditions, information that we've presented here, this is, you know, a specific response to what the Ways and Means Committee asked us to do. You know, there was bipartisan interest in determining whether these populations, you know, writ large, were experiencing access problems. And, you know, based on our findings here, at a very high level, we do not see any glaring access problems when we use these particular lenses to examine the populations -- duals, rural MUA, multiple chronic conditions, that sort of thing.

And so given that kind of null finding, as it were, we still -- I can't remember who said it at the beginning here; maybe it was Lynn, you know, somewhat half-facetiously, we know there are access problems, we just can't find them. But we do think that there is some

legitimate concern with respect to identifying populations that are particularly vulnerable to access problems, even though we haven't found those populations using the measures that we were asked to look at.

And so we still think, you know, that there is some value in us trying to identify these populations for a couple of reasons: one, you know, there's some intrinsic value in doing so, you know, helping the most vulnerable beneficiaries; but, two, better targeting and making more effective the support to the providers who serve those populations. And the reason that we should be doing this is twofold: one, you know, if there are broad policies that direct money to all kinds of providers, irrespective of whether or not they are true safety net providers, that is, they miss targeting of resources; and then, second, you know, one of the things that we hear from the stakeholder community all the time is that, you know, MedPAC's parsimonious update recommendations are going to disproportionately negatively affect safety net providers and, therefore, you need to give a generous update to everyone. And I don't think that is a fiscally sustainable position for either us or the Medicare program to take.

And so there is some value in us continuing to dig into the questions that the committee asked, but also it has implications for our update work going forward.

Does that help?

MS. WANG: It does, and I'll just save a couple of additional comments for Round 2. Thank you so much.

DR. CHERNEW: I want to jump in. We have had a pretty undisciplined Round 1, so I apologize for calling it out, but it has been a noticeably undisciplined Round 1. So we're going to -- Wayne, you're next. This has nothing to do with -- Wayne, you have not made your comments yet. I am just going to emphasize again, Round 1 is not for, "Hey, maybe you should do a whole bunch of these things." Round 1 is a clarifying question. How did you measure this? How did you not?

We will have this discussion, but I will also tell you I've been getting comments from some people who say, "This is frustrating because we're waiting to get to Round 2 and the conversation is going somewhere else."

So I don't mean to be such a stickler, but it kind of my job to make sure that we be a little disciplined. So I am just giving you a little reminder. I

wish I had a sign that says Round 1.

Wayne, I really apologize for you being the person to talk after that comment, but in any case you are the person to talk after that comment. So go ahead, Wayne.

DR. RILEY: Well, thank you, Mr. Chairman. I appreciate this topic, you know, because my one Yale economics course ill-prepared me for googling about 13 economic terms you used in our earlier discussion, so thank you.

Jeff and Brian, a question regarding sort of the line of inquiry that Jaewon mentioned, in terms of the erosion in rural hospital inpatient. And he just said maybe there a change in program, and the way to understand that is suppose someone, you know, in some of these rural hospitals they have one orthopedist, and that one orthopedist leaves, and then there's no option but to send a hip fracture 40 miles down the road. Or if someone needs a pacemaker, sure, they have cardiology but they don't have an electrophysiologist. Again, you've got to send that patient 40 miles down the road.

So some look at that might be helpful too.

The other thing, too, as you know, and I may have

missed this in the June report on rural hospitals, but do we know the difference between -- well, let's put it this way. Not all critical access hospitals are rural, and not all critical -- et cetera. So do we know the difference between rural hospital, critical access hospital in terms of closure rate, and then the specialty mix in DRGs between both? And again, it's consistent with the inquiry that Jaewon mentioned earlier.

DR. STENSLAND: Yeah. We know that data, and I think we'll probably get into it in more detail in December. I don't want to sidetrack it too much. But generally we saw critical access hospital and PPS rural hospital closures going up somewhat in 2019, and then with the pandemic, and the pandemic really -- there has been a dramatic decline in rural closures from where they were before the pandemic. And we'll talk about that more later.

DR. RILEY: And if you think about it, Jeff, but look at the specialty service mix, because, you know, I've got the suspicion -- unfounded, unsupported -- that that may have been a contributor.

DR. STENSLAND: Well, I kind of would go back to what I said to Jaewon. We saw this decline in admissions,

like this close to 50 percent decline for a lot of these closed hospitals. And we said, what can we explain that decline with? And we could explain almost all of it with just looking at like seven types of DRGs, and those were all kind of basic things.

So these weren't hospitals doing a lot of sophisticated stuff to start with. It was, as I said, like pneumonia and congestive heart failure and UTIs, and that was what they were doing before, and that was what they were doing after. It's just that they're doing a lot less of it in the years prior to closure than they were looking back five or six years.

DR. RILEY: Okay. Great. Thank you.

DR. CHERNEW: Okay. We are now on to Round 2. So, Dana, you have the queue.

MS. KELLEY: All right. We'll let Larry start.

DR. CASALINO: Yeah, thanks, Dana. I will just note, that's really important, Jeff, what you just said, because those common, relatively easy-to-treat conditions in most people are exactly what rural hospitals should be doing. When I was at the University of Chicago years ago, the university had a lot of trouble for saying, "Look, if

you come to our emergency room and you have run-of-the-mill pneumonia, you can wait for 18 hours in the emergency room to get admitted upstairs, or we can send you to one of the local community hospitals here where we have our doctors, and you can be treated there."

Anyway, what I wanted to say was, you know, it's interesting that practically our entire discussion so far, for however long we've been talking, has been about rural versus urban. And we actually did our report about rural versus urban in June. I think the MUAs for this report-- it's great work and there's not that much to discuss. It's just really good. But supposedly this is not multiple chronic and dual eligible, and I think the reason we wound up talking about urban and rural is that it does seem, at least to me, and I think probably to others, that it's more likely to be access problems between urban and rural than there is between people who have multiple chronic conditions and don't, and even dual eligibles versus other Medicare patients.

I don't think there are that many physicians that refuse to see dual eligible patients, as long as they have Medicare. So you wouldn't necessarily expect to find that

decision. So maybe it's no accident that we wound up focusing on rural-urban, even though we already did a report on that.

But I want to just point to a more general problem, which came up a little bit in the discussion between Pat and Jim. And we've had some of this discussion before, I think in relation to the annual updates, when, you know, MedPAC has to make updates for a lot of different types of providers and looks at access in fairly crude ways. And then, you know, somebody says, "Well, we don't see any access problem."

But I'm sure the staff, and Jim and Dana have thought about this a lot. But still, I think it might be worth thinking more. I would really welcome, and I would be very interested in any ideas from other Commissioners about other ways to measure access, and maybe we could spend some time on that today, not just for today on urban and rural but more generally, when MedPAC has to evaluate access. And it might be that some of these would be just more work than it's worthwhile doing every year, to do annual updates. But still I think looking a little bit more about what access measures we use might be worthwhile.

So I would just suggest a couple, and I'm not sure, really, that these are that good, but just, for example, we kind of actually talked about ambulatory care sensitive, or potentially preventable ED visits, potentially preventable hospital admissions and tertiary care admissions, and risk adjusted. I mean, in urban and rural, the risk adjusted is [inaudible] have to use HCC scores or the risk adjustment won't be correct.

But you get the idea. If things are potentially preventable and they're not prevented then one could infer, perhaps, that, I mean, that access may not be what it should be, or the physicians they have access to aren't that good. Or it could be just the base's fault. So any of those.

But I think that would be one area to kind of think of, and those are not very hard to measure. The others would be more novel things that might or might not work. So I could imagine -- and again, it's hard to get out of the rural-urban framing and thinking about this, although the obvious framing would be Medicaid versus commercially insured or Medicare insured, dual eligibles that are Medicare insured.

But I would assume that the time for a patient to see a specialist, after they have an ED visit, or after they have a hospital admission, obviously not all ED visits and hospital admissions need specialist follow-up, but there are ways of dealing with, but would be longer in rural areas than it would be in urban areas. It would be longer for Medicare patients, but that's not really our purview. I don't know if it would be longer for dual eligible patients. Something like that, and even kind of a looser thing, which might be hard to justify, but just as a way of thinking. If a patient sees a primary care physician, and then they see a specialist, it may or may not have been, and I understand, on referral from the primary care physician, or a lot of times it would be, how long is it, on average, between, say, rural and urban beneficiaries, or any other things we want to compare? So again, another way at trying to get at access.

So I think it would be good, although we might not want to bring out the full artillery every time, to think about, as you put it, Brian, more granular ways to think about access, whenever we're thinking about access, possibly in annual updates.

MS. KELLEY: Okay. Betty.

DR. RAMBUR: Thank you very much. I just wanted to open by sharing my enthusiasm for including nurse practitioners and PAs as part of the primary care workforce addressing the rural and undeserved citizens of our nation, given that they are increasingly doing more and more of the work.

I appreciated what you said about the coding differences between critical access hospitals and PPS systems, and I also just wanted to underscore my appreciation for having a population gradient. Rural frontier counties are, in fact, very different than other rural areas, and I don't know if this is still true, but at one time they were disproportionately very old, elderly, health was self-defined as the ability to work, so even that sort of different mindset. It seems like some of these things could be gotten at through some of the more granular analyses you talked about, like surveys.

I wanted to just make one quick comment, following up on Pat's comment, and I think Larry's, as well. As I was thinking about this I was thinking that we're actually talking -- I was thinking underserved for

what? We're talking about acute and hospital care, but I know that in a number of states, and certainly in rural areas, there are dual eligible programs that are looking at chronic collaborative initiatives that are looking at individuals who are sometimes called super-utilizers, people who are utilizing a lot of health care or dual eligible. And there are collaborations between nurses, not advanced practice nurses, and social workers, that use complicated IT platforms and predictive algorithms to identify, you know, who they need to reach out to individually, who they need to manage in some sort of other kind of way. And I don't know how we think about that when it's not in claims data, and that was one of the bases of my earlier questions.

So even if a report like this could just highlight some of those initiatives that are not easily accessible, in terms of, you know, a plethora of data, we could at least have some illustration of that, because I think there are very, very important initiatives, and certainly there is a lot of talk, or attention, at least, in the nursing world of the potential for nurses and social workers, not advanced practice, to really change the

landscape.

So thank you. Overall I think it's a very good start.

MS. KELLEY: Stacie.

DR. DUSETZINA: I agree. This is very interesting and well outside of my area of expertise. But I did want to bring up one issue related to the measurement issues you all bring up in the chapter, around the MUAs, and especially the idea of incorporating NPs and PAs.

I guess one thing that I was wondering is, do you plan to try to create this revised MUA and see if that improves identification of people who really, truly do have a limited access to health care practitioners of all types, and see if that does any better?

And I guess the other question that just came to my mind was around the issue of specialty care access, and I think Larry pointed this out as well, and others have made similar comments. That seemed to be a component that you flagged in the report as having been something that was difficult to access for the prior report, broken down by rural and urban. And I do think that that seems an important access question, and I didn't see it fully

reflected here.

So I'm just curious about those two items.

MR. O'DONNELL: Yeah. So I'll take a crack at them. I think the first thing is like are we considering recreating MUAs, incorporating NPs and PAs. I think the basic answer is that, you know, we work for you, so you will kind of tell us what to do. But I think stepping back a bit, right, is that philosophically, you might not want to go with an area-based designation of safety net provider writ large. So I think next month, I think what we'll do is take a step back and say like, yes, we did not like this particular area-based designation, which is MUAs, but here's a kind of broader perspective on how the Commission might want to define safety nets, and so you all will have the discussion of which one you kind of like better in terms of provider-based or area-based, things of that nature. So I think that's one thing.

And on your specialty question, you know, just to level-set, what we found last year was that comparing urban and rural beneficiaries, the use of PCP visits was about the same. We didn't find any difference, really. But even after controlling for state variation, the difference in

specialist use was about 20 percent different. So, you know, rural benes had about 20 percent fewer specialist E&M visits.

So we saw those data, and what we did was then we said, well, what does that mean? We looked at kind of survey data to say, are rural beneficiaries satisfied with their access to specialist care? And, in general, they were.

And so, you know, we then took another approach and we talked to a bunch of rural folks in different communities. And I think where we landed was that, you know, they certainly do use fewer services, it certainly is related to how far they drive -- so they're driving 25 to 50 miles, on average, compared to maybe half that for urban folks -- but that, you know, our kind of mean hypothesis is that they tend to bundle services. So they make a trip, you know, 45 miles down the road, and they might get more packed into one visit than otherwise, if it was 5 miles down the road. And that's how we square the kind of rural folks themselves saying they are satisfied with access, but then the substantially utilization of specialty care we see in the claims data.

So that's just kind of level-setting of what we see in the world.

DR. DUSETZINA: Thank you.

MS. KELLEY: Jaewon.

DR. RYU: Yeah. A little bit of piling on here. I'm excited we're doing this work too. It seems like we have many discussions related to all sorts of policies, and even the annual update discussion, where we talk a lot about unintended consequences and specifically vulnerable populations within the program and also underserved areas or providers serving underserved areas. So I think this is all very important, to have a grounding that's a little more accurate.

I'll be honest. I was a little surprised. I had no idea that the MUA framework was so inaccurate. So I think that was one bit of shocking news to me. But I thought what was really good in the chapter was the use of an example, and the D.C. metropolitan area example, I thought, in particular, really made that come to life. So thank you for incorporating that, Brian and Jeff.

I am eager to see what the alternatives are. I think that's where I'm curious what you will come up in the

next discussion we have on this, Brian and Jeff. And earlier, Brian, you referenced it may not necessarily be that it's a geographically oriented measure, like the MUA is, but perhaps it's more around the characteristics of the beneficiaries that certain providers take care of. And so I aligned probably a little more. I could wrap my head around that. I think that makes better sense to me. I think it's a more accurate framework.

I think Larry got into some of the other proxy measures of access that I also think make better sense than sort of what appears to be arbitrary geographic kind of cutoffs that are dated and based on criteria that were quite a bit of years ago.

So I'm eager to see what you all come up with, but thank you so much for a great discussion, great chapter.

MS. KELLEY: Pat.

MS. WANG: It's been said -- and I just want to sort of underscore, I really encourage MedPAC to take a deeper look in the definition of access, particularly is it the right kind of access, and in sort of making an assessment there, it's kind of the proof is in the pudding,

excessive emergency room use, excessive PQI, avoidable admissions. That is an indicator that something is not quite right, despite the head count of what might be considered primary care or the number of E&M visits per person.

As you develop out the tweaks to the MUA, I mean, the suggestions about including NPs and APRNs is really great, but I wonder -- again, I encourage you to think about maybe it's the MUA plus, plus, plus, you know, the indicators that Larry and I have both mentioned.

I think specialist wait time is hugely important, hugely important, just my experience. Primary care access might be fine, but if you have to wait months to get a specialist consult, you are going to wind up in the emergency room. So that's the way those things kind of happen.

I do wonder whether it is appropriate in this MUA plus, plus, plus to introduce some of the new indices. We talked about the AVI last time when it came to quality metrics. There's the social risk index, the SVI, social vulnerability index. There are a lot of indices now that can enrich the view of a geographic area.

The final thing -- and I don't know how to define this -- is to the extent that it's possible to identify the sort of effectiveness of a system of care in a region in which providers might be located, I think it has a big impact on the people that we care about. You can have lots of individual providers and lots of utilization, but it might be all the wrong utilization. It might be overutilization, and I personally think that if there are any indicia that people can think about, about systems of care where there's collaboration, that is a very important indicator.

Thanks.

MS. KELLEY: David.

DR. GRABOWSKI: Great. Thanks to Brian and Jeff for this work. I believe this is really, really valuable.

I want to build on Pat's comments on her definition of access and Larry's comments on measuring new types of access. I thought those were really important comments, and I agree with what's already been said and wanted to sort of build on that.

As was noted in the chapter, it's really hard to compare duals and non-duals based on their utilization.

How do we interpret what's appropriate and what isn't?

I also don't know that we have a sense of whether or not duals are accessing higher-quality providers, and I just wanted to give a quick example from one of our research projects. We wanted to compare duals and non-duals leaving the hospital, and their access of skilled nursing facility care, we found, not surprisingly, that duals' access lower quality SNFs -- this is all done within ZIP code, so we're controlling for area, and we're looking just within ZIPs, a dual versus a non-dual, where do they get care. Duals go to worst-quality SNFs. They're more likely to get stuck in those SNFs once they're there and transition to long-stay status.

Larry, when you're building that measure set, another possible measure, it's kind of successful community discharge, whether individuals are able to return to the community. Not surprisingly, duals have much less help in the community and so much less of an ability, both to access home health care on the front end but then to return to the community on the back end.

I think we have to be really careful in thinking about access here. It's not just appropriateness, but it's

also sort of the types of providers and the social support. I'm not so much trying to push the staff to adopt our research strategy as much as using it to illustrate, but there's a lot going on here, and you need to think about access broadly. So I hope we'll continue to do that.

Final point, and I wondered about comparisons -- and maybe I missed this -- within duals by race and ethnicity and whether you could look at differences there. That might be really interesting. We've seen a lot of research suggesting within dual populations, there's differences there, and so I'd be really interested. If you've already done that, great, and if I missed it, I apologize. But, if not, that might be something to add to the future iterations of this work.

Once again, this is incredibly valuable. I'm glad we're doing it, and I look forward to future versions. Thanks.

MS. KELLEY: Amol, did you have something on this point?

DR. NAVATHE: Yeah. I simply wanted to expand David's point, which is this notion around how we think about access has to be very broad and multidimensional

because -- I think there's also evidence that based on race, so beneficiaries of Black race, dual eligibles, patients who live in areas which have higher social deprivation indices, they tend to access a different network of providers to begin with. There's a pretty significant separation. So I think there's some estimates that look like 20 to 25 percent of NPIs account for 80 to 85 percent more of the care that's provided in an ambulatory setting for patients with dual status or patients with Black race, for example.

So I think that there has to be this nuanced sense of how we think about access. It's not just about physical utilization, which I think we have articulated here, but I just wanted to amplify that. Thanks.

MS. KELLEY: Okay. Bruce.

MR. PYENSON: Well, thank you. I'll be very brief. I would like to make two suggestions or three suggestions and a comment. The comment is that last month, we had what might have been termed "odd results" by looking at social deprivation index and dual eligibility with respect to quality outcomes for post-acute care. Here, we are finding what might be considered odd results for the

MUAs.

I'd like to suggest that we depart from our usual presentation and show confidence intervals or 90th, 10th percentiles along with the averages to give people a sense of the variability within the characteristics that we're measuring, because I think that emphasizes the point that we're not saying that there aren't disparities. What we're seeing is huge variability. And that probably points to those qualities.

A second point is that there is a lot of overlap, over a high portion of dual eligibles are institutionalized, and they have an odd impact on regions because of how nursing homes are located. So, if it's possible to break out institutionalized as in some of the analyses, I think that might shed light on otherwise this cloud of data that we're observing.

Thank you.

DR. CHERNEW: Jon Perlin?

DR. PERLIN: Well, thanks.

I'll go back a little bit to three related points. The first of those relates to better metrics of access that the group has really talked about.

The second, some of my concerns about the MUAs that I don't think we've been quite a pointed about.

And third, something I think we also have to contemplate, which is what ultimately are the implications in terms of a change to contemplation of MUAs. So, for example, MUAs remain critical for FQHC status, et cetera. So, on the change, even in areas that are not discriminated as, more or less, underserved may become more underserved if the MUA concept were eroded.

The first point is I think we have access to data to give a much more robust picture of what access means, 2021, ranging from information access, broadband availability, primary care or ambulatory care, sensitive indicators, mortality rates, and I would even hope some of the intermediate outcomes, blood pressure control, you know, diabetic management, et cetera.

Put that aside for a moment. I think we all agree to that. Let's go back to what I think we did, a sharper point, and I think the chapter does a good job on this, but there may be a couple more resources or a couple more statements on this. What are some of the problems of MUAs? Well, the more I look at it, I feel like we're using

a thermometer to measures distance. It may be the wrong tool, and it's a tool that's not stable over time. The units have changed.

So you just go back to the basic components. Is infant mortality as relevant as it might have been when MUAs were constructed in 1973? Well, I went back. Richelle Winkler wrote an article on the changing demography and the age segregation that's occurring. Now with highly concentrated populations of older and younger individuals respectively, that marker in itself shows that there may be instability in the use of MUAs over time because what may have been a critical piece of understanding access in a geographic area may have substantially changed.

In fact, in a recent Harvard Business Review article on this point of age segregation, there are notes made that the segregation of elders and younger are actually greater than Latinx, White populations, a direct quote from the article.

The second aspect of that is that there's a great review article on the Health Policy comments. I realized it's old, but it's not as old as MUAs. It's 2008 from Sara

Rosenbaum's group. Peter Shin is the lead author, and in it, they regress, you know, 20 variables, and find 9 that are more predictive than the elements of MUA. At just simply a mathematical basis, as Bruce and others have indicated, there are likely better predictors of what constitutes relative paucity of access versus access, and it gets back to that first principle that, I think, Jim Mathews articulated so well. It's really do we have the resources not only for the patients but for provider infrastructure to support patients with the use of this.

I get to this point about first I think we have a better set of indicators of access, as many Commissioners have articulated.

Second, I think our criticisms of MUA are even stronger, the terrific articulation of the concerns that are in the chapter.

But, third, as we do this, I worry about the potential for collateral damage that may not -- may inadvertently not benefit those areas that in fact are underserved but in fact diminish the infrastructure of those areas that are better served and highly reliant on things that are supported by the MUA designation.

Thanks very much.

MS. KELLEY: Paul.

DR. PAUL GINSBURG: Oh, thanks.

Yeah. I think following up on what Jon was talking about, I am really glad that you've done the MUA analysis, and it's not just a matter of research, as you say, Brian and Jeff. It's really a matter of this is the basis for policy, and the policies that are drawing on the MUA are probably not allocating resources very well.

Like the reading material and like Jaewon, I think Amol too -- I think just looking at the provider level rather than the area level and looking at providers that treat very high proportions of disadvantaged patients is really the best way to go forward and really digging in to study access in a way that we might be able to do something about.

Another comment I wanted to make is that pretty striking results about how terrible the health status is of dual eligibles, and what I want to just bring up is I don't think this is a reflection that being a dual eligible makes you sicker. I think it's a reflection of being sicker particularly during the potential earning years makes

people dual eligibles. I think that's really where most of the causation is going.

Thanks.

DR. CHERNEW: I think that's the end of Round 2.

Maybe we should go back to Round 1. I'm sure there were more Round 1 questions people wanted to ask. That's a joke.

Dana, is there anyone else in the queue? Does anyone else want to make any other comments before I say a few closing things about this, actually, I will say remarkably consisting set of comments?

MS. KELLEY: There's no one else in the queue.

DR. CHERNEW: I'm pausing for a second to see if anyone wants to say something.

[Pause.]

DR. CHERNEW: Okay. This broad issue of access is important not just for the Congress but important to us. I don't want people to interpret the notion that we're responding to a congressional request as we're only doing this because you were asked to. We were asked to, and we did do this, but I think as a number of these comments pointed out, this is a broadly interesting and

generalizable issue that we have to deal with writ large.

I take a few things away from the comments in terms of direction and reactions. Apart from the general enthusiasm and support for the work, which is hard, the first thing is the MUA designation in general isn't great for a bunch of reasons, and in fact, conceptually understanding the unit of access, what that means by area, by facility, by type of person, the equity issues, and all those things are really, really important. And I think, again, I can see all of you, so I'm going to try and read your now little faces.

I think there's a lot of enthusiasm for pushing some of these forward to understand how different populations are not just based on where they live but who they are, how they're covered and stuff, other traits of them, how they are accessing care is really important, and I think there's willingness on the staff's part to continue to push that.

The second thing I will say -- so that's really about how we define the basic unit of where we're going to say something about access. There's a series of other comments, all of which are well taken, about if we picked

area or population or whatever we picked, how would we know if access is good or bad? Our measures aren't very good. We tend to look at things like the number and counts of services, and we tend to argue if people are getting less of something, they have an access problem. That almost implies that the greater utilization is the right amount, and if you get less than the max, you have an access problem. And that's not necessarily true.

I think there was a lot of discussion -- and I appreciate that discussion -- of what I would call nuanced measures of trying to understand where the difference in utilization are actually affecting the health outcomes we care about, because we don't care that you use a lot of care. We care about that your health is well treated.

Larry mentioned ambulatory-sensitive conditions, for example, which is an indication that people aren't necessarily getting what they need. I think we can continue to push on those types of measures to understand where there's a problem beyond just intellectual paradigm of less use clearly a problem, although it's certainly the case that less use makes you wonder if there's a problem, which is why I think we look at it in the first place. So

I'm fine with that.

All I will say in my last point for now is going to be one thing that I particularly like about this chapter, I'm very much where Betty is. It acknowledges this changing production function of care, the role of non-physician providers, for example. I think as the world evolves and we have telehealth activity and a range of things like that, that the production function of health care -- I'm saying an economic comment again. The way we make people healthy, the way we make people health is changing the technology evolves in a bunch of complex ways, and we need to be aware of that when we think about what it means to have access and whom we have access to because the end of the day, we really care about the health of the Medicare beneficiaries and they can get the services when they need it, and that doesn't mean necessarily as much services as they want, just the services that they need to maintain their health.

The beauty of my summary is I've subsequently seen two people want to -- at least two people in the chat that want to add something. So, Dana, we now have a Round 3. The Round 3 is post-Michael ramblings. I think -- I'm

not sure -- Larry was first.

MS. KELLEY: I think that's right. Larry.

DR. CHERNEW: Yeah, so we'll have a few more comments. Larry?

DR. CASALINO: I'm just trying to ramp up my production collection here. I think Jonathan's comment, you know, led me to have another comment, his comment about, k possible unintended consequences of changing the definition of MUAs, not that I would argue that we currently identify them is all wrong and we shouldn't advocate changes, but what I would love to see in the report -- I don't know, Jim and staff, if this would be within the congressional mandate, but I realize I don't really have a good sense of what policies are dependent on MUAs, right? So like what does an MUA get in terms of resources on a policy level for being an MUA? So that would be -- probably a lot of Commissioners don't know that well, and -- well, I don't know about Congress, but, anyway, that would be useful.

And then the other thing about MUAs, there's been some talk, but we haven't really delved into it very much, about geographic based MUAs versus satellite provider-based

MUAs or even beneficiary-based MUAs. And I guess I'd just -- this would relate to the first thing I said in terms of like what policies are there, how do they work, MUA-based policies. But I think there would be really different policy implications if you're dealing with a geographic area than if you're dealing with an individual hospital, say, or a small medical group or whatever.

So, again, I don't know if this is going beyond what Congress wants in this report or what the staff has the desire or are intending to do, but if we're going to talk about not just using a geographic definition of MUAs, certainly some other definition, a little probing into what that would mean at a policy level I think would be useful.

MS. KELLEY: Pat, did have a comment?

MS. WANG: Just a real quick one. I think the thing that's confusing to me about this work, which is so important, is that, on the one hand, it's aimed at identifying safety net providers so we can make sure that payment policy supports them, which is really important. But it feels like the whole inquiry is much bigger than that, because it's not just about a physical provider anymore. We didn't talk about telehealth and the new

modalities that are coming in. So it feels like it's important to inform the identification of safety net providers that need, you know, special attention in terms of Medicare's payment policy, but that it should have a broader -- it should inform a broader picture of the kinds of investments that might be necessary in certain communities. And, you know, maybe it's beyond Medicare's purview, but I just think that the way that we're talking about providers is a little bit pre-pandemic or something like that, because there is a lot more telehealth now. There is more care that's coming into the home through remote devices if there's broadband.

But I just wanted to make sure that we have that on the radar screen. Thank you.

MS. KELLEY: That's all I have, Mike.

DR. CHERNEW: Thanks, Pat. That was what I was alluding to sort of in that last comment, that we have to think about that. And, again, I agree with you completely, and I appreciate that broad perspective.

I will say in closing this is a little bit of what I would call a magnifying glass or a microscope chapter where we're trying to identify problems and see

what's going on, and the ramifications of what we find will pervade out to a whole bunch of policies. Obviously, I have been interested in a lot of equity issues which is going to motivate some of the safety net discussion, so we have a similar theme next month. It will obviously help us think about our update chapters. To your point, Pat, it might make us think about some of the telehealth things we're thinking through, maybe some of our quality measurement stuff.

There's a range of things, I think Paul said, just a lot of policies are hinged on some of these definitions. And so I think this is a real opportunity for us to contribute there, somewhat foundational, and I think that part is good.

I was about to say good night and good-bye. Bruce, you started with a comment, and then you said, "Never mind." Bruce, now is your chance to mind or not. That's a no? Okay.

So I'm going to pause for a second to see if anyone wants to say anything else. Actually, think if you want to say anything else. While you're thinking, I will say to the audience remember there are a lot of ways to

reach us. I think -- Jim, you can correct me -- meetingcomments@medpac.gov is a way to get to the staff and explain what it is you think we should have said or should have done or would be useful. We do want to hear the public comments in this virtual public meeting.

Other than that, we will say good-bye for tonight and encourage you all to join us tomorrow when we will talk about one of my favorite topics, alternative payment models.

Anything else anyone wants to add?

[No response.]

DR. CHERNEW: Brian, Jeff, thanks. Commissioners, thanks. Jim and all the staff that presented today, great job and thank you. And to the audience, please join us again tomorrow. See you then.

[Whereupon, at 4:45 p.m., the meeting was recessed, to reconvene at 10:00 a.m. on Friday, October 8, 2021.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

Via GoToWebinar

Friday, October 8, 2021
10:01 a.m.

COMMISSIONERS PRESENT:

MICHAEL CHERNEW, PhD, Chair
PAUL B. GINSBURG, PhD, Vice Chair
LYNN BARR, MPH
LAWRENCE P. CASALINO, MD, PhD
BRIAN DeBUSK, PhD
STACIE B. DUSETZINA, PhD
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AGENDA PAGE

P R O C E E D I N G S

[10:01 a.m.]

DR. CHERNEW: Hello, everybody, and welcome to our Friday MedPAC meeting. Again, this is our West Coast-friendly time.

We're going to kick this off with Geoff and Rachel providing a lot of information about a very complicated topic, alternative payment models, and then we are going to jump into a somewhat different format for the deliberations. I'm going to call them "three lightning rounds": one on population base, one on episode base, and one on how they might work together. I'll describe that more when Geoff and Rachel are done, but to save time, let's take it away.

Geoff, are you starting?

MR. GERHARDT: Yes, I am. Good morning to everybody.

Today Rachel Burton and I will discuss four key features of Medicare's alternative payment models. We would like to thank Luis Serna, Dan Zabinski, Jeff Stensland, and Andy Johnson for their input and assistance with this work.

I'd also remind the audience that they can download a PDF of the presentation from the control panel on the right-hand side of your screen.

Today's presentation builds on work the Commission did last cycle on ways to improve Medicare's portfolio of alternative payment models.

We'll start by reviewing some of the challenges the Commission identified with Medicare's APMs and the recommendation it made on how to change the way CMS manages its portfolio of models.

Since part of that recommendation urged CMS to harmonize its portfolio of APMs, we will review four of the most important features that shape the implementation of Medicare APMs.

In addition to questions about each of the four model features, we will end by raising a series of overarching questions to consider as you continue to look at ways of improving Medicare's APMs.

Over the last 10 years, Medicare has implemented more than 50 alternative payment models, and last June's report identified problems that can occur when multiple APMs overlap with one another.

When a provider participates in multiple APMs, they can face different payment methods, quality measures, and reporting requirements. The differing rules can add complexity, discourage participation, and act to reduce financial incentives to reduce spending and improve care.

Likewise, having beneficiaries aligned with multiple APMs means that shared savings or losses either go to participants in just one of the models or are divided between multiple models. This can reduce anticipated financial benefits to providers and dilute incentives to transform care.

Model overlap can also make it difficult to evaluate the effects of a given model, since comparison groups can be contaminated by providers participating in other APMs.

In response, MedPAC recommended that Medicare implement a smaller number of APMs that are carefully designed to work together.

I'll now turn things over to Rachel.

MS. BURTON: Next steps for the Commission could involve developing more specific recommendations that operationalize our broad June recommendation.

Since one of our suggestions was that CMS make model features more consistent, this presentation looks at how Medicare APMs compare on four core features.

We first look at how spending benchmarks are set and how benchmarks are risk adjusted. We also examine how much financial risk providers face and how provider participation is incentivized or mandated.

In this presentation we focus primarily on Medicare's advanced APMs, which are the subset of models that require clinicians to take on financial risk and, in turn, earn clinicians 5 percent bonuses under MACRA.

We also look at tracks of these models that don't require financial risk and at the CHART Model's ACO Transformation Track, which is layered on top of the Medicare Shared Savings Program, and the Independence at Home Demonstration, which is essentially a one-sided ACO.

Some of these models are population-based payment models, which hold providers accountable for spending and quality over a one-year period.

Others are episode-based and hold providers accountable for a 90-day or a 6-month period.

Still others are advanced primary care models,

which offer partially capitated monthly payments that are adjusted based on quality.

For our first model feature, we look at how spending benchmarks are set in different Medicare APMs. Benchmarks are used in population-based and episode-based payment models and are compared to a provider's actual spending over some period of time to determine if they will earn shared savings or owe shared losses.

Benchmarks are customized for each participating provider in a model and represent provider spending that would be expected to occur if historical treatment patterns continued into the current year.

If a provider's actual spending is below their benchmark, they can earn shared savings from Medicare. If a provider's actual spending is above their benchmark, they can owe shared losses.

Across Medicare's APMs, we found that non-participating providers' historical spending is always at least part of the basis of a participating provider’s benchmark.

Models differ in whether they draw this historical spending from providers at the county, hospital

referral region, state, multi-state, or national level.

Models also differ in whether they use fixed or rolling baseline periods to identify historical spending. When rolling baseline periods are used, benchmarks are re-set annually and always use the most recent spending data available.

When fixed baseline periods are used, benchmarks are re-set every five years, allowing providers to have more predictable spending targets over a multi-year period.

APMs also use different factors to trend forward historical spending to a current-year benchmark. These trend factors are based on spending growth at the county, state, multi-state, and/or national level.

Given this wide variation, Commissioners could consider whether a more consistent approach should be used to calculate spending benchmarks in Medicare's APMs.

Specifically, we ask, should there be more consistency in the geographic area used to identify non-participating provider historical spending that is incorporated into a benchmark? Should there be more consistency in the baseline periods used to identify historical spending? And should there be more consistency

in the geographic area used to identify spending growth trend factors?

I'll note that Luis and Jeff Stensland plan to give a deeper dive on how ACOs' benchmarks are set at the November meeting.

Moving to our second model feature, Medicare APMs that use spending benchmarks risk-adjust these benchmarks to reflect each participating provider's unique mix of Medicare patients. Models use some or all of the variables in CMS's HCC risk adjustment model but don't always list all of the variables they use. So we can't fully assess how consistent APMs' risk adjustment approaches are.

The HCC risk adjustment model is also used to adjust Medicare Advantage payments and will be the focus of Dan and Andy's presentation later today, which will look at how to improve the predictive power of the HCC model.

For now, the key thing to know is that beneficiaries' risk scores are largely based on which diagnoses are coded in their claims data. Generally speaking, a provider with beneficiaries who have more diagnoses coded in their claims, is likely to have a higher average risk score and a higher spending benchmark and

will, therefore, have an easier time qualifying for shared savings payments. This means providers in APMs usually have a financial incentive to code as many diagnoses as possible in their claims data.

To minimize the effects of coding-induced risk score growth, CMS is experimenting with a number of approaches, including limiting the degree to which a provider's average risk score can increase over time, risk adjusting using only a beneficiary's main diagnoses, or basing payments on which of four tiers a provider's average risk score falls within. So far, no clearly optimal approach has yet emerged, and providers in APMs can usually still benefit financially from coding as many diagnoses as possible.

Models also differ in when risk adjustment happens and what year of data is used to risk adjust. In APMs for niche patient populations with unpredictable spending, benchmarks are risk-adjusted at the end of the year, using that year's data. This produces more accurate benchmarks.

In APMs where providers are accountable for larger, broader patient populations or for patients with

conditions that have predictable spending, risk adjustment is done at the start of the year, using prior-year data. This allows providers to more easily plan care transformation investments.

Commissioners could consider whether the current variation in risk adjustment across APMs makes sense or whether greater standardization would be better. Specifically, we ask, should models continue to vary in the approaches used to minimize the effects of coding-induced risk score growth? And should models continue to vary in their use of current-year vs. prior-year data for risk adjustment, depending on whether accuracy or predictability is more important?

I'll now turn things back over to Geoff.

MR. GERHARDT: The third model feature we'll discuss is the amount of financial risk providers face in APMs.

As we discussed last cycle, risk-based payment arrangements are intended to present providers and other actors in the health sector with different incentives than traditional fee-for-service, but there is no widespread agreement on what kinds of financial risk arrangements are

optimal in terms of getting providers to change their behavior in positive ways.

As such, Medicare has experimented with a wide range of risk arrangements in its APMs. For instance, models vary in terms of how much spending must be reduced before participants can share in any savings, the portion of savings above that threshold they are allowed to keep, and limits on the amount of shared savings they can keep.

One factor Medicare must consider is how a model's financial terms will affect participation in voluntary models. I'll talk more about provider participation in a couple of minutes, but Medicare has said that when designing a model where participation is voluntary, the agency balances the goal of presenting providers with meaningful financial risk, with the need to attract and retain participants.

Your mailing material show how financial risk arrangements work in each of the models listed earlier. One of the most important differences in risk arrangements is whether providers are faced with one-sided or two-sided risk. The size of risks and rewards varies widely across models, but potential rewards are larger in two-sided

models, some of which allow providers to keep 100 percent of shared savings, up to a defined limit, and vice versa for shared losses.

Officials at CMS have expressed a preference for two-sided models on the grounds that the higher level of risk is more effective in encouraging providers to transform care. As such, most Medicare APMs use two-sided risk or the option of one-sided and two-sided tracks.

Like some models, the Medicare Shared Savings Program requires that providers move from tracks with no downside risk or lower levels of risk to tracks with higher levels of risk over a set period of time.

It is also worth pointing out that several models vary financial risk terms according to provider characteristics, such as the number of aligned beneficiaries or provider revenue.

Given the variation in financial risk arrangements, Commissioners could consider whether and how risk features should be made more consistent across models.

We ask, under what circumstances should providers participate in one-sided models, and for how long? Should the size of financial risk be made larger to increase

incentives to transform care? Should financial risk be tailored to provider characteristics; for example, based on size, revenue, or patient mix?

In selecting and designing APMs, one of the things that Medicare gives a great deal of consideration to is our fourth model feature: how to incentivize or mandate provider participation.

According to CMS, each model should have enough participation to minimize the degree to which random variation in spending and quality metrics drive results.

Participation in each APM should also be broad enough so that what happens during a model's testing phase is a good indicator of what would happen if the model were expanded to a larger universe of providers.

As mentioned earlier, Medicare considers how the financial risk arrangements in a model will affect participation and can design risk-based features in ways that are likely to attract and retain participants.

Alternatively, Medicare can mandate that providers participate in a model, usually by requiring that all eligible providers located in specified geographic areas participate in the model.

Congress has also taken steps to encourage participation by establishing a 5 percent bonus for clinicians who participate in advanced APMs. The bonus is scheduled to expire at the end of 2024 and be replaced with a higher annual payment updates for A-APM participants starting in 2026.

In the vast majority of APMs implemented to date, provider participation has been voluntary. Providers have expressed several reasons for participating in voluntary models, including a desire to move away from fee-for-service payment, gaining better access to CMS claims data, and potential financial benefits from shared savings.

However, voluntary models can suffer from problems with selection bias if providers who believe they will be financially successful are more likely to sign up than those who think they won't benefit. This type of selection behavior may help explain why shared savings payments to providers often outstrip reductions in spending and repayments for shared losses in voluntary models.

Mandatory models have been far less common. They are usually used when CMS believes a voluntary model would lead to low participation or a non-representative group of

participants, the model involves a relatively rare clinical event, or when the agency wants control over the geographic distribution of a model.

Mandatory models are usually opposed by provider groups because they say providers may not be prepared to take on two-sided financial risk in such models. They claim that the required level of risk may cause providers to reduce the number of beneficiaries they see or stop providing services to Medicare beneficiaries altogether.

Given the need to ensure robust participation in APMs while avoiding the problems with provider selection bias, Commissioners may want to consider how to best approach incentivizing or mandating provider participation.

Specifically, we ask, should MACRA policies providing bonuses and higher payment updates to providers that participate in A-APMs be modified? Should traditional fee-for-service be made less attractive to providers who do not participate in an APM? Should the amount of financial risk in APMs be used to incentivize participation in voluntary models? Should more models be mandatory, and under what circumstances?

That concludes our presentation on four key

features of Medicare's APMs.

Using the questions raised earlier in the presentation as a jumping-off point, we invite your input on whether to develop specific recommendations related to any of the four model features we've discussed today.

We're also interested in whether there are other features of APMs that you would like to explore.

And as we look to build on the APM recommendations from last June's report, we invite your input on whether to provide CMS with more specific direction about how to streamline the number of models, as well how to improve policies that address model overlap.

We look forward to your discussion and are happy to answer any questions you may have.

DR. CHERNEW: Geoff and Rachel, thank you so much.

So we're going to do this a little differently. We're going to have some lightning rounds. The reason is based on some responses I got from the mailing materials. It seems that many people think that the answers to some of the questions may vary by types of model episodes or population base or whatever it is, and there was some

yearning for sort of a broader superstructure of things before we get into all of the answers for these questions.

So this has been really valuable information for those of you listening. The chapter does an amazing job of describing not only the models but also some of their inconsistencies.

But what we're going to do now, I think, is we're going to start with a lightning round for what I'll call "population-based payment models." So save your comments on whether episodes should exist or how they should be structured for a future lightning round. This is really just about population-based payment models. I'm going to throw out a strawman, not because I like it necessarily, just because it's a basis for a discussion, that strawman, and then I'll tell you some questions.

So, for example, the strawman I want to point out is the existence of a multitrack ACO model. I'm going to talk about four tracks. You may say there should be others for specific programs, but one I will call a high-risk track with symmetric high-risk features, think Next-Gen in some ways; a symmetric risk track with somewhat less risk, so that's sort of the intermediate risk track and upside

only track that the third track and the fourth track would be sort of an advanced primary care track.

In my straw man, large systems would be heavily incented/mandated to be in the high-risk track and heavily disincented or maybe prohibited from the lower-risk tracks, and lower-risk tracks would be voluntary. We could discuss how strong the incentives should be, as Geoff and Rachel just mentioned. And we may limit access to the upside-only track to organizations based on size, so not everyone could be in the upside-only track.

Smaller organizations could combine if they wanted and move up to higher-risk tracks through conveners or things like that. And the last point I'll say is once we get the tracks settle we could decide or discuss certain types of direct contracting features like sort of upfront payments or assigning risk to third parties.

In any case, I very much realize that went by quickly. It's a lightning round, of course. I'm interested in really two main questions, although, of course, you can say whatever you want. The first one is, what do you think about the track structure, particularly the upside-only track, and if we're going to have a sort of

harmonized set of tracks what do we think of this track structure? And the second thing is, what are your thoughts on the mandatory voluntary incentive aspects of this?

Some of the other things that Geoff and Rachel mentioned, benchmarks will be discussed next month, risk adjustment we're going to discuss later today. These are all very important issues. But for now I want to do a quick lightning round focused on population-based payment models. When we're done with this we will have a lighting round on episode models.

So, Dana, you're going to manage the queue.

MS. KELLEY: Okay. Lynn is up first.

MS. BARR: Good morning, everyone, and thank you for this work and your attention to these issues.

Michael, I do agree with your track approach, and I think it is very similar to how pathways exist today, although it's more of a glidepath. Not everyone is able to glide, and so having different tracks for different people is really important.

There are a couple of things that I want to make sure that we're thinking about as we're looking at data and thinking about these problems. One of them is problems of

scale. So when we started our first ACO in 2014, we thought 5,000 lives sounded great. And by 2018, Caravan had 38 different ACOs. They were all 10,000 lives. And we saw our results shift by 10 percent every year. Some were 10 percent up one year, then they're 10 percent down. When they're up they think they're great; when they're down they think, you know, that Medicare is messed up.

So we can't ask providers to participate in these programs and take downside risk if it's actuarially unsound for them to do so. And where we see the 95 percent confidence interval really reaching 2 percent, which is about the target we have for savings, it's 60,000 lives, and yet 80 percent or more of the participants in the ACOs today have less than 20,000 lives.

And this has created a lot of abuse of the program. And so there are organizations that play what I call "benchmark bingo." They will set up a bunch of 5,000-life ACOs and the inaccuracy also affects the benchmarks. So you can get lucky or you don't get lucky, and if you get lucky, you get to hold onto that benchmark forever, and monetize it forever, even though there's no real savings happening there.

And so this is a significant issue. As we think about these different tracks we have to think about the size of the organization. And I don't believe we should force risk on any organization that cannot amass 60,000 lives and get to a 95 percent confidence interval on a 2 percent MLR.

So that's just my personal opinion on that but I'd love to hear others. And we've done some great work with Milliman. I'd love to share some of the analysis we've done with the staff, to show what the true confidence intervals are.

DR. CHERNEW: Lynn, you're at two minutes.

MS. BARR: I'm at my two minutes. Okay. All right.

DR. CHERNEW: Nope. Nope. Dana?

MS KELLEY: Brian.

DR. CHERNEW: Brian.

DR. DeBUSK: First of all, thank you to the staff for a great chapter. You gave us a ton of things to think about. It's a little overwhelming, all the different design considerations.

Michael, to specifically address the issues you

raised, I do strongly support the four tracks as you've laid them out. I think that's an excellent framework. It's nice to see something we can go all the way from, say, a Next Gen all the way to a primary care model. I think continuity there is very, very important.

I would stress that we harmonize everything within that track except the risk and reward relationship of. I would love to see similar benchmark calculations, similar risk adjustment methodologies. I think even the attribution methodology should be harmonized. Because I think we should facilitate organizations being able to move up and down these tracks.

So, you know, part of the new technology here, for lack of a better term, is I do think it is exciting to see Next Gen all the way to a primary care-based model that, in theory, could be hosted by a relatively small organization.

As far as the upside-only, I see that as a good transitional vehicle. I think it should be limited to smaller organizations. I think it should be limited in time.

And then the other issues, this issue of

voluntary is a problem, and I do think, as the staff mentioned in the presentation, I think there is a selection issue there, provider selection issue there.

But I do prefer making participation effectively mandatory, as opposed to, say, a CJR, where you just simply sign people up. I do support the idea of making some form of APM participation mandatory through things like making fee-for-service progressively less comfortable. I'm really excited to see how we're going to address, for example, physician payment updates in the future. I would love to see more and more of the physician payments done through APM participation and other forms of advanced or progressive care as opposed to just simply --

DR. CHERNEW: Brian, your two minutes are up.

DR. DeBUSK: -- adding the conversion factor. Thank you.

DR. CHERNEW: Okay. Thanks, Brian. Dana.

MS. KELLEY: Jonathan Jaffery.

DR. JAFFERY: Thanks, Dana. So I will speak quickly. I too am very supportive of this notion of tracks, where we have progressive things. And like Brian, I think harmonizing the factors within them is a great

idea.

A couple of things, though, specifically, and I'm thinking about some of the goals we've talked about in the past, sort of a vision for having all beneficiaries in some value-based payment model, be that MA or an ACO model. And I think we should keep that in mind as we're thinking about the mandatory versus voluntary, and actually to inform some of our second- and third-round discussions this morning.

In terms of some of the specific tracks, I worry a little bit about pushing larger organizations into two-sided risk immediately. Some of the organizations we've seen that start off with low-cost care to begin with, you know, need some time, actually, to get to savings. And I would hate to either mandatorily make larger organizations lose money right away or ask them to voluntarily do so. So I think we need to consider that.

In terms of upside risk only, I'm in favor of that initially, but like Brian I think we need a track, over time, to get folks to two-sided risk, and the question of size and scope. I think CMS can offer some thinking about technical support, whether that's providing support for convening organizations to bring smaller groups

together to get to size and scope.

And then finally, that speaks a little to mandatory, in terms of the incentives I also think that this notion of trying to make fee-for-service updates over time in the fee schedule more and more attractive to organizations to be in alternative payment models is a good idea. I'm not sure we should limit it to physician payments. I think we might think about the same for other sectors as well.

So I could go on and on but I think I'm probably reaching two minutes, and so I'll --

DR. CHERNEW: You are. Jonathan, that's perfect. You're at two minutes.

DR. JAFFERY: All right. Thank you.

DR. CHERNEW: Dana, who is next?

MS. KELLEY: David.

DR. GRABOWSKI: Great. Thank you. So I am also supportive of a small number of tracks with increasing levels of risk. I think when it comes to population-based models I definitely think one size doesn't fit all here. I support a low-risk option for smaller organizations, where we can encourage entry of more innovative models. These

types of models, I don't think, need that downside risk to incentivize decreased spending. Larger organizations could have that downside risk, but I agree with what Jonathan just said, that having an onramp to encourage participation, that facing downside risk right off the bat could lead to decreased participation.

In terms of mandatory versus voluntary, you always hear this saying that mandatory solves everything. However, in this instance I think I favor voluntary with strong incentives to participate, especially for those smaller organizations. As Geoff suggested on Slide 15 during the presentation, we could incentivize participation by setting more attractive financial risk terms. I think if we build strong and equitable models we'll get that participation.

I think we need to think more globally about participation and not separate it from model features. We need to think about that in a more holistic way. We tend to look at participation and wonder why nobody wants to go into a model where we haven't built it very well. So I hope we'll take a different approach going forward.

I'll stop there, Mike, and just say thanks. I'm

very supportive of this work.

DR. CHERNEW: Perfect, David. Dana, who is next?

MS. KELLEY: Amol.

DR. NAVATHE: Thank you. I also am extremely supportive, like other Commissioners, of this broad approach. I would also say that the work that the staff did in preparing this chapter, with all the details, is really very helpful to go through, and does highlight the fact that these dimensions, in some sense, need to sit underneath the superstructure that we're discussing today.

My quick reactions to the lightning round stuff. So first, I think I agree with the stratification by size and capability. I agree, in general, with the notion of having voluntary, in particular, for the lower-risk tracks, for the smaller organizations.

I think that advanced primary care piece should be thought of less as a track and should be more thought of as a mechanism to pay for primary care. This could be something that is actually consistent across all of the different tracks, moving towards an advanced primary care type of payment for primary care.

On the upside track, I agree with the comments

that were made by, I think, Brian and David, that there should be some sort of clarity around what the future looks like in terms of stepping through. I don't think that we necessarily need to get to maximum downside risk as the way to drive results, based on the evidence that we know. I think we should strongly consider, for those tracks, asymmetric risk in the future, where we might have a big chunk of upside risk and a small amount of downside risk, because we know from behavioral economics that losses loom large, so sort of the concept of loss [inaudible].

And I do also agree with Brian. I don't think this is possible uniformly, but to the extent that we can create harmony or similar design features, for example, the way that attribution is done, across the tracks, I think that would also improve the simplicity, because I think it is likely that we may see some migration of organizations between tracks. And so there are not major friction points to move between those, virtually to advance over time, that would be very helpful.

DR. CHERNEW: Amol, you're hitting your time.

DR. NAVATHE: Done.

DR. CHERNEW: Okay. Thanks. Sorry I'm so

brutal, guys. There may be time at the end to say more before we move to the next lightning round. But who is next, Dana?

MS. KELLEY: Larry.

DR. CASALINO: Yeah. So like others I'm basically good with the tracks that Mike laid out. I do want to add something that hasn't been brought up yet, but which Mike had in his straw man. I think given more direct contracting features to at least some of the ACO tracks is a good idea. And I realize the horse is out of the barn with this but I am strongly opposed to giving large national insurers or financial entities, making it possible for them to basically own these basically ACO-like entities, though I would consider permitting minority investments. I think the Gilfillan blog in Health Affairs is very relevant to this.

I would like to hear more about what Lynn had to say about the level of risk versus the number of beneficiaries.

In terms of voluntary versus mandatory, I don't have such strong feelings. One idea would be to make things voluntary for two to three years, then mandatory in

some places so you could evaluate the program better. And then if it's a good program, let's make it mandatory for all, at least to take some degree of risk. I think we should probably have to give it to a very limited number of institutions from mandatory.

Something that hasn't really been discussed yet is the 5 percent bonus, continuing that, and it's through MACRA. I really disagree with continuing that. You shouldn't get money just for participating. You should have to earn rewards through good performance. Otherwise, government is picking winners and losers in a way that I don't agree with.

I strongly agree with Jonathan's comment that if we're going to make fee-for-service less comfortable, that should not just be for physicians but for others, notably hospitals, though they are being paid largely by DRGs. Still, less comfortable for them. Hospitals are a potential obstacle for the success of population-based models. So if we're going to make things less comfortable in fee-for-service it shouldn't just be for physicians. It should be others, and notably hospitals.

Thanks, Mike. This is a great idea to do this,

and I'm pleased by the degree of agreement that we seem to have, at least on a lot of things.

DR. CHERNEW: Thanks, Larry. And that takes us to two minutes. Dana, who's next?

MS. KELLEY: Betty.

DR. RAMBUR: Oh, thank you very much. I am a big supporter of population-based, total cost of care models for all payers and providers, in all delivery settings, not just physicians and not just hospitals, as in Maryland. And to me that's the only way to get to social determinants of health, equity, the only way to unleash innovation, more imaginative use of teams, and actually start to move towards real person-centered care.

I am not sure that the advanced primary care should be a separate track or tucked in a broader vision. I'm not willing to fall on my sword, but I do want to think about it.

As for one-sided risk, obviously that is bonus only. So I think that needs to be for very select groups that are small, a very limited time. Because one of the things I liked about MACRA is the message was there to providers, if you could decode it, that one way or another

you are taking on greater accountability for cost of care, and I do think that's important. So for really small providers, maybe exempt, but I'm tepid about upside only.

Otherwise, I think this is moving in an important direction. Thank you.

DR. CHERNEW: Betty, under two minutes. Dana, who's next?

MS. KELLEY: Paul.

DR. PAUL GINSBURG: Thanks. I think this is the right approach to talk about our visions about models before we get into the many issues in the next presentation before us. Like the others, I favor population-based approaches as the primary approach to alternative payments. I'm not going to use value-based payment after what I said yesterday.

And I want to point out that I think we need -- I think larger organizations it can be mandatory for, but for smaller organizations we should have incentives such as higher or lower, especially lower fee-for-service payment rates for the non-participants. And I think we have a situation that I can see physicians coming to Congress saying, "Well, no ACO wants me. Does that mean I can't

participate in Medicare?" And the answer should be, "Yes, you are welcome to participate, but your payment rate is lower."

I really like Amol's points about maybe considering a track, developing a separate primary care model that's applied and throughout all the tracks.

And so final comment -- that is the final comment. I'm going to stop.

DR. CHERNEW: Paul, thank you. Also under two minutes. Now we're super-lightning, I guess. This is good.

Dana, who is next?

MS. KELLEY: Jaewon.

DR. RYU: Yes, similar comments. I like the track structure, but I also don't think we need the advanced primary care track. To me it feels like if you have the other three offerings, that one feels a little different to me. And Amol's comment I think helped crystallize that a little bit.

The upside only I think does make sense because sheerly practicality, there are a lot of groups out there that I think need an option along those lines. But I think

as a feature, upside only, it should not have -- it should not carry the same benefit as those willing to take the downside exposure. So I think that's got to be incorporated into how we think about it.

As far as mandatory versus voluntary, I lean towards the mandatory side, and to me it feels like there's an interaction between if you get the tracks right and have the right accommodations there, I think you feel better about moving more quickly towards a mandatory framework, understanding that, you know, if the tracks aren't exactly right and if the right accommodations are not there, then I think you do need either a runway or a size-dependent kind of, you know, this group it's more voluntary as far as the approach.

Thanks.

MS. KELLEY: Dana.

DR. CHERNEW: Jaewon, thank you.

DR. SAFRAN: Michael, I'm just waiting. I hope you haven't started the clock. Can I go?

DR. CHERNEW: Yes, you can go.

DR. SAFRAN: Okay, thank you. Great. I appreciate this excellent work and the detail about the

different model features for us to consider. One point I'll make that I don't think has been made is that I would suggest that we not look to standardize the way we handle the different core features across models. You know, I think the way these ingredients are put together very much needs to be a product of the kind of model. And so I would rather see us have some principles than to try to pick how should risk adjustment be done, how should benchmarking be done, and do that all the time.

Like my fellow Commissioners, I do very much like the sort of varying levels of risk. I, however, don't favor having a model where one-sided risk is allowed to be sustained over time. I also don't favor having an advanced primary care model.

My thinking about the one-sided risk is I do understand that for smaller organizations we need the population size to be such that the total cost of care results are not noise. And if we allow smaller organizations to be in one-sided risk models in perpetuity, I think that essentially just leaves CMS to eat the savings that aren't real savings when noise indicates that savings have been made but they haven't. So I would much rather

see us encourage conveners along the lines of what Aledade does or for CMS to offer a convening approach, but not to have a sustained one-sided model.

On the mandatory-voluntary issue, I really am torn. I will say I lean a little bit toward voluntary, but making the alternative to voluntary quite unpalatable, and particularly unpalatable for organizations that have the size and scale that they could do two-sided risk on their own. That's based on my own experiences, you know, for --

DR. CHERNEW: Dana, we're --

DR. SAFRAN: I'll stop there.

DR. CHERNEW: Okay. Thanks, Dana. Who's next?

MS. KELLEY: Bruce.

MR. PYENSON: Thank you very much. A couple of items I want to point out is that the risk issue, the science for determining that is today's enterprise risk management, and in considering an enterprise and these issues, we have to think way beyond just the Medicare component. A billion-dollar health enterprise integrated delivery system might under reasonable circumstances have $80 to $90 million of ACO connected expenses. So I like the idea of tagging the level of risk to the size of the

enterprise, but keep in mind that that has to be determined on a holistic enterprise risk management basis. Like others, I favor mandatory or a transition to mandatory, and I don't see -- I could not support a PCP model other than in a transition. I would see that the big risks of not getting this right, of not moving into mandatory, is, as Lynn has pointed out, the harvesting and risk selection issues. But those aren't just about ACOs selecting particular providers, which is widespread. It's also about MA plans selecting more favorable [inaudible]. So a mandatory system would allow us to avoid a lot of that and actually measure on a regional basis both the MA plans as well as the participants. It's going to take a transition, but I think that kind of view will get us there. So I'd call on as next steps staff to think about this from an enterprise risk management standpoint because we're not going to get to the right place just looking at Medicare.

Thank you.

DR. CHERNEW: Bruce, thank you a lot.

Lynn, you were the first one, and I'm not sure it was clear how harsh I was going to be on the two minutes. I get the sense that you had two more minutes of something

to say, and I cut you off. So in a one-time-only mulligan, I'm going to give you two more minutes if you want to add things, and then we're going to move on to episodes. If you don't want to, that's fine, but my sense is you do.

MS. BARR: Thank you so much. So mandatory versus voluntary, first of all, the best way Medicare can save money is to get everybody in the program. No question about it. But from my perspective of actually trying to convince providers to get in the program, if there's a 5 percent upside on the fee schedule, it becomes mandatory. They want to do it. The problem is where 2 percent, nobody wants to do it. But at 5, they'll do it. So just give them the 5 percent one way or the other, you know. And MACRA is already built to do that, as I put in the chat box. It's already there, so let's just follow the MACRA framework.

Please think about the safety net. A third of our patients are seen in the safety net. They are very risk averse. We have to be sensitive to them. And my concern is in what I've seen has happened in the last 20 years is every time we have a program like this, we make it mandatory, but then we exclude the safety net and say,

well, we can't put that burden on them. And that's creating worse and worse disparities. So there has to be a way, and that's why I think voluntary with a 5 percent upside on the fee schedule, you know, however you want to earn it, it will get people where you need to go and will bring the safety net along as well, as long as you make sure that it actually does cover the way they get paid.

Thank you.

DR. CHERNEW: Lynn, that was under two minutes. I just for the record want it to be clear, so thank you.

I'm going to jump in now to the second lightning round, the episode lightning round. I want to be really clear what we're doing here. The lightning round we just had was sort of if we were going to do population-based, ignoring episodes, what would it look like? And, by the way, I really felt that was a useful discussion, at least for me. I hope you all did. It was really valuable.

I want to do the exact same exercise now for episodes. In that exercise, I am not presuming we will have episodes or making any other assumption about what will happen. That will be the third lighting round. This is just if we had episodes, what would that system look

like in a bunch of ways? And we can have that discussion, and then the third lightning round will be sort of how they might work together or some other version of that or if you want only one or the other, whatever.

So I'm going to give you another straw man for episodes, and I will give a shout-out to Amol because there's a lot of Amol's thinking behind exactly this. So we'll see if Amol gets in the queue.

In any case, so here's the straw man: Mandatory episodes for hospitals for clinical episodes with high evidence of benefits. This would be things like lower extremity joint replacement. We could talk about the specific episodes later. In some ways episodes is harder because there's a bunch of different clinical conditions. So that's point one.

Point two, voluntary episodes for a smaller set of clinical episodes with enough participation and some evidence of benefits. They could be surgical, they could be medical episodes, it could be both. Limiting the choice of specific clinical episodes and instead thinking in chunks such as broad surgical versus medical so you're not necessarily cherry picking a specific one. It might be we

make it all hospital-based. I'm not sure. You can discuss that. Or, more broadly, let me lead with the one overarching question I have here: Should each clinical condition be assigned to a unique episode program and design? Right now, of course, there's multiple programs and multiple ways you get into the same clinical condition.

So I'm very interested in your thinking on that and what you think about that type of straw man, and remember that all of the integration between what we say now and what we just said is going to happen in the next lightning round, and I will have a sort of straw man version of how we do that when we get there.

So, Dana, do we have -- I'm sorry. I was reading my notes --

DR. CASALINO: Mike, a quick question. Sorry. I'm unclear what you mean by each clinical condition. Do you mean each clinical condition that one would put in an episode? Or do you mean each clinical --

DR. CHERNEW: Yes.

DR. CASALINO: -- condition that exists?

DR. CHERNEW: No, I mean each clinical condition one would put in an episode. So if you do joints, is there

one sort of joint model as opposed to one for hospitals and physicians and one in CJR and a different one in BPCI-A. So I mean for the conditions you're going to put in an episode, have one episode way of getting into that condition. And, remember, that's the straw man.

DR. CASALINO: Right.

DR. CHERNEW: That's the straw man. So there could be a lot of clinical conditions that don't have episodes at all. In fact, many of you may something like very few episodes. In the straw man, just to be clear, there was a notion use only episodes where there's some evidence that episodes work for this condition. So if you think we should be very expansive for episodes, that would be the type of thing you could say in your lightning round comments.

Okay. Dana Kelley, I think I see there's some episode queue, so let's start going again through it. Can you tell me who's first?

MS. KELLEY: Brian is first.

DR. DeBUSK: Thank you, Dana. As far as episodes, Mike, just to work down the list of your questions, I do think episodes drive physician behavior,

and I do think we need to respect the evidence that's out there that episodes, at least in certain circumstances like lower joint replacement, do tend to be effective. So I do think they deserve a seat at the table, even as we collect more evidence on the effectiveness of ACOs.

To answer the other question, I believe the episodes should be done by specialty, but I think they should only be done by specialty when they're well defined -- again, lower joint being a great example. I'm not sure that an ongoing diabetes management episode makes a lot of sense. So, again, acute, well defined. I still think we should make them effectively mandatory simply by payment policy. I mean, we do the updates around the APMs. We don't do the updates around the core fee schedule.

Now, here my third point is where there will be a significant departure from my fellow Commissioners, I'm afraid. I really think we need to preserve the physician autonomy here and encourage and allow private practice physicians to participate in these episodes. I think we have some very well intended policies, but I think a lot of times they accidentally drive consolidation. And it really concerns me that when we drive private practice physicians

either into employment or into private equity, I don't think that's good for beneficiaries; I don't think that's good for taxpayers. And I do think that failing to do that could inadvertently drive further employment and further consolidation.

Thank you.

DR. CHERNEW: Brian, thank you. Dana, who's next?

MS. KELLEY: Amol.

DR. NAVATHE: Thank you. So I wanted to echo some of Brian's comments. I think it's worth noting that the evidence that we have for episodes to date really heavily focuses around hospital care and post-acute care once you go to the hospital, post-acute care, and on specialty, principally on surgery engagement, surgical engagement, which I think is an important kind of piece to recognize in terms of the evidence that exists there. And I think that should guide how we perhaps think about how we might advance an episode, harmonize the program or some programs.

So to most precisely answer the question that you asked, Mike, I think, yes, absolutely, we don't want

multiple clinical episodes or clinical conditions in multiple different programs. I think that makes it quite messy, which has happened previously. I agree with the general frame of a mandatory program where we have strong evidence such as LEJR. I think we should focus in episodes in a voluntary program where there has been traditional participation. BPCI started with 48, BPCI-A had 32, plus others in the outpatient setting. I think the tricky part there is there's been very uneven participation, so people, I think, hospitals and physician groups have voted with their feet, and we should look at that.

Secondly, I think the Commission could actually take on some very important and careful work to understand where are our spending patterns for these conditions actually episodic? If you take something like a diabetes condition-based bundle, it's likely not going to be very episodic. In fact, there's some literature that shows that it's not. It's actually fairly even, with some bumps in the way for hospitalizations. That is not fitting for an episode-based model. If you look at LEJR spending, there's a spike and it goes back to normal.

So I think we can do some empirical work to look

at the 48 or 32, whatever, pick our foundation, to actually refine where episodes do make particular sense based on how spending patterns look. There's not enough evidence in the literature, in fact, to point to that via, I think, a big point.

Another point is I think we should avoid piecemealing episodes. We've historically had some PAC-only episodes, some hospital episodes, some episodes that start in the outpatient, then stand. I think that gets very messy and could create a lot of complications. I think we should not have PAC-only episodes. We should at least have hospital-triggered episodes that include post-acute care. I think, again, that's where the evidence lies most strongly.

DR. CHERNEW: Amol, I know this is your passion. You're getting to two minutes.

DR. NAVATHE: Last point. I think another question to ask the Commissioners along with what is the span of the episode is who should the participant actually be. In this case, I think the strongest evidence is for the hospitals. I will say we have some unpublished work that shows physician groups do well, Brian. They don't

actually do quite as well. I agree with the points around the consolidation --

DR. CHERNEW: All right, Amol.

DR. NAVATHE: -- physicians, not PAC. I'm done. Thanks.

DR. CHERNEW: Okay. Thanks, Amol. There may be time at the end, you know, but right now I just want to make sure everyone's going for two minutes. So who's next?

MS. KELLEY: Pat.

MS. WANG: Thanks. I actually fell out of the Round 1 queue. I had my name in, and then we moved on quickly. I just want to put a period at the end of the sentence that I don't think that we should be dogmatic about two-sided risk. I think one-sided risk is plenty for some organizations that are just never going to have the capability to get two-sided for whatever reason, either size or the nature of a population that they serve.

As far as episodes are concerned, I think episodes are worthwhile, but I think given what we discussed in Round 1 that they should be harmonized to fit underneath the total cost of care models instead of sit separately --

DR. CHERNEW: That's going to be Lightning Round 3, Pat. That's going to be Lightning Round 3. We're going to have a whole discussion on that point, how they get harmonized. I agree, but just within episodes. Sorry. Put Pat first for Lightning Round 3.

Who's next, Dana?

MS. KELLEY: Lynn.

MS. BARR: Well, I'm not sure how we can talk about this way, Michael, without -- because my comments are the same. I think bundles are great, but they need to be incorporated in a population health model. I don't understand how I can talk about it without talking about it.

DR. CHERNEW: That's all right. As you see, Amol has a lot of thoughts about what to do just within episodes. So we just might be very short, and then I will go around and ask a very specific question, which is exactly what you want to talk about now. It's exactly what Pat said. There will be, I guarantee you, time to make those points; in fact, more time if this is shorter. But right now, there's a whole bunch of complexities within episodes. So let's limit this discussion to that, and then

we will have a discussion about how they fit with population base.

MS. BARR: Okay. So the complexities within episodes are the scale issues. I just don't see how it works for the majority of providers.

Thank you.

DR. CHERNEW: Okay. Who's next, Dana?

MS. KELLEY: Paul.

DR. PAUL GINSBURG: Yes. Episodes should be a part of alternative payments. It's not the primary part, but it could be very useful parts.

I think the key is good selection of clinical episodes for the approach. We need to use it selectively for important episodes where there are a lot of them but also episodes that fit, where their risk adjustment is not particularly problematic.

I think there is some chronic conditions that are candidates as well as acute conditions, but probably, it's more difficult to find one.

My friends in ophthalmology believe that glaucoma managements is potentially suitable for an episode. So I think there's potential there. I think this should be the

role of CMS to decide what conditions should be episodes and what conditions should not be.

DR. CHERNEW: Thanks, Paul.

Who's next, Dana?

MS. KELLEY: Betty?

DR. RAMBUR: Thank you very much.

So, briefly, we're all shaped by our own previous history, and I just want to underscore how strongly I support episodes for certain kinds of conditions.

Just very briefly, as a nurse practitioner, I initially worked in primary care and then worked with surgeons, otolaryngologist, and was just stunned by sort of the amazing unbundling. So I very much support the use of episode-based payment for things that are surgical discrete and episodes, not things like diabetes management or congestive heart failure that you would think would be within a population-based model or at least connected to it. And I'll have more comments about that later.

But I absolutely feel very strongly about the importance of mandatory bundles for certain conditions, particularly given -- I don't know if the stats are still the same, but 17 conditions responsible for 50 percent of

the Medicare spend. So some of those are things that could be addressed for episodes.

Thank you.

MS. KELLEY: Okay. Jonathan Jaffery?

DR. JAFFERY: Thanks, Dana.

I'm tempted to just yield my time to Amol.

[Laughter.]

DR. JAFFERY: So I agree largely with what's been said about this. To get to the specific question you posed, Michael, I absolutely agree that if we're going to have a clinical condition and episode, it should be assigned to a single program and design. It's very confusing for people when there's multiple options.

I think we should absolutely stick to the evidence around this, where we're going to have episodes and not just try and make it broadly for clinical conditions just because they're expensive or they're common.

I think the one thing I might add that hasn't been said, before I have some other thoughts like others on that Round 3, but this notion, as Amol was saying, diabetes may not work as an episode because the spending is more

consistent, I think there's also an issue about physician responsibility for that and who cares for people with diabetes. It becomes a lot messier than when we have episodes around lower-extremity joint replacement, as we've talked about.

Looking forward to Round 3. Thanks.

MS. KELLEY: Dana?

DR. CHERNEW: Thanks, Jonathan.

DR. SAFRAN: Thank you.

I would favor a very parsimonious use of episodes that are mandatory. I'll reserve my comments on voluntary episodes for the next round because that really has to do with how I see them potentially complementing total cost of care models.

When I say parsimonious, it's either the mandatory episode models being used only if certain clinical and utilization conditions are met. I really liked Amol's idea of u sing the data to help guide us.

A couple of criteria that come to my mind is that we would consider having mandatory bundles in situations where clinically there is no or very low risk of fee-for-bundles incentives, meaning driving up volume in order to

get additional payment because of the bundle, also in circumstances where the provider typically becomes the primary provider over the course of the episode, like oncology, and also where the episode provider is a clear customer of the upstream risk-taking provider. Those are some of my ideas of where it's useful to consider mandatory, but I think it should be very parsimonious.

Since I haven't yet used up my two minutes, I'll mention something I meant to mention in the previous round, which is I think we should, as we think about how to handle small groups and the amount of risk, consider the impact that that could have for good or for ill on consolidation or deconsolidation, because the market will respond when there are opportunities available for smaller provider groups. And we should be sure to think that through.

Thanks.

DR. CHERNEW: Thanks, Dana.

Who's next, Dana?

MS. KELLEY: Bruce.

MR. PYENSON: Oh, I don't particularly have strong opinions on episodes versus population health, but I would say that having mandatory episodes could be very

appealing for circumstances such as organ transplants or other types of care that have a high amount of fluctuation and ought to be best delivered in special circumstances.

I prefer mandatory system, but episodes makes it more difficult to line up fee-for-service with Medicare Advantage, which is a challenge.

I, again, think there's a lot of detailed game-playing that can go on in underwriting if episodes don't have a strong mandatory component, and there's plenty of actuaries and academics that can look into the nuances of that and set up businesses doing that, which, of course, would not be a good thing.

Finally, I think the episodes play a role, should play an increasing role in the Medicare fee schedule, such as the radiation oncology approach. So one way to use episodes is to just transition it into the regular Medicare fee schedule, which does, in effect, have an upside and downside.

DR. CHERNEW: Thank you, Bruce.

Dana, who is next?

MS. KELLEY: David?

DR. GRABOWSKI: Thanks.

So I also believe there is a role for episodes. I was part of a team that evaluated the CJR. We published that work in NEJM. We found big savings, and as Amol hinted at earlier, it was largely on the back of post-acute care. We didn't observe any decline in outcomes. So I kind of left that project believing for a small set of conditions, mandatory bundles is a good approach.

I agree with Amol on eliminating the post-acute-care-only bundles. That doesn't seem to be the sweet spot. Mike often says post-acute care is the piggybank for APMs. I don't understand if you have a PAC-only bundle, how that actually works. I don't think we're actually leveraging the evidence today.

I like bundles that original with the hospital and then encompass that post-discharge period.

Just to sum up, I do think there's a role for episodes, but for a small number of conditions, and hopefully on a mandatory basis, originating with the hospital.

Thanks.

DR. CHERNEW: Thanks, David.

MS. KELLEY: Larry?

DR. CASALINO: Yeah. I have just a little bit to say. I think Brian already said this. I think we want to be careful about any episode-based system basically giving hospitals even more control over the delivery system and forcing more consolidation. I think that it would be very unfortunate, and it's a very likely effect of an episode-based program that is separate from population-based models.

Then the other thing I have to say, I can be pretty quick about -- and it's been already said somewhat by Brian, Amol, and Jonathan -- I think that there are still people who think that bundling everything is the right thing to do. That, I think, is very mistaken. Not only would that promote more fragmentation, it's really not workable, as every primary care doctor and probably other practices as well know. If you have a patient with congestive heart failure and COPD and diabetes and who comes in with an ankle sprain -- and there are lots of patients like that in primary care -- which one were they in? There's lots of room for gaming and complications, impossible for physicians to understand. Every practicing physician I've talked to about bundling everything thinks

it's crazy.

The glaucoma is a good example. It sounds like a good idea bundling glaucoma, but think about it. I personally know of a case where cataract surgery led to complications, which led to repeated iritis, repeated inflammations to the eye, and then the treatment for that led to intraocular pressure. This played out over months and years is probably a permanent problem. So where's the bundle? Is this a glaucoma bundle? Is it a cataract surgery bundle? It is a iritis bundle? I think, at most, I would see a place for a limited number of bundles, which is basically what other people have said, and I would agree with that.

That's it, Mike.

DR. CHERNEW: Yep. Larry, thank you.

I think Jon Perlin is next. Is that right, Dana?

MS. KELLEY: Right.

DR. CHERNEW: Okay.

DR. PERLIN: Well, thanks.

Let me start with just a background statement that episodes meet much of the world where it is. I appreciate the intent to differentiate on the basis of

strong versus weak evidence, but I wonder if the real question is really differentiation on the basis of very consistent and stereotypical care processes versus apropos of some of Larry's comments, care processes that may be widely distributed for a particular clinical circumstance. I think that's the sort of inherent confounding aspect of episodes itself, but that may be the delineation more so than evidence specifically, though I think the intent of that phraseology is the same.

I do have one concern about sort of bundling. I think it makes sense to have some sort of grouper of similar bundles, but there are likely certain providers that, if compelled to provide a number of different bundles, are unable to provide certain features of a group of bundles or, frankly, shouldn't. You know, volume outcomes, relationship, the other way around, really, more you do, the better you get at a particular activity.

I do just want to make a point that one of the attractions to me of bundles is reflected in our conversation of yesterday which is that this may be one of the better mechanisms to control or improve drug utilization among similar choices. I just put that as a

piece.

Then, finally, anticipating Round 3, I think this is a useful construct to have in the armamentarium for areas where there weren't population or population model may not be feasible, i.e., rural areas or mechanisms where there's not the infrastructure to support the sort of model that might be more tenable in a more populated area.

Thanks.

DR. CHERNEW: Jon, thank you.

Dana, is there anyone else in the queue?

MS. KELLEY: No. That's all.

DR. CHERNEW: All right. Thank you, everybody. That was useful, and I do appreciate the focus.

The next one, in some ways, is the most complex and may be the most important, and because we've been so disciplined here, I think we'll go to three minutes as we go through this integration discussion.

Pat, I'm about to give my strawman, but I can't quite see your face. If you're willing -- I sort of cut you off. I apologize very much for that, but if you'd like to go first, I'd love to hear your thoughts on this point. I can't quite see you, so you can respond in the chat.

In any case, here's the strawman that I'd like to put out. The first one is episodes and ACOs co-exist. I'm not sure everybody agrees with that, but for the strawman, they co-exist in the high-risk track. So now there's a lot of population-based risk. The total cost of care models, the ACOs, take dominance over that, and so, essentially, patients that are assigned to a high-risk ACO track would effectively not be assigned to the ACO because their risk in savings is already captured by the high-risk, ACO track or the population-based track. But a low-risk track, the ACO benchmark gets -- the episode benchmark gets charged to the ACO, but savings within the episodes would accrue to the episode initiator.

So, for example, in an upside-only track, if someone was in an episode, you could imagine the savings within the episode going to the episode initiator and otherwise going -- the number of episodes and which person gets referred to goes to the ACO. I actually have some problems with that, but at least it's a strawman that I can coherently lay out, and by the way, it captures a lot of the status quo.

So here's my three main questions: Should we

have both population-based and an episode-based track, and if not, which one do you prefer? If we have both, how extensive, how many episodes should we be? Should we err on the side of more or fewer? And if we have both, what are your reactions to the general strawman I laid out regarding how they would coordinate?

So I pause for one second to let that sink in, and now, Dana, if you will, please manage this queue. Remember I'm giving you three minutes, and again, Pat, I couldn't quite see you because I was reading my notes. If you want to go first, please do.

MS. WANG: I just have a couple of comments, just to finish what I was trying to say before.

I think that episodes are important. I like Bruce Pyenson's idea, moving them, to the extent that there is evidence, into the fee schedule so that they just become part of the baseline for any benchmark. If they're good, then you don't call them mandatory. It's just the new way that Medicare pays for certain types of care.

To the extent that there is a total cost of care model in place, though, I think it's very important for the episode benefits to be counted towards that wrapper because

the main problem, of course, with episodes is you connect solid episodes and save money against a benchmark but then increase the number of episodes. So I think that there does have to be a higher-level governor around that, along the lines of the heterogeneity of the delivery system and their capability and readiness to start taking risk or effort to take risk. I'd be more in favor of sort of supporting episodes where the total cost of care models really are not suitable.

Since most of them seem to be in a hospital setting, I'm guessing that it will be possible to tuck them inside of a total cost of care construct, but whether they're voluntary or mandatory, I think that they should be counted towards the top line total cost of care that that ACO is responsible for.

Thanks.

DR. CHERNEW: Thank you very much, Pat. Dana, who's next?

MS. KELLEY: Paul is next.

DR. PAUL GINSBURG: Yeah. I think Larry's population-based model should be primary, and there's an important role for episodes of subsidiaries. What I would

like to do, as much as possible, make the responsibility for administering the episode models that of the population-based systems. So my goal would be that I would like the population-based systems to receive a lot of the credit for steering -- you know, for those patients that need a procedure for an episode, give them credit for steering the episode to the more efficient specialists who are providing the episodes.

You know, I don't know if this involves actually having them even making the payments, incentive payments, to the clinicians or others, or not. There is a lot to think through if we want to go through this approach, and I haven't figured out all the answers yet.

But that's what I was going to say. Since I have a little more time, Jon had something about using evidence to decide which would be at episodes, and generally I support that, but to me the evidence should be more conceptual evidence, given what we know about medical practice, that Episode A would make sense and Episode B would not. I don't want to commit us to another five years of studying various kinds of episodes to decide which ones work out. I think it should be mostly conceptual, having

the potential for success. Thanks.

DR. CHERNEW: Lynn.

MS. BARR: Thank you. So Amol's point about, you know, when population health and bundles come together then it all gets better, right, and so, you know, the idea of bringing these two programs together I think is the right way to think about this. We want everybody in a pop-health model, and so tucking the bundles into that pop-health model makes the most sense to me. However, as everyone said, you know, you're cannibalizing your shared savings, and that makes it very complicated. But we want people to focus on these bundles, particularly the joint bundles. There's a ton of savings that we could generate if we could get them to do that.

So what I would propose is that in a harmonized model there is your population health model that has bonuses for higher performers in the population health models. So if you look across all of the participants in the Medicare Shared Savings Program and you say, look, if you do well in bundles you can get an additional payment. So maybe you hold back 5 to 10 percent of the Medicare savings that's generated from that and pull that, and say,

okay, high performers, and that gets people focused on the bundles. That's what we try to do. We give them bundles data. We want them to focus on bundles. That's really good for everyone. And so can we do that as an add-on bonus program that incentivizes them, because once you change the behavior you've monetized that forever, and that's really what we're trying to do.

MS. KELLEY: Okay. Amol.

DR. NAVATHE: Thank you. So I agree with much of what you've outlined, Mike, in that I agree with the idea that they can and should coexist. As Lynn points out, I think the evidence that we have to date supports it. I think there is evidence from a paper in JAMA Health Forum in August, that shows that there's additive benefits when you have a beneficiary who receives care under an ACO and a bundled payment model. And so I think, to some extent, there is some evidence for it.

And I also agree with Jon Perlin and Paul's points around sort of tractability of how you actually get carry design and the clinical suitability for it. So in that sense I think it does make sense to leave the population health models. I agree with Lynn's point that

it would be great if every beneficiary were aligned into some sort of population health model entity.

At the same time, I think we should recognize where each of the program types tend to insert most of their effects, or at least complementary wise. So population-based models, for example, have an outside impact on avoiding hospitalization. An area that we haven't seen any effect, because of the design probably, but nonetheless, in episodes.

So I think where we see episodes shine, if you will, relative to population-based models are specifically around specialty care. There's quite a bit of evidence that population health models have brought, at least in the early tracks at MSSP, engaged surgical care, for example, and other specialist, and the post-acute care incentives are just stronger and the results thus, magnitude-wise, have been stronger for episodes relative to population health models.

So I like the idea, Mike, that you're proposing in the framework, which is if you have, for example, a large health system that's either in a mandatory or voluntarily participating in a heavy downside risk pop-

health model, probably you don't need episodes there. They're probably large and sophisticated enough, they have downside risk, to over time get all the savings out there.

In the upside-only or lower downside risk type tracks, that's where there's likely to be less infrastructure, and that's where episodes like these have an important complementary place, focused in areas where again we see that the tractability is suitable, the clinical design, the way that people consume care is suitable to the episodic style of care. So I think there is a smaller role, in a targeted fashion, in those that may expand where you have less risk and less infrastructure.

I think Paul's point about steerage is really important. I would say it is premature to think about how we view the accounting of savings in some sense. But there's an important element of a population health-based entity which is basically trying to consume the most efficient episode possible. That steerage concept, I think, is a fundamentally important one to try to bring into this concept of coordination between ACO bundles.

So I'll stop there. Thank you for listening.

DR. CHERNEW: Amol, you hit three minutes

perfectly. Thank you. Dana, who is next?

MS. KELLEY: Jaewon.

DR. RYU: Yeah. A lot of what's been said. To me this strikes at -- it feels like an issue of heterogeneity, I think where you have population-based models with large entities, with large portions of risk at stake. I think that they do have, and I like that Amol framed it through the lens of infrastructure. I was going to say, where do you deploy resources? I think those entities have the ability to deploy resources, and they are already tackling this game, and the advantage is that they're doing so without the introduction of dilution or potential fragmentation by having an additional layer of programs.

On the flip side, though, to the extent you have some of these smaller groups or smaller levels of risk -- and earlier we talked about upside-only -- I don't think they have the level of resources or infrastructure to be able to tackle this area where there is ripe opportunity to be had.

And so ultimately that's what lands me at, I think the two programs do have to coexist in some way, but

I believe the population-based model should take primacy, and then the things that fall out or the things where there isn't a clear, you know, who's on first, who's got the ball, I think that's where the role of episodes can come into play.

DR. CHERNEW: Thank you, Jaewon.

MS. KELLEY: Okay. I have Larry next.

DR. CASALINO: Thanks. Thanks again. So, you know, I'll just start off by saying the more I think about it, the more I think that there's no place, or only a very narrow place, for episode-based payments, outside of population-based models, and the outside of population-based models is the key. You know, I think there could be exceptions for when population health models can't work, for whatever reason, and already a couple of people have mentioned one of those situations might be where there are organizations that are small, not taking much risk, might not have the infrastructure to really improve care in areas where episode-based models can.

The problem with that, though, is it's kind of a chicken-and-egg problem, in that to the extent that episode-based models are used, it provides no incentive

then for the physicians in hospitals that are involved in those models to join a population-based model, and that's exactly contrary to what we would like.

So I think when we talk about evidence, I think there is pretty good evidence that in certain types of episodes, as several people have said, there is benefit from a cost, and maybe quality, basis. But, you know, using the word "evidence," there's evidence for that but there's no evidence one way or the other about whether having episodes teach providers and hospitals who might otherwise be in population-based models out of those models. And to me that's an extremely important consideration, so we have to think about that.

The other reason I'm skeptical about widespread use of episodes is that I do believe that if there are episode-based models extensively and population-based models, it will be very complex to administer, very complex for providers and everyone else to understand. And you have to ask, is the gain worth the candle, or vice versa. All that complexity to gain what?

Several people have mentioned that episode-based models, they don't provide an incentive to limit the number

of episodes, and that could be a problem, and I agree with the model, that the evidence shows that so far this doesn't look like a problem in terms of the number of episodes being increased in episode-based models.

But I think it's important to note that if that's compared to the control groups -- so if the number of episodes, in general, is too high for certain kinds of joint replacement surgery, for example, if it's too high altogether, the fact that episode-based models don't increase it isn't that great a thing. Population-based models would have an incentive to decrease the kind of standard number of episodes, but episode-based models don't give an incentive to increase that.

And then in terms of Mike's second point in the straw man, what to do with low-risk tracks, how to assign the savings, you know, I think that's plausible, worth thinking more about. Again, it would disincent participation in high-risk population-based models that we want to see more of. And I think it might have, also, I think the possible unintended consequences of that second point would have to be thought through, because I can imagine some kind of complex behavioral effects.

That's it, Mike.

DR. CHERNEW: Thank you Larry. Dana?

MS. KELLEY: Jonathan Jaffery.

DR. JAFFERY: Thanks, Dana.

DR. CASALINO: Mike, I'm sorry. Just 20 more seconds. ACOs themselves might want to either administer, if they're paying, a way that would allow that, episodes internally. So I'm saying not so much a place for episodes outside of ACOs, but ACOs might choose, and this is complicated to think about. We'll talk about this, but ACOs might choose. That's it.

DR. CHERNEW: Okay. Thanks, Larry.

DR. JAFFERY: Okay. Thanks. So I'm in agreement with a lot of what has been said. I just want to add one or two comments related to the infrastructure point that Amol made, and that Jaewon sort of built on. I think there's a lot of truth to that.

You know, when we started in MSSP, and also around that time as a system we're participating in CJR, it was really my team's infrastructure that brought to bear things around that bundle. And while there were some improvements in savings around some of the efficiencies

during the hospital, as David won't be surprised to hear, basically we maxed out savings completely by shifting care from nursing homes to home health, and did it virtually overnight. And it was with a really small amount of infrastructure that my team brought.

And then when we entered Next Gen, in this two-sided, high-risk model, we dropped out of CJR at that point and it shifted from mandatory in our area to voluntary. We dropped out and presumably continue to reap some of the benefits of those changed patterns, post-surgical patterns, just as an ACO. So I think there is something to that.

I guess one of the questions about having the savings accrued to the episode initiator involuntary, you know, maybe does that -- I guess I'd have to think about that a little bit and wonder if there's some modeling we could do to see how much that might impact the potential savings. I mean, if that is some low-hanging fruit in some of these episodes and the ACO is not going to reap those benefits, then does that make them less likely to want to participate in that voluntary or is it just making their hurdle rate even greater? So I think that's worth thinking about a little bit.

And then one last thing I'll say, you know, it's a little bit maybe off this topic, in particular, but it gets to some of these bigger questions. And I think going back to this notion of do we have a vision that all Medicare beneficiaries will ultimately be in some value-based payment model, be that Medicare Advantage or an ACO, which I think I support, I think we want to think about how really do we get there. And one other piece that we've talked about in the past, that goes back to beneficiaries choosing to participate and beneficiaries choosing PCPs. So it's a little bit off-topic but I don't want to lose track of that, because I think that does feed into some of this broader picture of how we might get broader participation in value-based payment models. Thanks.

MS. KELLEY: Dana.

DR. CHERNEW: Thanks, Jonathan.

DR. SAFRAN: Thank you. So this has been a very interesting discussion, and it's, I think, heartening to see that there's a lot of agreement in this group about the kind of vision that the total cost of care models would be the prevailing model and where we would like to see all beneficiaries, or as many as possible, aligned to total

cost of care models. That would include Medicare Advantage, as, you know, I think Jonathan just pointed to, but then the question becomes how we design those ACO type models, and it gets us back to the discussion about the four features that the staff teed up for us.

I do, as I said in the previous round, like the idea of a parsimonious, mandatory episode set that fits in under there. I really like the point that I think it was Paul first made, and Pat underscored, about the idea that for those mandatory topics it could just become this is how Medicare pays for this area of care, period. So I think that's really good.

And then the final piece I would add is what I referenced, I would come back to, around voluntary. I really see, for other areas that are, you know, worthy of episodes but not meeting whatever criteria we ultimately set as being mandatory episodes, that CMS could play a role in defining these and then allowing ACO providers, you know, those who have taken total cost of care accountability, to use them as drivers of success in their results. And, you know, I think a couple of people have sort of pointed at this. I think Lynn, at least in the

chat, indicates that's part of how her organization helps groups be successful, is showing them the data on how they're doing on episodes.

So I think of them a little bit as analogous to how we talked about in the quality measurement space, little-dot and big-dot measures, right. So if total cost of care models are out big dot then episodes are the little dots, and we would expect those who have taken on big-dot accountability for total cost of care to need to use episodes as part of how they drive their success, both for monitoring how they're doing, for evidence-based referrals, and so forth.

So I do really like the idea of CMS playing a role in helping us standardize how those episodes are defined so that those who take on total cost of care can use them in that way.

That's all I had.

DR. CHERNEW: Thanks, Dana.

MS. KELLEY: David.

DR. GRABOWSKI: Great. Thanks. I'll be brief. I'm certain, Mike, I can bank my time for a future meeting, right?

DR. CHERNEW: Absolutely.

DR. GRABOWSKI: For the three questions you raised, first should we have both ACOs and episodes, absolutely. I believe we want these two models to coexist. I was a little worried today about the structure, that it was somewhat siloed and there would be an us-versus-them sort of mentality, but I think the discussion sort of shaped up to one where I think they can work in a complementary fashion. So I'm excited about this.

In terms of how extensive should the episodes be, your second question, Mike, I don't think we need an extensive number of episodes. As Dana just suggested, I like a small number of kind of mandatory episodes.

And then to your third question about my reactions to your coordination idea, I am supportive of how you outlined that. I like the idea of kind of the two models coexisting in that way.

So I'll stop there, Mike, and say I'm really excited about the way this discussion is proceeding, and I like the idea of both episodes and ACOs coexisting. Thanks.

MS. KELLEY: Betty.

DR. RAMBUR: Thank you. Just to pile on, I am very excited with the direction as well. I absolutely think that they can co-exist. The model, I think Pat used the term "tucked inside," so with bundles tucked inside, and as Dana and others have talked about, they're already accountable for the overall cost of care. So episodic specialty care outside of a population-based model, I'm supportive of empirical as well as conceptual evidence, as Paul brought up.

But I wanted to just close by underscoring what Jonathan had stated about that the transition for their episode was actually -- I think I'm paraphrasing it correctly -- relatively easy to undertake. And at sort of what I call the working surface, an episode is more manageable because it's by definition an episode. And it's across the continuum of care, which isn't something providers have to always think about, but is an important responsibility and opportunity.

So I'm very supportive of the idea where they co-exist and that there -- or those who are not in some sort of accountability for cost, there is sort of stand-alone bundles when the evidence makes sense for it.

Thank you.

MS. KELLEY: Okay. Bruce?

MR. PYENSON: Thank you. I want to use my three minutes to tell a story, and it's really pretty much a story in line with some of the -- a lot of what Larry said and others have said, and I'm calling this the five stages of grieving over risk. And if you kind of imagine a new program over the course -- the story runs out over 18 months. The first three months are getting ready for the launch of the new risk program. It could be a new insurance company. It could be an ACO. It could be a vendor who's taking risk for outcomes such as high-cost beneficiaries or lots of other things. And I've seen this unfold with dozens of organizations.

So there's a period before launch of enthusiasm and imagination. The launch comes, and the first several months -- three months, maybe even six months -- is also a lot of enthusiasm and a lot of hard work as the program gets launched and, you know, work is being delivered and care is being delivered. And during that period -- that's the second stage. The enthusiasm is a lot like the enthusiasm before launch.

The next six months -- the third stage -- results start to come in, and almost invariably those results are really good, and the enthusiasm just builds. The results look great. All the plans and all the thinking and replanning and everything else seems to have borne fruit. That's the third stage of almost people patting themselves on the back.

And then the fourth stage, and sometimes that happens as late as after the close of the financial year when the other accruals start to come in and what happened, very rosy financials turn south very fast. It could be, for example, that, oh, the ACO hadn't planned on the interaction with credit for the bundles, or just accrual accounting, that claims come in late where there's adjustments or CMS has made an adjustment for risk scores, something of that sort. So the fourth stage, depression, hits in.

Now, some organizations just by luck avoid that fourth stage. Actually, ultimately that's probably bad luck. But the financial results for the first year when the accrual is done almost invariably look worse than expected during the year. And then the fifth stage is an

organization either decides to keep going and realizes this is really hard and there's a lot of hard work that has to be done, or they shut down. But often the complaints come in that the program wasn't designed right or that it wasn't fair.

I wanted to use this story to say that, as Dana mentioned, the big dot is what happens to the totality and the whole program, and to not lose sight of that, and that we have to -- whatever we do, we have to make sure that we envision financial success or programmatic success as a whole and not get distracted by what's likely timing and data issues that are going to be blamed on episodes or blamed on some other program.

So that's my three minutes.

DR. CHERNEW: Great, yes, and, Bruce, I gave you a little bit because it turns out you are last. Is that right, Dana? At least last in Round 3. So what I'd like -

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MS. KELLEY: Wait, Mike. I'm sorry. I think Marge and Stacie are still on the list.

DR. CHERNEW: Yeah, so I think -- so per my comment, I think Marge and Stacie still want to give

comments, but just so folks know broadly, we are now in -- we have about 15 minutes left, and so people can -- if they want to make comments, I'm not -- I'm going to stop the timing. Marge and Stacie I think wanted to add some broader comments. I have some broader comments.

This has been -- I view it as an unbelievably productive and very focused discussion, and I imagine many people have comments that are on the cutting room floor. So if you want to say those comments briefly, appropriately, or if Geoff or Rachel want to add anything, we're going to do that. But I want to go to Marge and then Stacie because they haven't had a chance to jump in. Wayne, if you want to say anything, you're also obviously welcome. Marge?

MS. MARJORIE GINSBURG: Okay. Thank you. Very insightful, intriguing conversation. My comments have almost nothing to do with what everybody else has been talking about. I think most of you know my background and experiences around what the public as patients and as citizens think should be done on the broader topic of health care policy.

It came to mind, the model, I think it's of the

disabled community, nothing about me without me. So one question and then one comment. As I recall, a couple years ago I thought CMS was requiring that all physicians who were participating in ACO programs had to let their patients know that they were. And when I probed this further, it wasn't CMS that was going to let them; it was supposed to be the individual physician groups. I have no idea if that ever happened, so, one, I am curious what the obligation is to tell members of -- patients about the program they're in. So that was number one.

The second comment was just I would love to see some work done -- and I know we do focus groups and deliberative discussions as part of MedPAC's role -- of really bringing the citizen voice in on this. This is very technical. We can hardly understand what's going on. But at a higher level, it's not that complicated, and it seems to me we shouldn't lose sight of the fact that our obligation, MedPAC's obligation, is also to act what's in the best interest of patients and citizens.

So I just wanted to throw that out there, no need to comment on it now, but perhaps we need to bring their voice in on this topic as well. Thank you.

MS. KELLEY: Stacie.

DR. DUSETZINA: Thank you. I also have appreciated all of this conversation and generally agree. I wanted to make a couple of broad comments, maybe reacting to this great chapter that Rachel and Geoff put together. And thank you very much for this incredible work.

I think one thing that really kind of stands out as someone who is a bit more distanced from this is the desperate need to streamline some of the options and reduce overlap. But I appreciate how the conversation has kind of moved into a place of thinking about the population-based models over the episode-based models. I like the way of thinking about integrating those.

I guess the one other thing that maybe I haven't -- you know, there's that tension between mandatory and voluntary, and the chapter does a really great job of showing how challenging it has been to have savings when you give the example of the model that starts as mandatory and then allows for opting out and dropping out and how problematic that is. So I guess one maybe vote for ideas of allowing organizations to volunteer to come in, but make it much more difficult to opt out and drop out later on.

But, overall, this is really excellent work. I like where the discussion is going.

DR. CHERNEW: Stacie, thank you. I haven't seen more requests to speak, so I'm going to pause for a second to see if anyone wants to add anything. I know there are a few things that I know people think are important, and I will just say them now because they have not been dropped because they aren't important. It's just I really needed to focus this discussion in a way that I cannot tell you how happy it went. One of them is the integration of all of this with Medicare Advantage plans. It's a topic that I think is unbelievably important. Medicare Advantage plans are population-based payment models in many ways, and they have a lot of ways to do a lot of things. We spend a lot of time on MA. There are challenges with what we pay them, but I think how that works with this is very important in a bunch of ways that will make the benchmarks and stuff. No one mentioned -- and I want to say thank you; I explicitly asked you not to. I'm saying this mostly for the audience. No one mentioned the importance of multipayer models. They are very important. It's just hard for us to do everything all at once, so we will think through that. Understand

that as we go through this in a whole range of things, there's other very important issues. Equity will be one. But a slew of other issues that we're going to talk about a bit separately. We're going to talk about risk adjustment after lunch. We're going to talk about benchmarks in November. So there's a lot of broad other things to do.

In a moment I'm going to summarize where I think we were on this admittedly focused discussion, but before I do, I want to see if anyone else wants to say anything. We have about ten minutes left if someone wants to add a reaction to sort of a broader point on anything.

MS. KELLEY: Mike, I have Amol and Pat.

DR. CHERNEW: Okay. Amol, then Pat.

DR. NAVATHE: Great, thanks. I promise to be brief. So I loved the discussion. I think the vision of what we're talking about with population health models are absolute chassis for all APMs, and reform in the future makes a lot of sense. I think it's also important to recognize a couple things.

One, especially in the structure that we were talking about in the pop health world where we have maybe mandatory for large systems and then a series of voluntary,

we may not end up with 100 percent participation, 100 percent beneficiary alignment in the short run. So a question to think about there is if we're subsetting the episode discussion underneath when we have pop health models, then what about where we don't have pop health models? Do episodes have a role there? And at least observe that in what we've experienced over the last decade, providers have voted with their feet. Many who weren't part of ACOs still participated in episodes. And so potentially that's momentum to be mindful of.

The second point is I think there are reasons pop health models -- I think Pat has mentioned some of these -- are good gatekeepers or checks on episode models and can decrease the number of episodes where we wouldn't otherwise see. I think large organizations also have potential political economy challenges, to use an economist term. I've done some work with private insurers where we've designed ACO models and we've talked to health systems and ACOs, and I've had specific couple of conversations with cardiologists and oncologists who will go unnamed where they said, "Well, I'm not going to cut my revenue. I don't care if it's going to drive savings, because if I cut

revenue, then my department goes down. I lose docs. I lose medical assistants." And so there is -- you know, there's an important piece of, I think, how the sort of specificity in some sense, incisiveness of the way models and incentives work, we should be mindful of that as well.

The last point. When we think about voluntary participation, one thing that's important to recognize is this is agnostic to model type -- population health, ACO, episode-based, doesn't matter. You tend to get more participation in areas where beneficiaries are generally more affluent, and you get avoidance of these models or lack of participation in areas of safety net populations, populations that face social drives of health challenges. That creates inequity in access to the benefits of these models, and I think that's a really important piece that we should keep in mind as we think about voluntary models going forward.

Thank you. I'll stop there.

MS. KELLEY: Okay, Mike. Pat tells me she does not have a comment to make, so I think we're all done.

DR. CHERNEW: Oh, okay. All right then. So I will jump -- going once, going twice. I'm going to jump to

my -- going three times, and gone.

So I'm going to give a quick summary of what has been a really, really, I think, rich discussion. The first thing is I heard strong support for a sort of harmonized, multitrack ACO program where things kind of fit together and understand that the straw man was just a straw man. There are other types of things we're going to have to think about, like how we deal with the safety net things that you raised and what we do -- we might have different versions in rural or safety net. We have to think about that. The key point is they should be harmonized clearly, and I think there's a lot of support for the population-based models.

I think there was some acknowledgment that we like mandatory, but understand that not everything can be mandatory. So once we have those models, we have to decide what the incentives go across the tracks. We have to be careful along the way not to force people into things where they're obviously going to lose a lot of money. That will fit in, by the way, to the benchmark discussion. But I do think at least philosophically there was a lot of harmony in the population-based side.

I was worried about the harmony on the episode side, but, actually, it went really quite smoothly, in my view, in that there seems to be a sense that we should try and have as few episodes as possible -- as few episodes as possible within a condition. So we don't want three episodes for the same clinical condition. And we are going to have to think through how to harmonize that, and I think broadly speaking that matters. I think that discussion was useful, and we'll go back and look at some of those aspects of how episodes can work. And there was, as I thought there would be, a very rich discussion on the point of integrating, and as Pat kicked off and others said, we need to get the episodes in some sense -- I'm not sure what word you used, Pat, or others, but underneath -- someone else I think said this as well -- tucked in -- I'm sorry to the person who said that exact phrase. I can't remember now, but someone said that. I agree with that.

I will say -- I don't see Brian's camera on now. He may have stepped away for a second. But Brian used the phrase in a previous conversation with me "under the water line" where you have mechanisms whereby the system bearing population risk can build versions of their own episodes

and engage the people in their communities in ways that work for them because health care is, of course, local. And I think there's some merit for that.

I want to echo one point that I have worried a lot about and will come up in the future iterations of this, so this will not be the last version of this discussion. Larry probably said it most clearly, others may have said it, which is how the impact of putting a lot of episodes into the world influences participation in the population-based models as we begin to -- the word I sometimes use is "siphon" savings and where there's low-hanging fruit or not and how we build that out. That's going to require some attention. We don't have to have it all resolved now. We may end up in the chapter just giving advice to CMS to think about that carefully. So I think there's merit in raising the issues, even if we don't resolve all the issues. So that, I think, is useful.

I want to make one other closing point, and then I can tell the public how we would love to hear from them. My closing point is all of this population-based payment stuff is important. All of it is built on top of a fee-for-service chassis. Understand that we need to get the

fee-for-service system better. When we do all of the work we do on fee-for-service, it seems like it's separate from this. But because of the way these APMs work, we have to continue to strive to get fee-for-service better as well.

So that's what I heard. I hope that was reasonable. Jim, is there anything that you want to add to how this all went or, for that matter, Geoff or Rachel?

DR. MATHEWS: Yeah, I think this was an extremely constructive discussion, and we'll sort out, you know, the Commissioners' comments with respect to the three straw men, and, Mike, we'll talk next week about anything that needs to be reconciled going forward. But I think this was an extremely helpful discussion.

DR. CHERNEW: Yeah, and I think the evidence that you put in the chapter is going to be really helpful as we get down to a sort of broader -- narrower set of questions and see where we go.

So we are about to jump for our break, I think, if I have this right, and we're going to come back, I think -- again, I'm looking at your face, Jim -- at one o'clock, or maybe Dana will -- I think one o'clock is the time. But for the people who are listening, we understand that

virtual isn't always ideal for giving feedback, but we are very anxious to hear what you say. I think you can reach out to us, if I have this right, at meetingcomments@medpac.gov. Did I say that right, Jim? Send us a message, otherwise reach out. We do very much take the public nature of these meetings as important and want to get your feedback. So, again, please let us know your thinking.

With that said, at least for me, it has been a challenging morning. I apologize to all of you who I have cut off. I really did not mean to be a jerk. It is hard for me. I don't always do it as well or as graceful as I would like. Again, that's a shortcoming on my part. But I appreciate your patience. It was important that we got where we got to, and I'm happy with where that is. And so, again, thank you for your playing along.

For those of you that are wondering, the two sessions this afternoon on risk adjustment and wage indices, we'll follow the more normal Round 1 traditional MedPAC structure. So I will put my stopwatch away, and we will go with how that plays out.

Again, thank you all. We are off to lunch, and

we'll be back at 1:00. So thank you all.

[Whereupon, at 11:59 a.m., the meeting was recessed, to reconvene at 1:00 p.m. this same day.]

AFTERNOON SESSION

[1:02 p.m.]

DR. CHERNEW: Hello, everybody. Welcome back for our afternoon session.

We have two very important topics we're going to discuss today, a little bit technical. This first one, we're going to jump right in with Andy and Dan talking about Medicare Advantage risk adjustment; in fact, for that matter, risk adjustment more broadly.

But, Andy, take it away.

DR. JOHNSON: Thank you.

Good afternoon, everyone. The audience can download a PDF version of these slides in the handout section of the control panel on the right side of the screen.

In this presentation, Dan and I will discuss a potential modification to Medicare Advantage risk adjustment that improves the accuracy of the model by limiting the influence of outlier predictions.

I will start by discussing the risk adjustment model, how it is estimated, and the proposed modification to the model. Then Dan will walk through our analytic

results, explaining how the model's accuracy would be improved by the modification.

Medicare payments to MA plans are unique to each enrollee and are the product of two factors. The first is a base payment amount that is calculated for each plan. The second is a risk score, which is the ratio of a beneficiary's expected spending to average fee-for-service spending. A beneficiary with a risk score of 1.0 has expected spending equal to the average fee-for-service beneficiary.

Risk scores increase payment for beneficiaries who are expected to be more costly and decrease payment for beneficiaries expected to be less costly.

The risk model uses demographic information as well as certain medical conditions which are identified by diagnosis codes and grouped into hierarchical condition categories, or HCCs.

Each demographic and HCC component in the model has a coefficient that represents the expected cost associated with that component. A risk score for a beneficiary is the sum of the relevant coefficients for the beneficiary. In the rest of this presentation, we will

focus on how these coefficients are estimated.

To determine the size of each coefficient, CMS conducts a regression using fee-for-service data that essentially distributes a beneficiary's medical costs to the coefficients that are relevant for that beneficiary. The regression includes all fee-for-service beneficiaries. So each coefficient reflects the average fee-for-service cost associated with the model component.

To use risk scores for payment, the sum of the dollar-valued coefficients are divided by the average fee-for-service spending to create an index value.

For the modification we are discussing today, we are going to focus on coefficient values expressed in dollars.

Before we move on to the modification, slide 4 shows an example calculation of a beneficiary's predicted cost and the same beneficiary's risk score. I will start by discussing the middle column showing the dollar-value coefficients and the predicted cost.

This beneficiary has an expected cost of $3,579 based on her age, gender, community status, and lack of Medicaid benefits. These costs may be generated by

spending on conditions that are not included in the model.

The beneficiary has three identified health conditions, and each has a different expected cost. The sum of all the expected costs for this beneficiary is $14,357, which is the amount of annual Medicare spending that the model predicts for this beneficiary.

In the right column, each score coefficients is equal to the dollar coefficient divided by the average annual fee-for-service spending, which was about $10,588 in 2019. This beneficiary's risk score of 1.356 is equal to the predicted cost divided by the average annual fee-for-service spending.

The benefit of the modification we are discussing today is that it improves model accuracy. The purpose of risk adjustment is not to predict costs accurately for each beneficiary. Rather, risk adjustment strives to predict costs accurately on average for a group of people with similar attributes.

The demographic characteristics and HCCs included in the model have been selected, in large part, for their ability to predict medical costs.

However, no set of model components, based on

commonly observed information, can predict a majority of medical costs, leaving a large share cost variation that is unexplained by the risk adjustment model and allowing opportunities for improvement.

More accurate risk adjustment improves the accuracy of payments to MA plans, increases payment equity among plans, and counters incentives for favorable plan selection where plans may seek to attract and retain beneficiaries that contribute to plan profits and avoid beneficiaries that contribute to plan losses.

Since the CMS-HCC model was fully implemented in 2007, the model has been improved several times; for example by adding variables and stratifying populations.

One risk adjustment feature common in many health insurance markets is a system of reinsurance and repayments that redistribute the original premium payments to plans. However, in Medicare Advantage, cost data are insufficient to support such a system of financial transfers.

The modification to the model that we are considering today, developed by Tom McGuire, Sonja Schillo, and Richard van Kleef, seeks to improve the model's accuracy by limiting the influence of outliers when

estimating the model coefficients.

The method essentially simulates a system of reinsurance and repayments in the data used to estimate model coefficients.

To evaluate the modification, we consider metrics assessing the model's accuracy overall and for certain groups of beneficiaries.

There are five general steps to implement this method. First, model coefficients are estimated as usual for the current CMS-HCC model.

Second, using those coefficients, we predict costs for each beneficiary and calculate a prediction error that is the predicted cost for a beneficiary minus the beneficiary's actual cost.

Step 3 simulates reinsurance by applying a loss limit on actual costs for the beneficiaries with the largest underpredictions. When the prediction error is larger than the loss limit, we reduce the beneficiary's actual cost in the data by 80 percent of the difference, simulating reinsurance.

Step 4 simulates repayments by applying a gain limit on actual costs for beneficiaries with the largest

overpredictions. When the prediction error is larger than the gain limit, we increase the beneficiary's actual cost in the data, simulating repayment, until the gain limit is satisfied.

By adjusting the actual cost data in Steps 3 and 4, we generate a new data set were the fee-for-service costs have been redistributed to simulate reinsurance and repayments.

The fifth and final step is to use this new data set to estimate CMS-HCC model coefficients that would be used to calculate risk scores for paying MA plans.

Now I'll turn it over to Dan to discuss the specifics of our analysis and the results.

DR. ZABINSKI: Okay. As Andy mentioned, we started by estimating the standard CMS-HCC model in this sample of 10.2 million fee-for-service beneficiaries. A more detailed description of our method is in your paper.

We then use the estimated standard model to calculate predicted cost and prediction errors for each beneficiary on this analytic file. That is, we calculated underpredictions and overpredictions for each beneficiary.

A vital part of our analysis is identifying the

loss limit and the gain limit, which we used to calculate cost adjustments to simulate a system of reinsurance and repayment

Largely through trial and error, we used the prediction errors to determine the loss limit and the gain limit. We determined the loss limit so that the aggregate reduction in actual costs across all beneficiaries affected by the simulated reinsurance would equal 2 percent of total cost of all beneficiaries in the sample.

Similarly, we determined the gain limit so that the aggregate increase in actual costs, across all beneficiaries affected by the simulated repayments, would equal 2 percent of total costs.

The resulting loss limit was $106,500, and the resulting gain limit was $25,300.

We then used the loss limit and the gain limit to adjust actual costs for underprediction and overprediction outliers. If a beneficiary had an underprediction that was greater than the loss limit, we trimmed the beneficiary's costs by 80 percent of the difference between underprediction and the loss limit.

And if a beneficiary had an overprediction

greater than the gain limit, we augmented the beneficiary's costs by the difference between the overprediction and the gain limit.

In the end, the decrease in actual costs for the underpredictions offsets the increase in actual costs for the overpredictions. So the modification to the model is revenue neutral.

We then used the adjusted costs to re-estimate the CMS-HCC model, and we called the re-estimated model simply the "modified model."

Then we evaluated how well both the standard model and the modified model predict beneficiaries' costs using the two most common measures for evaluating risk adjustment models in the literature, the R squared and the predictive ratio. R squared tells us how well beneficiaries' costs predicted by a model match their actual costs.

This measure is always between zero and 1.0, and the closer to 1.0 the better. I want to emphasize that outliers that we deal with here in this analysis reduce a model's accuracy, which can result in lower R squared.

While the R squared evaluates a model for an

entire population, predictive ratios, or PRs, focus on beneficiary groups who have the same health characteristic, such as a medical condition or similar age.

We calculate the PR for a group as the cost predicted by the model for the group divided by the actual cost for the group. If a PR is less than 1.0, that indicates that the model predicts costs below actual costs for the group; that is, we have an underprediction for the group. And if a PR is greater than 1.0 for a group, that indicates that the model predicts costs greater than the actual costs for the group, and we have an overprediction.

We found that the modified model that limits the effects of outliers would improve how well beneficiaries' predicted costs match their actual costs.

The standard model had an R squared of 0.13 while the modified model had an R squared of 0.30, which is 127 percent increase. This tells us that the modified model explains 127 percent more of the variation in costs than the standard model, and this is consistent with findings from similar work by McGuire and colleagues.

In contrast to our results, the changes that CMS has made to the CMS-HCC model since 2007 increased the

model's R squared by a small amount from 0.11 to 0.13.

Improved accuracy under the modified model would reduce incentives for plans to use information about beneficiaries' costs to identify favorable risks.

We also found that the modified model would improve the predictions for beneficiaries who have the largest prediction errors.

We evaluated beneficiaries under the standard model who had the greatest 1 percent of underpredictions and the beneficiaries who had the 1 percent largest overpredictions.

Recall that earlier that we said that a PR less than 1.0 indicates underprediction, and a PR greater than 1.0 indicates overprediction.

We found that for both groups, the PR is closer to 1.0 under the modified model, indicating the PR improves. For beneficiaries who had the 1 percent largest underprediction, the predictive ratio improves by 100 percent, from 0.13 to 0.26.

Also, for beneficiaries who had the 1 percent largest overprediction, the PR improved by 28 percent under the modified model.

And by predicting costs more accurately for both the largest underpredictions and largest overpredictions, the modified model would reduce the probability that plans experience a substantial financial gain or loss.

So the conclusions that we've drawn from this analysis is that by limiting the influence of outliers, we could improve how well predicted costs and plan payments would match actual costs, which reduces incentives for plans to use beneficiaries' costs to identify favorable risks. Also, the extent of substantial underpredictions and overpredictions would be reduced so that plans would face less risk from substantial losses.

So, for today, in our discussion, we will address Commissioners' questions and concerns about the method and the content of our analysis. Then we will address the feedback that we receive and continue our analysis for future presentations and reports.

And, finally, we would like to discuss any issues or ideas for further improving risk adjustment in the future.

That concludes, and I'll turn it back to the Commission for discussion.

DR. CHERNEW: Okay. Dan, thank you. Andy, thank you.

We have a bit of a queue forming. So I'm going to turn it to Dana to run the queue.

MS. KELLEY: All right.

DR. CHERNEW: At some point, I may jump in with another point.

MS. KELLEY: Okay. I have Amol first with a Round 1 question.

DR. NAVATHE: Yes. I apologize in advance. I have a few Round 1 questions that, hopefully, truly will be Round 1 clarifications.

So my first question is, in the paper summary, it said that the language used is CMS standardizes a base rate. This is just for the regular HCC MA model, Medicare model. CMS standardizes the base rates using the health status of the national average beneficiary in fee-for-service Medicare. I'm just curious. Can you explain exactly how that's being standardized?

DR. JOHNSON: That is by dividing the predicted costs or output from the model by the average fee-for-service beneficiary's cost.

DR. NAVATHE: I see. So you take the service area, and you're basically adjusting for the difference between the prediction in that area versus the national average. Is that right?

DR. JOHNSON: There isn't an area-level adjustment. This is just to standardize all risk scores to the national average fee-for-service cost.

DR. NAVATHE: I see. Okay. All right. I may have to follow up with you offline on that, Andy.

DR. JOHNSON: Sure.

DR. CHERNEW: Amol?

DR. NAVATHE: Yes.

DR. CHERNEW: Amol, this may help you. They run a regression to get a predicted value. It's going to be in dollar units. Then they divided it by the national average spending, which is going to be basically the mean of the Y, and so you end up with a ratio that's going to be like 1.2.

DR. NAVATHE: Yeah. I got that part. I thought that there's a step in between that, that you're taking a prediction -- I may have misinterpreted. The prior sentence says units determine the plan's base rate using the plan's bid and county benchmarks for the plan service

area, and then it said it standardized the base rate. So that's --

DR. CHERNEW: I think what they meant was they just multiplied that base rate by the risk score, the way I described it.

Again, I don't mean to jump in, Andy and Dan, but I think that's what they mean by standardizing the base rate. They basically mean they multiply it by --

DR. NAVATHE: In other words, there's not an extra step. That's what I was confused about. That's okay.

My next question is --

DR. JOHNSON: The one additional piece is that the base rate is already standardized to a 1.0 risk score, and so they take their bid when the plans miss the bid, and it is already accounted for the difference in risk. So it's a bid for a 1.0 beneficiary, and the benchmark is also for a 1.0 beneficiary. So that base rate is set up to be for a 1.0 beneficiary, and then multiply that by an individual beneficiary's risk score.

DR. NAVATHE: Okay. Got it. Thank you.

The second question I have -- I'm trying to run

through these quickly -- the dependent variable that's used in the derivation of this, does it include all Medicare spending, including hospice?

DR. ZABINSKI: It might. I think hospice is excluded. That's correct.

DR. NAVATHE: Hospice is excluded. Okay.

And then the other question I had, when they're deriving this model, so again in the derivation model, how are beneficiaries who die treated? Are they excluded, or are they included?

DR. ZABINSKI: You mean beneficiaries who die -- okay. There's sort of two years to concern yourself with. There's the base year where you draw the beneficiary's conditions. Then there's the payment year. I think you're talking about the payment year when --

DR. NAVATHE: No. I'm talking about the derivation year.

DR. ZABINSKI: Well, in the estimation of the model -- and the CMS does this as well when they estimate the model -- we just use beneficiaries who were in Part A and Part B throughout the base year. They have a full year of diagnosis data to draw from.

DR. NAVATHE: I see. So decedents are excluded. So is it adjusted linearly then for partial enrollment in the performance year, the year that you're talking about?

DR. JOHNSON: Dan, I think it is weighted. Is that right? So a beneficiary has to make it all the way through the initial data collection year where the diagnoses come from, and then in the next year, if they die partway through the year that is the cost year or the year that they're predicting costs for, I think that beneficiary's influence in the estimation is weighted by the number of months they have.

DR. ZABINSKI: Right. What we did and what, again, CMS does is somebody dies halfway through the estimation year or the payment year. You divide their cost by the fraction of the year that they're in, and then in the regression, you weigh them by that fraction as well.

DR. NAVATHE: Okay.

DR. ZABINSKI: Basically, you annualize their cost, and then you weight them in the regression by the fraction of the year that they're in.

DR. NAVATHE: Got it. Okay.

Next question -- so this is my last general

question and then I have a couple of questions on specific stuff from the McGuire paper. So am I correct that all the HCCs have a coefficient that is greater than zero, and if that's correct then how is that being guaranteed?

DR. ZABINSKI: Well, once again we follow CMS's method always. If a variable has a negative coefficient it is not included in the model. It's just simply excluded. They throw it out and then they start over and re-estimate.

DR. NAVATHE: And each beneficiary -- so, for example, if you use another comorbidity score, like the Elixhauser comorbidity score, obesity has a negative coefficient in the Elixhauser model, so it's negatively correlated with in-hospital death, for example, in that example. So here if obesity were an HCC or a CC and it had a negative coefficient, then they would exclude it and then re-estimate the model?

DR. ZABINSKI: Yes, but I don't know if this makes you feel better. It actually has a positive coefficient, so it's included.

DR. NAVATHE: Okay. Right. Oh, the obesity specifically, but just using it as an -- okay.

DR. ZABINSKI: Right.

DR. JOHNSON: And each beneficiary has a coefficient on their age and gender category, and all of those coefficients are positive. So the lowest coefficient would be the lowest age and gender, no HCC in the score.

DR. NAVATHE: Right. Okay. Thanks, Andy, for that clarification.

On Slide 7, if it's possible to go there, I was curious, this is using the methodology. The point was made -- I'm sorry, maybe it's the -- yeah, so in Step 3 and Step 4 here, you're saying you're applying the loss to individuals with the most underpredicted costs and the most overpredicted costs to get to that aggregate of 2 percent. How is that happening? I think in the paper it refers to an iterative process, but hypothetically speaking you could start with the most extreme individuals and correct them fully, or you could correct them partially. So is there a particular methodology that's being used to arrive at what that individual correction looks like?

DR. ZABINSKI: Let's see. I'm a little confused by the question.

DR. NAVATHE: My question basically is, what is the algorithm that was used? What was the methodology that

was used to allocate the 2 percent adjustment to individuals?

DR. ZABINSKI: I see. Okay. Well, we determined ahead of time -- we could have chosen any percentage we wanted, but we chose 2 percent of the adjustment for the overpredictions and 2 percent of the adjustment for the underpredictions. You know, that's just what we decided on. And it was just a lot of it a trial-and-error method. We just tried to identify a limit. You know, we just ordered the data from the largest overpredictions to the smallest and just made an initial guess, you know, where a 2 percent aggregate would be, and if that didn't go we tried a different line. And we were able to narrow it down, through trial and error, to determine basically what we called the loss limit, you know, the limit beyond which, you know, costs are adjusted.

You know, so it was a trial-and-error method. I'm not sure if this is answering your question or not.

DR. NAVATHE: So, in other words, if I'm understanding what you're saying, in fact, if you go to Slide 8, the reason that we end up with a higher threshold for overpredictions than underpredictions is because the

distribution is skewed and it basically is different for overpredictions. It's higher for overpredictions because you have a lot more overprediction on the extreme end. And so there is a smaller number of individuals who have overpredictions that were actually applied this correction for.

DR. ZABINSKI: Correct.

DR. NAVATHE: Am I correct? Am I understanding that correctly? And so we're trying to evenly distribute above a particular cap as a way to sort of operationalize this adjustment, as opposed to having some sort of -- you could imagine, to optimize R squared, that we could actually have a different way that we might try to do this, but we're trying to keep it simple, I guess in the context of this reinsurance frame. Correct?

DR. ZABINSKI: That's correct.

DR. NAVATHE: Okay. Those are all my questions. Thank you for putting up with me.

DR. CHERNEW: Dana?

MS. KELLEY: Paul is next.

DR. PAUL GINSBURG: Thanks. This is a really fascinating idea that you've brought up, and we should

really work on it because I think the potential is very large.

And I have two questions. One is that, you know, as you imagined in response to Amol, you know, that 2 percent was, you know, kind of -- that's the number you worked with. Any thoughts about whether, you know, what would be the effect of going to a smaller versus a larger number, as far as desirable or undesirable outcomes?

DR. ZABINSKI: Not at this point. You know, I guess we chose 2 percent because that's what McGuire did in their analysis. But, you know, 1 percent might be better. I don't know. I haven't really considered that. I'm not sure if Andy has. We haven't talked about it.

DR. JOHNSON: We haven't talked about it. I think the best way to go about it would be to simulate those other sizes of the redistribution, like maybe 1 percent and 3 percent, and see what the effect is on the accuracy of the statistics.

DR. PAUL GINSBURG: Good. There's certainly --

DR. CHERNEW: I think --

DR. PAUL GINSBURG: Go ahead.

DR. CHERNEW: Yeah, exactly. I think the key

thing here is we can do a lot once we sort of outline what is basically going on, and that can come up much later when we see it. I think the broader point is to give people a sense of what this sort of technical adjustment is, and I think as we go through the Round 1 questions I fear we are going to see some more questions about trying to figure out, along Amol's line, what actually happened and why. But I might be wrong.

Is that okay, Paul?

DR. PAUL GINSBURG: Yeah. Yeah, that's okay.

The other question I have was as far as, you know, obviously to implement this you would need to be collecting cost data from MA plans, that is not done today. Could you comment on how challenging that would be, what would be involved?

DR. JOHNSON: So the way that we are thinking of implementing it would not be using the MA cost data. It would be just sticking with the current configuration, where the fee-for-service data is the basis for calibrating the coefficients. And so this adjustment would be used as long as the fee-for-service data is the basis for the risk model. I guess there would be a different consideration as

to what the effect would be under an MA cost-based risk model, but that's not something we've talked much about. Dan?

DR. ZABINSKI: No more to add.

DR. PAUL GINSBURG: Okay. Thanks.

MS. KELLEY: Okay. I have Bruce next.

MR. PYENSON: Thank you very much. This is really terrific work, Dan and Andy, and I thought it was very clearly laid out, a very complicated process. I've got a couple of basic questions.

In the paper you describe that you have not assumed transactions outside, such as reinsurance. I think that's what you said. And you discussed how you've redistributed, if you will, the claims that you took out, sort of spread them back into the mix. So, of course, the coefficients change.

First off, did I get that right, because I was confused about that this was not going to affect payment transactions outside risk adjustment.

DR. JOHNSON: That's correct. This would be another step. Each time CMS calibrates the model using the fee-for-service data this would be an additional step they

do during that process.

MR. PYENSON: So that's the advantage of, you're not setting up a reinsurance program which has, you know, a whole nother set of complexity.

Now about 15 percent of beneficiaries, non-duals, at least, don't have any claims in a year, to Amol's point. So a lot more of that spreading in terms of people would come from probably those people who are all outliers, low outliers as you defined it.

So what I think that means, you know, it's hard to know how coefficients get readjusted in multiple regression, but I suspect that this puts more weight into the demographic factors and the eligibility factors, but I could be wrong. Did that happen? Did those coefficients go up?

DR. ZABINSKI: Yes, they did, some. It wasn't huge but yeah, they went up.

MR. PYENSON: Okay. So that sort of picked up the extra amount, so thank you. Those were my methodological questions.

MS. KELLEY: All right. I have David next.

DR. GRABOWSKI: Great. Thanks. I'm also very

excited about this technical adjustment. I'm glad we're pursuing this work.

I had a question, and I don't know if this falls into the bucket. Mike just wanted to cut off of Paul's, so, Mike, if this is inappropriate. But I was just trying to think through this of like where the under- and overpayments and types of beneficiaries -- and I know, as Bruce was just saying, some of the demographics goes, you know, race, ethnicity, area factors like urban and rural. Did you push it all on this to sort of think about kind of stepping back other characteristics, if that makes sense?

DR. ZABINSKI: Not for this specific analysis. We are, to some degree, considering some sort of area deprivation, perhaps, and how that fits with risk adjustment, but that's still in the planning stages.

DR. JOHNSON: David, just to understand, is what you're talking about like an impact analysis about how the changes would show up among different areas or different types of beneficiaries? We haven't done that yet.

DR. GRABOWSKI: Right.

MS. KELLEY: Larry.

DR. CASALINO: Yeah, just an echo, really. I

think this is very interesting work, laid out very clearly. I really appreciated it, and I think it's going to lead to some good things. And I would just echo Paul and, I think, Amol, in suggesting some, I just call them sensitivity analyses -- what happens if you simulate insurance at 3 percent or 1 percent, for example. That's all I have to say.

MS. KELLEY: Pat.

MS. WANG: Thank you. So great effort and initiative and goal to improve the accuracy of risk adjustment.

The thing I guess I wanted to ask, because the way that I think I understand this is that you kind of used the current CMS model, and this was, I'll call it the tweak. It's more than a tweak, but this was the thing that was different. You didn't change other elements of the model that CMS currently uses? Okay.

You know, I don't know, but my understanding is that risk scores today are based on 2014 diagnosis codes and 2015 fee-for-service costs. The diagnosis codes were derived from ICD-9. They've been crosswalked sort of mechanically, I guess, to ICD-10. But I just wondered

whether, in the effort to improve the accuracy of the system you considered whether or not that basic construct, 2014 costs and crosswalked with 2015 -- excuse me, reverse, ICD-9 to ICD-10, was actually, whether there might be potential in updating some of those elements of the current model that could push accuracy before you applied this additional step.

DR. JOHNSON: I think that's right, and I'm not sure. Initially I thought that they might be waiting until a year in which they didn't have to use any data related to 2015, which is the year that they switched from ICD-9 to ICD-10 codes, but they could use much more recent data where all of the diagnostic data collection year is based on ICD-10 codes and the cost information is also based on ICD-10 codes and related claims.

We hadn't talked about that in this context, but I think you're right, that updating the model for more recent data. And Dan can correct me, we used data that aligns with the 2019 risk scores, so we used 2018 diagnoses and 2019 costs in our analysis.

MS. WANG: How interesting. So if this methodology or construct were adopted by CMS, they would be

applying it, at least under the current construct, to a completely different cost basis and HCC mapping.

DR. JOHNSON: I think the two methodological decisions are separate. So I would not suggest that they do that, but theoretically they could continue to use the same 2014-2015 data with the method we're describing today. They could also use updated data without the method we're describing today, or they could do both. I would guess that doing both would be the biggest improvement in accuracy for the model.

MS. WANG: Okay. That, it seems to me -- this is a Round 2 comment -- that seems to me an important thing to include in any potential recommendation.

The other question I had, and this is around the 2 percent, and you answered the question about how you came up with 2 percent, I just wonder, does it make sense or is there a place in looking at outliers to look at sort of how duals, full duals, and also partial duals and non-duals sort of distribute in that outlier scheme? This is the aggregate, I understand, but I just wonder whether there is more to be gleaned about when you isolate those populations, because you know, they would certainly be on

the higher end, I guess, on the outlier, of utilization. But I just wondered whether you thought there could be value in looking at them separately, to understand how they fit into this.

DR. ZABINSKI: Well, the way CMS has set up the CMS HCC risk adjustment, they have separate models for, you know, partial duals, full duals, and non-duals, and we're looking at a non-dual population, because that's the biggest population of all seven models that CMS uses.

So you apply this to the existing models that CMS uses. You know, there's not sort of a distribution of duals, because you're going to be looking at either all duals or no duals in your file that you're analyzing. So within the context of the way risk adjustment is done right now it's not something you could do.

MS. WANG: Okay. You know, I don't understand the methodological things here, but I think, Dan, you said you couldn't do it. But if there were a way to do it, maybe the 2 percent turns into 4 percent, or maybe it turns into 1/2 percent. I don't know. There might be a very different pattern when you looked at duals, full duals, separately, partial duals. I think that those are two

important populations.

DR. JOHNSON: Technically, I think, you know, in the CMS models there's -- what? -- six community models: aged and disabled and then divided by non-partial and full duals. So, effectively, you could take each of those six populations and do a -- make the adjustments to their cost data for each of those six models separately, and so that it wouldn't be as though you are taking a whole population, cutting off a certain type or a set of beneficiaries that would only affect a certain model and not affect the other models. I think that would be something we could do. And to be clear, Dan, I think the way we did it, we only looked at the one population or one model, so we wouldn't have cut off a certain type of beneficiary or, you know, to put it differently, the redistributions for reinsurance repayments weren't disproportionately among one type of beneficiary, because we already were starting with just the one type of beneficiary for the model we looked at.

MS. WANG: All right. Thank you.

DR. CHERNEW: So I think now we're ready to go to Round 2. Is that right?

MS. KELLEY: Yes.

DR. CHERNEW: Okay.

MS. KELLEY: Brian is first.

DR. DeBUSK: First of all, Dan and Andy, absolutely loved the chapter, and I hope you're going to have a really positive experience from this presentation overall. The work's greatly appreciated, and I hope we pursue this area more.

I think this is a really novel approach that you guys did in the paper, particularly the way you iteratively backed into the stop and reinsurance limits. I think that was -- or the repayment and reinsurance limits. I think that was really, really clever. And, in general, I was really, really excited to see more nonlinear thinking in how these models are fit and how these models are designed anyway, because I suspect that the companies -- the MA plans aren't using or restricting themselves to linear models for sure. So, again, I was really, really excited to see you guys move in that direction.

I did want to mention, if I'm reading the chapter correctly, your approach would require some type of settle-up from the MA company, because by de-emphasizing the outliers, obviously you're going to fit the middle much

better -- again, which I think is clever, novel, and really a good thing. But walking those caps down would actually make the value of either selecting an underspender or avoid an overspender more valuable.

So, again, I think adding settle-up -- and I think that's what Paul was asking about when he was asking about the limits and how we would deal with people on the ends.

The other thing in this topic that I want to mention, the McGuire paper talks about measuring persistence. I'm really excited to see that look at these persistent beneficiaries that either overspend or underspend year after year. And I hope that we'll do some more work there, too, because I think the real benefit of favorable selection or favorable avoidance -- because, again, it cuts both ways. I think the real benefit there is when plans can identify those persistent enrollees or persistent beneficiaries, because those are the ones, even if the HCC model overall is a reasonably good fit, if they don't qualify in your outlier area, those persistent beneficiaries are an ongoing source of consistent underspending or overspending, because, again, as you guys

mentioned in the paper, the HCC model itself doesn't try to pick per beneficiary spending. It's really trying to do average spending for a group that's within a general category of clinical conditions. You have to realize that this isn't really random. There is a correlation from beneficiary to beneficiary and from year to year.

But, again, love the work and really like what you guys are doing. Thank you.

DR. JOHNSON: Thanks, Brian. I just wanted to say to the first part of your comment, we're not saying that there would be a settle-up in an actual payment transfer, that these adjustments would be made to the risk adjustment models that the initial payments to the plans would go out with the simulated reinsurance and repayment incorporated into them. Does that make sense with what you're saying? I may have misunderstood.

DR. DeBUSK: It makes sense, but, for example, if you're going to have a model that focuses more on the mainstream beneficiaries, for example, that's less sensitive to the outliers, it would -- presumably it wouldn't fit the outliers as well as it would fit the mainstream -- or are you saying that by not trying to fit

the outliers, you actually got a better fit of the outliers?

DR. JOHNSON: I got it. So I think you're not talking about an actual financial transfer and a settle-up, but the distribution of outliers.

DR. DeBUSK: Yes.

DR. JOHNSON: I think it's possible that at the very tails, by de-emphasizing the importance of the outliers in the model calibration, that when it predicts those outliers, that there are some beneficiaries at the extreme tails that would actually have worse predictions overall. But I think, you know, the overall finding is that the improvement in accuracy across the entire distribution net of those potential worse predictions is a significant improvement. And so to the effect that those small -- and I think it has a pretty small share of beneficiaries who might have a worse prediction under the modification mainly because advanced numbers of the smallest 1 percent -- the top 1 percent and bottom 1 percent, on average the accuracy of that group improves. So it would have to be a small share of that 1 percent at the top and the bottom that would be --

DR. DeBUSK: Yeah, we're saying the same thing. Again, I totally -- the McGuire paper, for example, when they plotted those residuals, they only looked at the top 1 percent and the bottom 1 percent, but they didn't -- it isn't obvious the first time you read the paper that the 6 to 55 range -- or, no -- yeah, I think the 6 to 95 range was actually compressed into the center of that graph. But, again, it will make those people in that extreme 1 percent -- it will make the overprediction worse and the underprediction worse. But I'll send you some things offline.

Again, love the work, love the paper. I'm a big fan. Thank you.

DR. CHERNEW: Yeah, so let me just jump in and say one thing as we're about to get more comments. This issue of the extent to which there is or is not a reinsurance transfer and what that means for selection incentives will be, I think, the next step we have to take through in doing this. So that's just a general statement of where we are.

The McGuire paper was actually designed for exchanges where there was separate reinsurance payments

going on. So this is the same idea but applied in a different setting with different institutional constraints. I think that's basically right, Andy. And we will continue to discuss the ramifications of that as we go through, but, Brian, as an aside, I think your points were spot-on. Thank you.

Dana?

MS. KELLEY: I have Lynn next.

MS. BARR: I just want to support this work. Thank you very much. I'm very supportive of the direction you're going and look forward to reading more about this.

Thank you.

MS. KELLEY: Bruce?

MR. PYENSON: Thank you. Just a note since I'm older than almost everyone else here that the risk adjustment within CMS has a long legacy, actually the HCCs do. And when risk adjustment was first being developed, computing power wasn't what it is today. And the use of least squares regression tends to emphasize outliers, especially the high outliers. And I think very similar results would happen with just using absolute value regression which now is much easier to do.

But that legacy of HCCs and the orthodoxy of risk adjustment as it was defined in, I think, the 1990s was supposed to be purely using diagnosis codes in order to keep providers from, you know, having an incentive to use more inexpensive kinds of treatment. So it was supposed to be pure with diagnosis codes.

Now, the weakness of the HCCs has led to a whole plethora of private risk adjustment methodologies, and the Society of Actuaries has a competition every so often on which one is better in a variety of ways. Now, what works much better than diagnosis-based risk adjustment is claims-based risk adjustment. Claims are a much, much better predictor of future costs than diagnoses are. Well, what that means is it's fairly easy for an organization that has access to someone's claims to compare their actual claims prediction for the next year to what the HCCs would be -- in other words, what the revenue would be. And Lynn has alluded to organizations that profile providers to find who do you want to invite into your ACO, because their actual costs are going to be less than their risk-adjusted costs. And certainly that capability is not lost on Medicare Advantage plans. And I'd suggest the interested enrollment

brokers might be associated with that by the MA plans.

So where does that leave me? I think the concern, at least from the MA plan perspective, is whether the new model will actually make it -- make selection more attractive, and, you know, it's hard to say. There's lots and lots of moving parts. But at least for the care avoiders or the very low-cost beneficiaries, I think the answer is yes. But, anyway, I think that's something we have to be concerned about.

I'll remind folks that I thought there was excellent work done by the Commission maybe six years ago on the value of using two years of data instead of one year of data in risk adjustment. And I'd really like to see that brought back into the discussion so that the work we're doing here, which I think is superb, is compared to that prior work.

But thank you. Again, terrific work.

DR. JOHNSON: Bruce, can I ask one follow-up question? Concerning what you said about the potential for selection to be more attractive, is that driven primarily by the beneficiaries -- I think you mentioned this in Round 1 -- who have had zero claims but for the plan would still

receive an age- and gender-based, you know, positive payment for that -- is that the part of --

MR. PYENSON: That occurs to me, but there's other, you know -- and this is where you have to see the numbers. You know, lots of people have hypertension, and lots of people have hyperlipidemia, and maybe outliers aren't so important, an important influence on those factors either. So it's -- you know, you think about things --

DR. CHERNEW: Can I jump in, Bruce? I'm sorry to interrupt. Andy, what I think Bruce is saying -- and, again, I'm sorry to interrupt, but I think the key is the gap between the new predicted risk score, and let's assume that doesn't change the actual spending at all, so what does the new predicted risk score look like relative to the actual spending? And if this new method makes that bigger, it becomes more advantageous to select those people if it's positive and less advantageous to select them if it's negative. And so this is really what Brian said, so I'm looking at you, Brian. Essentially by flattening this out by sitting in the middle, you may be having effects in the tails, the low end and the upper end, which incents

selection in varying ways. The way that the McGuire paper would deal with that would be having risk transfers at the upper and the bottom end, which would then negate that. But without those risk transfers, then there's the concern about what selection is.

Now, I may not have said what Bruce was trying to so, so, Bruce, again, you're small on my screen. I'm sorry if I can't see. And, Brian, I may have misquoted you, so I'm also sorry for that. But that's my understanding of the substance here. Brian's giving me a thumbs up. Bruce is giving me -- this is like the best day I've ever had. I got a thumbs up from Brian and Bruce. Thank you, everybody, for the meetingcomments@medpac.gov. Time to go on. Sorry. This actually will probably never happen again.

But since I got the two thumbs up, maybe if you're okay with that, Andy, we can go on. If not, please keep asking.

DR. JOHNSON: That makes sense. I think the one point I would make again is that the average of the 1 percent bottom and 1 percent top was still an improvement in accuracy so that the ne predicted estimates were closer

to the actual than the old predicted estimates. So it could be that there are some tails, but I think those tails are a fraction of a 1 percent such that the average across the 1 percent is still an improvement in accuracy. I understand the points. Thank you for clarifying.

MS. KELLEY: I have Amol next.

DR. NAVATHE: Thank you. So fascinating work. Congratulations for taking us in this direction. I think it's really terrific, and I'm highly, highly supportive.

I think these questions that have come up regarding selection and coding and other things are all very important, and it strikes me that, if nothing else, it might be good to look at simulations of how even historical fee-for-service spending has looked over the past, whatever, 10 or 12 years if we could, to see if we can generate any situations that actually look materially different from one another, because I think the answer -- as I understand it, the answers to the questions that Brian, Bruce, and Mike are discussing around, you know, what is the value of selection separately, what is the value in the sense of the coding, they're empirical questions, right? You can look at where the predictions

are. To Andy's point, we can identify individuals for whom the predictions are getting better versus getting worse, and we can quantify the value of those. So I think actually it's an empirical question we should try and look perhaps at various different samples or, you know, we can do random samples, we can do historical samples, something would certainly help.

I think the other point which overlies with that to some extent is it seems to me -- and Mike's comment earlier was very helpful, but it seems to me that, if nothing else, an application that we're looking at here is one where there aren't necessarily risk transfers; there aren't transfers between low and high risk. And so, hypothetically speaking, this could work in the fee-for-service system. This could work in the context of APMs like the ACOs which are using the HCCs as a risk-adjusting mechanism, where reinsurance is probably not as practical as I understand it.

And so if that's the case, I think we should also look at what the impacts are there, a la my earlier point around simulations. I think Larry mentioned one dimension of sensitivity analysis. What if we changed it to 1

percent? What about 5 percent, 3 percent? My question is: What if we look at different settings, different samples of populations, as well as in the context of ACOs where we can't have transfer and the like?

I will say that, generally speaking, my understanding of the data is similar to what Andy described, I think in the last comment, which is that if you look at the predicted ratios that result across the distribution, it does look like the center of the distribution is pretty similar in the quality of prediction and the tails, particularly the high end of the tails, high spenders, the predictions are actually better there. And so that should help to some extent.

One thing that's important to recognize, I think -- and I'm open to -- other people like Bruce, Andy, others, your comments backed on this -- is when we see the R squared go up, when we see the predictive power of this go up, that means there is inherently greater power in the observables, meaning the HCCs here, the codes that we're putting on, the diagnosis codes, to predict spending. And so to some extent that does emphasize those observables more because we're explaining more variation in spending

than we were previously. So I think it could be a mistake to overanchor on that point and say, oh, my gosh, this is going to make coding really important and it's going to, you know, cause huge distortions, relative to the point that overall the predictive power of the risk adjustment model is getting better, so we're getting better risk adjustments.

So there may be some trade-offs to outline, but I think we should also be careful that we're not so hunting for the problem of the unintended consequence that we forget the large benefit we could get from the, quote, intended consequence or intended benefit.

So hopefully that's helpful. Thanks.

MS. KELLEY: Pat?

MS. WANG: Thank you.

And, Amol, just picking up where you left off, I really agree with you. I think the fear around selection -- I don't know how people do that exactly to the level of laser focus that people fear and imagine. The goal really should be get the risk adjustment right. We'll worry about bad behavior or what have you separately.

I appreciate the clarification around risk

transfers, et cetera, because, Andy, the way you and Dan explained it is you're kind of doing it inside of the model to change the ultimate weighting and risk scores. Just to endorse, from my perspective, after the fact, risk transfers occurs at the exchange for ACA plans is really not a desirable way to run a railroad. It's after you've incurred all the costs, and you either get a bill or you get a check, and you have no idea why. So trying to build it into the risk-adjusted model up front so that you're getting the appropriate amount of money is really a great goal.

I do recommend that as we continue this work, which I think it's great to keep pursuing this work, that we take -- I am worried about the mismatch in the current models and the age of the cost year. I mean, you know, 2014 was a really long time ago. I'm worried about -- and I don't know. You know, we've gone through a pandemic. We're still in a pandemic. Isn't that relevant to perhaps change some of the outputs of the model? It just seems like it's important to keep the cost base updated, and I certainly appreciate what you guys did, that you used actual ICD-10 coding as opposed to some kind of mechanical

crosswalk. So I think it's important in the future work is to kind of like emphasize that so that a more refined model is not imposed on very old data.

I do appreciate also and hope that we will have an opportunity to look at how this phenomenon plays out for the subsets of full duals and partial duals. I think that's really important.

One of the questions that I didn't ask is, is it implicit since outliers are by definition outliers -- I may not have understood this properly -- that they may fluctuate more because they are at the tails, that they may fluctuate more? I mean, I don't know the answer to this question, whether this is an analysis that needs to be run every year on updated information or whether it's static.

The final thing is a little bit off the topic, but I hope that we always look for opportunities to apply these refinements in risk adjustment to Part D risk adjustment. We haven't really talked that much about it, but I think that in part D, folks have observed that the current risk models, which do use their own version of HCCs, I guess, are really pretty good about predicting cost to a certain point, but then the scatter plot is enormous

in terms of actual costs and predicted costs. So I'm hoping that any lessons that we glean from the good work that you guys are doing, that we think about applicability to improving risk adjustment in Part D as well.

Thank you.

MS. KELLEY: Dana?

DR. SAFRAN: Yeah. Very, very brief. Just offering my support, strong support for this work. It's really very sound and exciting to see when you can improve the models in the way that these have.

I loved the context that you offered for what previous improvements to the models have accomplished as opposed to what these do.

The only other thing I'd say is by way of a tie back to our morning conversation about progress toward advanced payment models. This work is so critical toward getting that work to be successful, and I know here, we're talking about MA, but I suspect the risk adjustment methodological advances that you've got here will work just as importantly there and are such an important safeguard against selection issues. So thank you very much for this work, and I really appreciate the conversation.

DR. CHERNEW: Dana, was Dana last?

MS. KELLEY: Yes, she was.

DR. CHERNEW: Great. That was a really, really good discussion, and I am really thrilled with how well people dug into what is a very technical set of issues. So, starting from Brian's comments, some of which he had sent me earlier, I think he was spot on in understanding the nuances of what's going on here, and the issues between fit and selection incentives and those things, it was really a very, very good discussion.

So I take several things away from this. One is there's a lot of enthusiasm to keep going. There's a lot of enthusiasm to do simulation. There's a lot of enthusiasm about how to both take these ideas and broaden them to other programs or tweak them in various types of parameters, and I think all of that is very well taken.

I think we recognize the importance of risk adjustment writ large.

Again, there's sort of how well we're distributing the money across the organization, be they MA plans or ACOs, and then concerns about coding overall and what the coding incentives are and then concerns about

selection within or not between programs.

So I think that really is a pretty good list of things to worry about, emphasizing as we move towards more population models of which MA is a type of population model, we really have to think about this risk adjustment.

Andy and Dan, you really did a remarkably good job, so thank you. Take the compliments you were given to heart, and we will continue to see where we go next with this. But I really did appreciate it and the engagement.

Anyone else want to say something for a minute? Andy? Dan?

[No response.]

DR. CHERNEW: Okay. We are then going to move to our last session, another really important topic, and I am excited to -- maybe horrified -- excited to hear this presentation. So I guess we're going to start with Alison to talk about the hospital wage index, a topic of continuing importance.

So, Alison?

MS. BINSKOWSKI: Actually, you're going to be starting with Bhavya.

MS. SUKHAVASI: Good afternoon.

The audience can download a PDF version of these slides in the handout section of the control panel on the right side of the screen.

The role in the Medicare hospital wage index is to adjust national base payment rates in the inpatient and other prospective payment systems for differences in wage rates across geographic areas.

In 2007, the Commission recommended an alternative method to compute the wage index that would address specific issues of concern.

Since the Commission's work in 2007, Congress and CMS have added additional adjustments to the already byzantine IPPS wage index, and more hospitals have received existing adjustments. As a result, the share of hospitals receiving at least one special wage index adjustment increased from about 40 percent in 2007 to 67 percent in fiscal year 2022.

Given that the wage index problems the Commission identified in 2007 have been exacerbated, it is an opportune time to revisit the topic and solicit the Commission's interest in updating MedPAC's 2007 work. As a first step, this presentation provides a background on the

mechanics of the hospital wage index and the Commission's concerns.

To calculate each hospital's wage index, CMS collects cost report data on hospitals' wages and hours, aggregates this data across all hospitals in all geographic labor market areas and nationally, calculates an unadjusted wage index for each labor market area as the area's average hourly wage relative to the national average hourly wage, and finally applies numerous wage index adjustments.

CMS uses the same underlying hospital data and approach, though generally with fewer adjustments, to create the wage indices used to adjust base payment rates in other prospective payment systems, such as those for post-acute care providers. Due to time constraints, this presentation will focus on the version of the wage index used in the IPPS.

First, CMS collects wage data from all IPPS-eligible hospitals' cost reports. In fiscal year 2022, CMS calculated the wage index based on wage data from about 3,180 hospitals' cost reports.

Included wage data are salaries and wage-related costs, such as pension and other deferred compensation

costs, of staff providing IPPS services. Wage data from staff providing services in other components of the hospital or reimbursed outside of IPPS are excluded from wage index calculations.

CMS defines geographic labor market areas for the wage index using metropolitan statistical areas or cities with a population of at least 50,000 and its surrounding counties that have commuting ties and a statewide rural area, which includes all counties in the state that are not in MSAs.

In fiscal year 2022, CMS calculated a hospital wage index for 412 urban areas, defined by MSAs, and 47 rural areas, defined by balance-of-state.

CMS then aggregates wage data by labor market area to calculate an unadjusted average hourly wage by, first, summing total wages for all hospitals in an area and then dividing by the sum of all hours for those hospitals.

To calculate the national average hourly wage, CMS aggregates wage data from all relevant areas.

To calculate an unadjusted wage index for an area, CMS divides the area's average hourly wage by the national average hourly wage. Areas with wages rates less

than national rates have wage indices less than one, while those areas with higher wage rates have wage indices greater than one.

Based on requirements in statute and regulation, CMS applies numerous adjustments to the unadjusted wage index. The majority of these adjustments are applied in a budget-neutral manner. As the table shows, there are six categories of adjustments, three of which are applied at the area level and three at the provider level.

Some adjustments, like the occupational mix adjustment, affect all hospitals. However, the vast majority are applied only to hospitals with certain characteristics. In general, these adjustments are not mutually exclusive, and hospitals can and do receive multiple adjustments.

Due to time constraints, we will only describe two notable adjustments during this presentation -- geographic reclassifications and two types of wage index floors. However, the accompanying meeting brief provides more detail on the methodology and impact of each adjustment.

Congress created geographic reclassification

pathways that allow hospitals that meet specified criteria to be treated as if they are located in a different geographic area for the purposes of the IPPS wage index. For example, an eligible hospital can reclassify from its geographic area to another rural or urban area as long as it meets specific criteria.

In response to legal rulings, since 2016, hospitals can hold multiple simultaneous reclassifications. For example, a hospital can reclassify from its geographic urban area to a rural area and then to another, different area or even back to its original home area. While only the final reclassification holds for the purpose of the hospital's wage index, the intermediate reclassification can affect the hospital's eligibility for subsequent reclassifications as well as its non-wage-related payments.

In fiscal year 2022, 33 percent of IPPS hospitals had one or more reclassification, up from 23 percent in 2007. In 2022, 14 percent of hospitals dually reclassified, whereas no hospitals did in 2007.

In addition, because CMS calculates a post-reclassification wage index for each area which can include hospitals that reclassified, the third of hospitals that

reclassified increased the wages of an additional 11 percent of hospitals that did not reclassify.

Among the third of IPPS hospitals that reclassified, most received an increase in their wage index, with a median increase of 5.8 percent. However, the effects of reclassifications on wage indices varied greatly, ranging up to 40.7 percent.

In addition, 11 percent of hospitals did not reclassify but nonetheless had their wage indices increase due to the actions of other reclassifying hospitals. While these effects were much smaller, the increase in wage index was large for a few hospitals, with hospitals in one rural area that did not reclassify experiencing a 14.5 percent increase in their wage indices solely due to the reclassifications of other hospitals into that area.

Collectively, CMS estimated that these geographic reclassifications and other related polices would increase IPPS base payments by about 1.3 percent in fiscal year 2022, almost all of which would go to rural hospitals. However, as these adjustments are required to be implemented in a budget-neutral manner, all hospitals' payments were decreased by 1.3 percent in order to fund

increases to the subset of hospitals benefitting from these adjustments.

Congress and CMS created four wage index floor policies that set a minimum wage index for certain hospitals. Due to time constraints, this presentation will focus on two of those floors -- the rural floor and the imputed rural floor.

The most common type of floor is the rural floor, which ensures that a hospital located in an urban area of a state receives a wage index no less than hospitals located in the rural area of that state. The imputed rural floor, which was reestablished in fiscal year 2022, is a variant policy that sets a minimum wage index for urban hospitals located in all-urban states.

In fiscal year 2022, 11 percent of IPPS hospitals received either the rural or imputed rural floor. In one notable example, the rural floor in one state was set using the wage data of a single, rural hospital, resulting in an increase of more than 30 percent to some urban hospitals in that state.

The Commission has previously stated that the rural floor is based on a false assumption that urban wages

are always higher than wages in rural areas.

All IPPS hospitals subject to the rural or imputed rural floor were positively impacted. For example, the median marginal effect on hospitals subject to the rural floor was 3.9 percent, ranging up to 55.8 percent.

The rural floor, unlike the imputed rural floor, is implemented in a budget-neutral manner. So payments to all hospitals are decreased to fund the increase in payments to the subset of urban hospitals that receive these floors. To offset the increase in payments as a result of the rural floor, CMS applied a budget neutrality factor to all wage indices of negative 0.7 percent.

In contrast, the imputed rural floor is required to be implemented in a non-budget-neutral manner. CMS estimated that the imputed rural floor would increase IPPS payments in fiscal year 2022 by $195 million, all of which would go to urban hospitals located in five all-urban states.

Next, Alison will talk about Commission's concerns with wage index policies and our next steps.

MS. BINKOWSKI: Since MedPAC's 2007 report, both the number of wage index adjustments and the share of IPPS

hospitals receiving one adjustment have been increasing. In aggregate, the share of IPPS hospitals have received at least one special wage index adjustment, increased from about 40 percent in 2007 to 67 percent in 2022. A subset of these hospitals received substantial wage index increases, including 5 percent receiving a greater than 20 percent increase in their wage index and corresponding increases in their payments.

Because most wage index adjustments are funded through budget neutrality adjustments, IPPS hospitals with wage index adjustments benefit at the expense of all other hospitals. On the other hand, non-budget neutral wage index adjustments increase IPPS payments, which place added strain on the Medicare trust fund and increase beneficiary cost-sharing.

The Commission continues to have serious concerns about Medicare's wage index policies. These concerns can be grouped into three main areas.

First, the source of the wage data. Using cost report data from a relatively small number of short-term acute care hospitals to set wage indices for those same hospitals is circular and it is not necessarily

representative of relative wages for other types of providers. In addition, cost report data only includes data on aggregate wages and hours across occupations, and CMS only collects occupational mix data across four types of nursing staff.

Second, the definition of labor market areas. The use of MSA and balance-of-state to define labor market areas can mask substantial wage variation within a single area. In addition, these large areas and lack of smoothing have resulted in large wage index differences across adjacent areas, referred to as wage index cliffs.

Third, the numerous adjustments. Over time, Congress and CMS have continued to add additional adjustments to an underlying flawed wage index policy, and more hospitals have taken advantage of these adjustments. The result has been an increasingly burdensome and complicated process, with increasing opportunities for wage index manipulation and thus volatility in the wage index over time.

Based off these concerns, in 2007, the Commission recommended replacing the wage index and its numerous exceptions, starting with the following principles: to use

wage data from all employers; to use boundaries for geographic areas that are commonly understood, such as counties; to smooth differences across areas, as a replacement for wage index exceptions; and to phase in any large changes in wage indexes over time.

In the spring we will discuss whether these design principles for wage index redesign still hold and if modifications are warranted.

That concludes our presentation. During the discussion we look forward to answering any questions the Commission has on current Medicare wage index policies. In addition, we would appreciate input on any other concerns the Commission has with current wage index policies or suggestions for wage index reform design characteristics to include in our spring presentation.

And with that I turn it back to Mike.

DR. CHERNEW: Great. Thank you both. I think now, if I've got this right, the only person in Round 1 is Betty, and Betty, I think you're also the first one in Round 2. So that means we're going to let Betty do a join Round 1/Round 2, unless someone else, Dana, is in Round 1.

MS. KELLEY: No. That's what I have.

DR. CHERNEW: Okay. That's what we're doing. We're doing a short Betty round. We're going to Rambur Round 1 and we're going to then move into Round 2. Go ahead, Betty.

DR. RAMBUR: I'll try to be. Thank you so much for this important report that I have to say, in many ways, was alarming.

I have a question about the out-migration adjustment. You mentioned, on page 19, that it's calculated as the percentage of hospital employees residing in the county who are employed in any higher wage index area, and then there's more.

What is the source of that data? Is that from the cost report data?

MS. BINKOWSKI: That's based on an excerpt of census data, a special cut of the American Community Survey.

DR. RAMBUR: Okay. It might be helpful to have a little more detail about that. And does it include all categories? Like are employee physicians in that as well?

MS. BINKOWSKI: I will need to check on that. It's based on all, what are considered hospital employees

that reside in the county, not necessarily that are for that hospital, but I can circle back with the exact definition of hospital employee.

DR. RAMBUR: -- you know, a pop-out box or something I think would be helpful, because it ends up being important.

And then -- so this is still Round 1. I wanted to make sure I understood this correctly. In those states identified with frontier counties, am I reading this correctly in that even places in urban areas, for example, Fargo, North Dakota, that has a service area of roughly a quarter million people, would still be eligible for that additional dump that comes with being in a state with a lot of frontier counties?

MS. BINKOWSKI: Correct.

DR. RAMBUR: Okay. All right. So now, shifting gears here, I had a question about -- and this is something I don't expect us to resolve right now, but I had a question about the four nursing categories and the staffing model, and in the report we talk about it as a choice. And I'm just having a little bit of a hard time reconciling a couple of disparate -- somewhat disparate for me -- pieces

of information.

We know that the better-educated nursing staff, there's a lot of evidence about higher-quality outcomes, less failure to rescue, or whatever. So we have this piece here and then we have hospital value-based purchasing, and that has a lot of nurse-sensitive indicators, hospital-acquired conditions.

So I don't necessarily expect us to reconcile that now, but I feel like those two pieces of Medicare policy or situations are somewhat discordant, because it implies that a less well-educated mix is more cost-effective, some better, but the data doesn't bear that out in terms of outcomes. And then also add in the complexity around the nursing workforce shortage, coming from COVID, which we've talked about in other dimensions.

So I don't necessarily expect answer to all of that now, but those are things that I had a little bit of a hard time placing together. So thoughts on any of that?

MS. BINKOWSKI: I agree those are much broader issues than wage index per se. I think in this context the thought would be not only is there choice hospitals can make in the types of nursing staff but also in the types of

non-nursing staff, which are right now all lumped into the "all other" category. And so in 2007, we recommended just being more detailed in the number of occupations that were included. I think we could talk more internally in another context about some of the implications for other sectors, as you discussed.

DR. RAMBUR: Thank you. That's it for me, other than to say thank you. I think this is really critical to take on and clearly convoluted and challenging.

DR. CHERNEW: So in that spirit, actually, we're about to go to the rest of Round 2, but let me just make a general comment. I would like some sense from you all about how far we should push this in terms of things like recommendations and stuff. I should say, by way of history, I was actually on MedPAC when the 2007 recommendation was made, and that just makes me feel particularly old, but I indeed was. And I think, depending on what you say in the next hour or so, we could reiterate, go further.

I think there's a lot of stuff in this chapter suggesting we need to look into stuff more. I would be very grateful to get a general sense, if you guys want to

tell me, about how, for lack of a better word, urgent we should be in bringing this to a policy option or recommendation versus continued exploration of the issues.

So, Betty, I take your comment as being you're enthusiastic about moving further, faster, but we're about to get into the broader Round 2. I could make it us do it all in a lightning round, since I'm so happy with how that went, but let's just see how we do it in a regular Round 2.

DR. RAMBUR: Michael, briefly I would say absolutely enthusiastic and urgent.

DR. CHERNEW: Okay. Dana, you're calling on who's next.

MS. KELLEY: Okay. I have Brian next.

DR. DeBUSK: First of all, thanks to staff for a wonderful report. I'm so excited to see this issue come up, and I would echo Betty's comments -- urgent and important, I think, are very fitting.

First of all, I live in Knoxville, Tennessee, which is a hospital wage index desert. We were, prior to the 25 percent adjustment, we were running at 0.71, and if you look at your chart on page 24 of the reading materials you'll see we're on the far, far left-hand side of that

chart. So it's one of the lower wage index that you're going to see in the Continental United States.

I will tell you, being in a wage index desert is miserable. The report talks about circularity as a vulnerability. I mean, I can show you what circularity looks like. I mean, they can't afford to pay nurses competitive wages. They can't afford educational assistance programs. They cannot afford benefit programs. I mean, they're in a perpetual cost-cutting mode. Once you get in that downward spiral, because every year as you cut costs, as you try to -- you know, because you're having this massive adjustment done to your fee schedule, what happens is you basically get rewarded with a lower hospital wage index, successively, year after year. So when you get in this spiral it's virtually impossible to get out.

The 2000 MedPAC report was and is a fantastic piece of work. I'm really excited to hear that we're going to bring that back out. I'm sure all the numbers could do a refresh, but, you know, Michael, to your comment about being on the Commission at the time, you do fantastic work, so thank you. That report, I was also excited to see the word "Byzantine" used yet again. I'm pretty sure that was

in the 2007 report too, and I think that's a very accurate term.

Just elaborating on that, you know, really, the hospital wage index is the ultimate tournament model here in that hospitals that are providing more benefits and providing higher wages basically are taking, or shifting money away from the lower hospital wage index hospitals. And one of the reasons that I think there's a sense of urgency here is we're only two years into this four-year adjustment. There's a temporary adjustment period that started in October of 2019, where the bottom 25th percentile of the hospitals were lifted up, were average with the 25th percentile. So basically they brought the bottom end of the curve up to the lowest 25th percentile.

And I can just show you what that means to Knoxville. That took Knoxville's hospital wage index from 0.71 to 0.77. And when you talk about the importance of this issue, consider, you know, for us, a huge holdback, a penalty, a severe penalty for hospital is like 2 percent. Well, when you're having 62 percent of your fee schedule monetized, you know, the biggest holdback Medicare proposes, that I'm aware of, of 2 percent, is only a 3.22

shift in your hospital wage index. So you can imagine if Knoxville reverts back from 0.77 to 0.71, that's like receiving a 100 percent holdback penalty two times over.

So to give you a feel of the magnitude of this -- and here's the other thing that's really interesting. To the best of my knowledge, and if I'm mistaken someone can correct me, I believe the hospital wage index is not corrected for in calculating ACO benchmarks. So look at what happens in Knoxville. If their hospital wage index, when this four-year period ends, let's say it drops from 0.77 back to 0.71, all those hospitals in Knoxville look like they just produced 3.7 percent cost reductions, even though they'd be treating the same patients in the same way. That puts every ACO in Knoxville in the money, simply because their hospital wage index snapped back.

And with that, again, thank you for the chapter and thank you for letting me make the comments.

MS. KELLEY: Okay. I have Stacie next.

DR. DUSETZINA: Thank you for a very intriguing chapter and all of the work that went into it. I'm going to apologize because I think now that my question is more of a Round 1 question, but, you know, that's just how it's

turned out.

DR. CHERNEW: No one ever does Round 1 questions in Round 2. They always do Round 2 questions in Round 1. So this is really refreshing.

DR. DUSETZINA: Okay. Good.

DR. CHERNEW: I'm sorry. I'm joking with you.

DR. DUSETZINA: I do think that some of the comments in the chat have helped me reinforce that maybe I'm not the only one who maybe has missed this point. But it was really thinking about how hospital administrators and CEO pay is included. It just strikes me as something that could really pull up an average, given how high compensation can be for the C suite. And I was just curious how that was being managed in this.

MS. BINKOWSKI: So we can dig more into that, but at a high level, physicians that bill and are not providing IPPS services, are providing, say, fee schedule services, are excluded from the wages used to calculate the wage index. There is now a patient methodology that's used for certain administrative roles, but the details of that are something we can follow up on.

DR. DUSETZINA: Okay. And then I will follow

that with something that is a little bit more Round 2 and just related to the chapter. You know, I think that obviously the formula seems overly complicated and something that's more streamlined is always attractive to me.

It did strike me that it seemed like at least the groups that were getting some of the largest corrections maybe were ones where we thought that would be helpful. I know you pulled out Puerto Rico and Indian Health Service and some rural areas, and it seems like, oh, that seems like maybe not the worst thing, as groups maybe we would think about needing additional compensation, or to have a larger adjustment. But it does strike me that there must be an easier way to get at that, if that's what we would like to accomplish.

So again, thank you very much for a really interesting chapter and all this work.

MS. BINKOWSKI: Just two brief responses to that. The Commission can discuss whether certain types of hospitals warrant additional payments, but I think we would say they should be outside of wage index policy which, is an inefficient way that affects other hospitals. And

secondly, some of the areas with the largest percentage increases in their wage index aren't necessarily the areas that receive the largest monetary benefits from them, because as you said, some of those hospitals are small.

MS. KELLEY: Okay. I have Paul next.

DR. PAUL GINSBURG: Thanks. You know, this area of the hospital wage index is one of what I would characterize as over an almost 40-year period. You know, this was developed in 1983, and implemented very quickly after that. You know, it was a weak policy from the start, and it seems as though it has only gotten worse over time. It's been modified many times. So this has been a policy failure.

In fact, there are examples that were not in the presentation that are even worse, as far as the legislation, moving a particular, often named or at least described in a way that, you know, was equivalent maybe, a single hospital, and a lot of this has gone on.

I think the staff has done an excellent job of bringing us up to speed on, you know, how this is being used now, all of the complexity, how it's gotten worse, so I think it's prepared us.

My feeling is that any work that we should do in this area should be on a comprehensive reform. I don't think we want to spend time, you know, in the weeds in this area. We really want to move forward with a comprehensive reform. You know, maybe the 2007 recommendation is as good as we can do, but maybe we can kind of look at sort of refining it.

The main concern I have is really a question that Jim may not want to answer now, or maybe later, is what is the appetite in Congress for a comprehensive reform to this important part of a hospital prospective payment system? Will they just blow it off and continue to do tweaks that benefit hospitals in their districts, or is there really an appreciation of how the integrity of this whole policy has been repeatedly trashed over time.

DR. MATHEWS: Right. So I am going to take the Fifth on that one. That said, I think if there is an appetite among ourselves for pursuing what is an appropriate and correct policy, and Paul, you used the phrase "policy failure" here, that is what we do, and there might be an argument for just doing what is right, irrespective of how it might be received by members

individually or collectively.

DR. CHERNEW: For what it's worth, I agree.

DR. PAUL GINSBURG: Yeah, thanks, Jim. That really makes a lot of sense.

MS. KELLEY: I have Wayne next.

DR. CHERNEW: Wayne, I think you're muted.

DR. RILEY: Sorry. Thank you, Alison and Bhavya, for the presentation. What do we know in the state of play with regard to the wage index issue with safety net hospitals? I think Betty mentioned, you know, rural providers and the whole issue there, but as a relatively new Commissioner, I wonder, has the Commission looked at this issue vis-a-vis safety net hospitals in particular? And I think Brian touched on it as well in the Knoxville area.

MS. BINKOWSKI: So maybe that's something we can circle back on and maybe after our November presentation where we'll be having a larger discussion about safety net and the myriad of ways in which that currently is defined and could be perhaps better defined moving forward. To talk a little bit about what Brian -- the point he made was referring to the low wage index policy which would apply to

all of the areas that were in the bottom quartile of wage index, some of which you may consider safety net and others not. There are not specific wage index increases, for example, for DSH hospitals. So maybe we can follow up offline with the particular types of information you're interested in.

DR. RILEY: Yeah, just, you know, in terms of transparency, you know, I'm in New York City where my friends across in Manhattan are able to pay a higher wage generally than I am, so I'm in hand-to-hand combat with them from Brooklyn and serving, you know, predominantly minority and underserved communities.

For example, just because of COVID, we have a 29 percent vacancy rate in our emergency room nurses, 19 percent overall just over the last year because of, you know, various sort of burnout issues, vaccination mandate, whatever. So we're kind of sensitive to any shift going forward that, you know, we just should be aware of as Commissioners and as staff to really look at how this could have some level of impact, positive or negative. I just don't know. I'm just openly wondering should we look at that.

MS. BINKOWSKI: So when and if we decide to do additional modeling, we can look at those for impact analyses. But to your specific example, I'd say that currently the wage index is based on metropolitan statistical areas, and all of New York City and its surrounding counties are in a single area. Now, some other hospitals within that are may be qualifying for special exceptions, but -- I'll stop there.

MS. KELLEY: I have Jon Perlin next.

DR. PERLIN: Right. Well, first, let me thank the staff for a very articulate exposition of what is, I think, fairly described as Byzantine. I wanted to bring a perspective from hospitals and someone who's in a system that operates across multiple states, thus, winners and losers, frankly, in the AWI sweepstakes.

I'm not going to justify the policy of AWI, or try to, but my comments really are on the impact of our considerations here in terms of fundamental stability of hospitals, and this builds to a certain degree on Wayne's comment about the cost structures of hospitals and the environments in which they operate.

I think when we look at a particular policy and

we fix that policy, let's say we made this perfect, it's destabilizing if you can't simultaneously consider the hydraulics in terms of the effects of other policies simultaneously. And I just want to make, you know, a few points about some of the basis. It strikes me that, you know, we're a little bit inconsistent. In our last discussion, we talked about a fix in risk adjustment with reinsurance, transfers on the ends of the distribution. And, you know, in a sense, this is derived from a number of transfers that have gotten to be very arcane. I think we're on shaky territory if we say BLS alone will absolutely fix that. Let me just sort of elaborate on that.

Wayne made the comment about the impact of COVID, as did Betty, and this group has discussed the impact of nursing shortage and rates for nursing travelers and temporary personnel that are double or treble what they were before.

I would argue that BLS, by virtue of its distribution across a number of different fields, not being hospital specific, not actually aggregating or including the benefits, just wage and salary, by virtue of being a

voluntary survey, you know, doesn't address those sorts of issues. Similarly, it doesn't discriminate between areas that are heavily unionized and non-unionized in hospitals disproportionate to other industries.

So if one were to envision a more perfect system, certainly you'd want cognizance of something that's more stable, less engineered, but, similarly, reflective of both the occupation wages in health care and hospitals specifically, but that operates with, you know, greater predictability at the outset.

We make the point that -- or it seems sort of as a given as if BLS will be more reflective than AWI. I mean, AWI is audited and it is what it is. It is a direct reflection. So, you know, there has to be something that transects both sort of secular trends in a particular MSA, but also those things that are kind of parochial trends within health care, hospitals specifically.

Lastly, I want to come to this issue of stability. You know, it's really interesting because as you might imagine, over the course of my career, I've received a lot of input on AWI. Let's take a look at our own data. We know that, you know, the top -- the most

efficient hospitals have approximately a negative 1 percent margin on Medicare patients. We know that the average margin is minus 13 percent. If one uses other data, you know, we know that roughly a third of hospitals really have operating losses a third or -- you know, at or near violation of bond covenants and a third are performing more favorably.

If you look at the same data, they're not solely distributed in the low AWI area. They're more broadly distributed. So this could adversely impact a slew of hospitals.

To that end, I remember when this discussion came up in another context, and I won't name the particular academic institution, but the CEO of this institution, you know, near teary-eyed, said, "I get that this is unfair. I get that this is problematic. But if this were to occur, I would have to close clinics for special needs populations; I would have to lay off X number of staff," et cetera, et cetera, et cetera.

So I think that recognizing that this could have a profound impact on the stability of hospitals, ironically not just in the low end but in the high end, that may have

other reasons for dynamics, safety net, disadvantaged population, et cetera, I just think we have to be really thoughtful about what the mechanism is of transition and find a set of data that both reflect those experiences unique to health care such as those we said as well as those that are more general and, you know, consistent.

So I'll offer that from a bit of an insider perspective of what the kind of real-world impact might be. Thanks.

DR. CHERNEW: Dana, if I'm correct, that was the end of the queue.

MS. KELLEY: Yes, that's right.

DR. CHERNEW: Yes, so first I'm going to thank Bhavya and Alison for really a terrific chapter. I realize there's a lot of enthusiasm amongst Commissioners to look into this issue, so let me give you my very quick summary of what I heard.

In general, I heard a lot of enthusiasm. There is this issue, and I agree with you completely, Jon, and it's a perennial problem, which is when we make things that seem to not be working well work better, we worry about the distributional consequences. And in everything we do, we

do a distributional analysis.

There is a situation -- and this is a perfect one -- where if there is a problem with safety net hospitals, for example, to build on Wayne's comment, the right way to solve that problem is not to have, say, an imputed rural wage floor. The right way to do that would be to find a targeted policy to help those institutions that you really think need help. That requires in some sense a bit of a policy bank shot where you're making a recommendation to address one policy and then a recommendation to address another policy kind of bundled together to get what you need. That will be hard, and given the interest in sort of safety net hospitals and the populations they serve, that's why we have a chapter about those institutions in some ways as opposed to just all the policies that affect them. So I think there's a general MedPAC principle of trying targeting the support where the support is needed as opposed to paying in ways that are unfair for a lot of people because you're trying to help other places.

That's my general view. Luckily, we have a lot of time left, so later you can go to Round 3 and you can complain about it. But what I take this all together is we

will continue to do this with continued urgency. Jim and I and the staff will have the discussion about if we can get to a type of recommendation in anything we do, I will assure you we will be very, very sensitive to the distributional consequences and make it clear that when there are changes that influence wages in certain places, that that matters and may need to be adjusted, oftentimes we say with transitions, with budget-neutral rules, with a whole slew of other things. And, of course, this will come up again, versions of this will come up again, Jon, I'm sure, and there will be a vigorous discussion around the hospital update this year.

So I will look forward to continue discussions on this point. I think it is very hard to imagine if there was no Medicare program and we saw down to design it and we recognized, you know what, we need to adjust payments for differences in costs across areas, that this is what we would come up with. I don't know what we'd have to be thinking to come up with something that kind of looked like this. But we ended up here in this Byzantine system, and I think, to Jim's point, there's probably a strong case for trying to simplify it, to target it better, to make sure

we're not overpaying in some cases, because, honestly, we have to make sure that we're not underpaying in other places. And that certainly would be my goal, and, of course, doing it all in a way that guarantees that the providers can hire the labor that's necessary to provide the care that our beneficiaries need and understand that that sort of -- I used this earlier in context. That's sort of the North Star of this debate. We can't serve Medicare beneficiaries without providers. They're the backbone of the Medicare system, and the providers need support. But we need to do that in an efficient and fiscally responsible way, and I'm not sure all of these systems lead to that.

So I'm glad no one was timing me for two minutes. Again, that was surely over. Let me pause to see if anyone else wants to add any comments on this or any other particular topics.

[Pause.]

DR. CHERNEW: Okay. Hearing none, we are now going to break -- that is going to draw to a close our October meeting. To those listening, please reach out to us, meetingcomments@medpac.gov. Once again, that's

meetingcomments@medpac.gov. Jim, I hope I got that right. If not, interrupt me. We really do look forward to your feedback. We know these are complicated issues. We've had a very good day today, I think, really with three very complicated and important topics from APMs to risk adjustment to wage index. And, of course, yesterday we dealt with prescription drugs, which is on top of everybody's mind. So I really am quite excited about the meeting that we just had, and I wish everybody a healthy and happy long weekend. We will then see you again in November. Thanks.

Jim, do you want to add anything before we go?

DR. MATHEWS: No. All good.

DR. CHERNEW: Okay. Thanks, everybody.

[Whereupon, at 2:54 p.m., the meeting was adjourned.]