MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Thursday, April 6, 2017
9:01 a.m.

COMMISSIONERS PRESENT:

FRANCIS J. CROSSON, MD, Chair
JON B. CHRISTIANSON, PhD, Vice Chair
AMY BRICKER, RPh
KATHY BUTO, MPA
ALICE COOMBS, MD
BRIAN DeBUSK, PhD
PAUL GINSBURG, PhD
WILLIS D. GRADISON, JR., MBA, DCS
WILLIAM J. HALL, MD, MACP
JACK HOADLEY, PhD
DAVID NERENZ, PhD
BRUCE PYENSON, FSA, MAAA
RITA REDBERG, MD, MSc
CRAIG SAMITT, MD, MBA
WARNER THOMAS, MBA
SUSAN THOMPSON, MS, RN
PAT WANG, JD

B&B Reporters
4520 Church Road
Hampstead, Maryland 21074
410-374-3340

AGENDA PAGE

P R O C E E D I N G S

[9:01 a.m.]

DR. CROSSON: Okay. I think we can be seated and begin.

The first agenda item for this morning is a return to the discussion of Medicare Part B drug payment policy issues, and we have got Kim and Nancy here. Kim, it looks like you are ready -- no, Nancy is starting. Sorry.

MS. RAY: Good morning. Today Kim and I will walk you through a draft recommendation aimed at improving the current ASP payment system in the short term while developing the Drug Value Program, the DVP, an alternative, voluntary program in which providers could choose to enroll instead of remaining in the buy-and-bill system. We have discussed issues related to Part B drugs for a couple of cycles and have developed the draft recommendation over the last several meetings.

Here is an outline of today's presentation. Before beginning, I want to point out that the draft chapter has been revised to reflect your questions and comments from the March meeting as outlined in the attached memo. For example:

Warner and Jack, we added a section on the broader context for Part B drug spending which includes the financial performance of drug manufacturers.

Bruce, we have added discussion about improving the quality of the ASP data that manufacturers report.

On the inflation rebate policy, Bill Gradison, we included a discussion of an exception process for high-cost drugs in shortage on a case-by-case basis. And, Paul, we have added more discussion on the rationale for the inflation rebate policy.

Some of the changes to the DVP section include:

In respond to David and several other Commissioners, we expanded discussion on shared savings opportunities for providers in the DVP.

Several Commissioners -- Craig, Pat, Brian, Amy -- we added the discussion about providers' incentive to join the DVP.

In response to Pat and Craig, we have added discussion about the potential for providers to purchase drugs at the DVP rate for their MA patients.

And in response to several Commissioners, we have expanded the discussion on the design elements in the

binding arbitration that could be used in the DVP.

In terms of background, the information is not new to the Commission, so I'm going to move fast on this slide.

Medicare spending for Part B drugs is substantial, totaling $26 billion in 2015.

The Commission's interest in reforming the Part B drug payment structure over the last several years has been driven by concerns that include the rapid growth in the prices of and expenditures for Part B drugs.

Since 2009, Part B drug spending has been growing at a high annual rate of growth, and between 2009 to 2013, half of the growth in expenditures was driven by price growth, which reflects price increases for existing drugs and a shift in the mix of drugs.

This slide gives broader context for how the package of reforms fit together and the timing of the reforms. As the figure shows, the first set of reforms is aimed at improving the current ASP system and could be implemented almost immediately.

The figure also shows the implementation in 2022 of the DVP. As part of the transition to the DVP, the

current ASP add-on of 6 percent would be reduced to give providers an incentive to enroll in the DVP.

Now I will start walking through the short-term policy reforms, beginning with improving ASP data reporting.

As we discussed in March, only manufacturers with Medicaid rebate agreements are required to report their ASP data. Some entities, such as repackagers, do not have Medicaid rebate agreements and are, therefore, not required to submit ASP data. Also, some manufacturers who are required to report ASP data fail to do so in a timely manner.

This policy reform would require manufacturers to report ASP data for all Part B drugs and increase the civil monetary penalties for failing to report the data in a timely manner.

We discuss in the text giving the Secretary the authority to exempt special cases from reporting. For example, repackagers could be excluded from reporting to ensure drugs are not double counted.

Our second policy reform concerns drugs that are paid solely based on manufacturers' list prices, which is

referred to as the wholesale acquisition cost, or WAC.

New single-source drugs and the first biosimilar are typically paid at WAC+6 percent for nearly three quarters because of the lag in ASP data reporting. WAC-based prices do not incorporate discounts that manufacturers commonly provide.

We found that for a subset of new, high expenditure drugs, small discounts were common while the drugs were WAC-priced. Consequently, Medicare currently pays more for the same drug when it is WAC-priced compared to when it is ASP-priced.

To bring WAC-based prices and ASP-based prices for the same drug closer together, this policy reform would reduce the WAC add-on by three percentage points, roughly the high end of the discounts we observed.

In addition, to maintain parity to ASP-priced drugs in the future, the WAC add-on could be further reduced when the ASP add-on is reduced to encourage enrollment in the DVP.

So let's move to the third short-term policy reform. Growth in the ASP payment rates are driven by manufacturer pricing decisions. There is no statutory

limit on how much Medicare's ASP payment for a product can increase over time.

This policy reform would require manufacturers to pay Medicare a rebate when ASP growth exceeds an inflation benchmark. The savings from rebates would be shared with the beneficiary by basing cost sharing on the lower inflation-adjusted ASP. The provider add-on payment would also be based on the inflation-adjusted ASP.

To address the concern about CMS administrative resources to implement a rebate, low-cost drugs could be excluded from the policy. On a case-by-case basis, high-cost drugs under shortage could be excluded as well. Also, duplicate discounts could be avoided meaning that the ASP inflation rebate could exempt Medicare utilization already subject to a 340B discount or Medicaid rebate.

An inflation benchmark would need to be chosen. It could be CPI-U like the Medicaid inflation rebate, or an alternative could be considered that results in a growth rate no greater than provider fee-for-service updates.

Moving to the last of the short-term policy reforms, under the current ASP system, we have not maximized competition between the reference biologic and

its biosimilars because the reference product is assigned to one billing code and all its biosimilars are assigned to another separate billing code.

This policy reform would require the Secretary to group the reference biologic and its biosimilars in the same billing code. The Secretary would rely on the FDA approval process for biosimilars that was established by the Biologic and Price Competition and Innovation Act determine which products to group together.

Under this policy, the clinician would continue to have the choice to prescribe the product most appropriate for the beneficiary, and Medicare's payment could be based on the volume-weighted ASP of all products assigned to the code. The Secretary could be given the flexibility to implement a limited payment exception process under which Medicare would reimburse the provider based on the ASP of the higher-priced product. This would address the concern that beneficiary access could be harmed if some providers are unwilling to supply the higher-cost product to a beneficiary who needs a particular product due to clinical reasons.

Lastly, we discuss in the draft chapter that the

Secretary could study the use of a broader consolidated billing code policy for groups of drugs with similar health effects and for groups of biologics with similar health effects.

Now Kim will discuss the DVP.

MS. NEUMAN: So next we'll talk about developing a Drug Value Program, or DVP, which would be a voluntary market-based alternative to the ASP system. This policy would give the Secretary the authority to create a Part B DVP that would use private vendors to negotiate prices and offer providers shared savings opportunities.

The DVP would be informed by lessons learned from the CAP program, but structured differently to increase vendors' negotiating leverage and encourage provider enrollment.

So let's review the key design elements of the DVP. The DVP would be voluntary for physicians and outpatient hospitals. Annually, these providers would decide whether to enroll in the DVP or remain in the ASP buy-and-bill system.

To encourage provider enrollment in the DVP, the ASP add-on would be reduced gradually in the buy-and-bill

system. The reduction to the add-on would be timed to coincide with the target date for operationalizing the DVP. The add-on reduction could begin by that target date regardless of whether the DVP is operational in order to create pressure for the DVP to be implemented.

We envision that Medicare would contract with a small number of private DVP vendors to negotiate Part B drug prices. Having a small number of vendors would give providers a choice of which vendor they wanted to work with and would also consolidate volume among a small number of entities to increase negotiating leverage.

DVP prices would not be public. Different from the original CAP program, DVP vendors would not directly ship product to beneficiaries. Instead, providers would buy the drugs in the marketplace from distributors or wholesalers and in some cases directly from manufacturers at the DVP negotiated price.

In terms of payments and shared savings, here's how we anticipate it would work.

The provider payment would include three components. There would be payment for the drug, which would be the DVP negotiated price with no add-on. There

would also be payment for drug administration services, which would continue to be paid at an amount specified in the physician fee schedule or the outpatient prospective payment system.

In addition, providers would have the opportunity to receive shared savings if the DVP program resulted in lower total cost of Part B drugs.

Vendors would be compensated through an administrative fee, which might be a fixed dollar fee or a fee per enrolled provider, or a combination of these approaches. Like providers, vendors would be eligible for shared savings if the DVP resulted in lower total cost of Part B drugs.

Beneficiaries would also share in savings because they would pay lower cost sharing, and Medicare would share in savings because the Medicare payment rate for the drugs would be set at the DVP negotiated price.

The DVP would be designed to include several tools to increase vendors' negotiating leverage.

First, DVP vendors would be permitted to operate a formulary. We would expect that a formulary would spur price competition among products with similar health

effects -- so, for example, when there are multiple brand products in the same therapeutics class -- and this would lead to lower prices for these products.

Second, prices under the DVP would be limited to no more than 100 percent of ASP. This would ensure that vendors can get at least typical market prices for all drugs.

Third, vendors could be permitted to use additional tools like step therapy and prior authorization.

Fourth, binding arbitration could be used in the DVP program for expensive drugs without close substitutes. I'm going to pause here and spend a little time talking about a few of the principles we outlined in the draft chapter for designing a binding arbitration process within the DVP and provide clarification.

First, binding arbitration, when it occurs, would be between manufacturers and DVP vendors, not CMS.

Second, we would anticipate that the process for binding arbitration would be developed through rulemaking, which would allow opportunities for public comment.

Third, we envision that DVP vendors would have one opportunity to invoke binding arbitration for a product

in a given time period.

Fourth, as we've discussed, including binding arbitration as a tool in the DVP might actually promote more negotiations between manufacturers and DVP vendors as they might prefer negotiating rather than entering arbitration where they may risk the arbiter ruling for the other party.

Fifth, the paper touches on other design issues such as approaches for selecting arbiters and criteria that the arbiter might use to make a decision, and we'd be happy to discuss any aspects of this on question.

So now to finish on a couple other design elements for the DVP: DVP prices would not be included in the calculation of ASP in order to give vendors more leverage with manufacturers. Finally, it will take time to develop the DVP so it could be phased in beginning with a subset of drugs where savings potential appears to be greatest, such as drug classes that include multiple products with similar health effects.

At the March meeting, a question came up about what are providers' incentives to join the DVP, and there are a couple different factors that create incentives for

DVP enrollment.

We expect that providers that are on the higher end of the price distribution would have an incentive to join the DVP because the buy-and-bill system is less likely to be attractive to these providers.

As higher-priced purchasers move into the DVP, this may lead to a reduction in future ASPs as these purchasers' prices would no longer be reflected in the ASP calculation. A reduction in future ASPs might lead more providers to consider DVP enrollment.

Another incentive for DVP enrollment is the reduction of the ASP add-on from 6 percent to 3 percent over time. A lower add-on would lessen the attractiveness of the buy-and-bill system and create broader incentives for DVP enrollment.

Another element that may make the DVP more attractive to providers would be the incorporation of provider input into DVP tools, such as the formulary and other management tools.

And, finally, shared savings opportunities available through the DVP also create incentives for enrollment. DVP savings would be expected to come from two

sources. First, we anticipate that DVP vendors' use of tools like a formulary would yield lower prices on individual products. Second, providers would have an incentive to shift utilization toward lower-priced products where clinically appropriate. To the extent that savings are generated from these two dynamics, providers that enroll in the DVP would share in those savings.

So next we are going to move to the Chairman's draft recommendation, and before we do, we have the overview slide that sort of shows how all the pieces put together and the time frame for potential implementation.

So the draft recommendation reads:

The Congress should change Medicare's payment for Part B drugs and biologicals as follows:

One, modify the average sales price system in 2018 to:

Require all manufacturers of products paid under Part B to submit ASP data and impose penalties for failure to report.

Reduce wholesale acquisition cost-based payment to WAC+3 percent.

Require manufacturers to pay Medicare a rebate

when the ASP for their product exceeds an inflation benchmark, and tie beneficiary cost sharing and the ASP add-on to the inflation-adjusted ASP.

Require the Secretary to use a common billing code to pay for a reference biologic and its biosimilars.

Two, no later than 2022, create and phase in a voluntary Drug Value Program that must have the following elements:

Medicare contracts with a small number of private vendors to negotiate prices for Part B products.

Providers purchase all DVP products at the price negotiated by their selected DVP vendor.

Medicare pays providers the DVP-negotiated price and pays vendors an administrative fee, with opportunities for shared savings.

Beneficiaries pay lower cost sharing.

Medicare payments under the DVP cannot exceed 100 percent of ASP.

Vendors use tools including a formulary and, for products meeting selected criteria, binding arbitration.

Three, upon implementation of the DVP or no later than 2022, reduce the ASP add-on under the ASP system.

In terms of implications, the draft recommendation is estimated to decrease program spending relative to current law by $250 million to $750 million over one year and between $1 billion and $5 billion over five years.

In terms of implications for beneficiaries and providers, the draft recommendation would: generate savings for beneficiaries through lower cost sharing, and would not be expected to affect beneficiaries' access to needed Part B drugs.

In terms of the effect on provider revenues:

For providers choosing to remain in the ASP system, ASP add-on payments would be reduced, but the effect on providers' net revenues would depend on how manufacturers respond to the policy.

For providers that choose to enroll in the DVP program, they would be paid the DVP price with no add-on and would be eligible for shared savings opportunities. Whether these providers' net revenues increase or decrease would depend on whether the shared savings is bigger or smaller than the net revenue they would have otherwise earned on drugs with an add-on under the buy-and-bill

system.

Beyond the specific text of the draft recommendation, we would intend to add in the June report additional text to reflect more detail on certain issues or to reflect conversations that occurred among Commissioners about alternative approaches or other ideas.

For example, on the ASP inflation rebate, the text would mention the exemption of low-cost drugs; the case-by-case exceptions process for high-cost drugs in shortage; avoidance of duplicate discounts; and the need for policymakers to select an inflation benchmark. The text will also mention that there is another way to structure the ASP inflation limit.

On consolidated billing, the text would encourage the Secretary to examine the potential for consolidated billing more broadly beyond biosimilars and reference biologics.

The text would also discuss the timing of gradually reducing the ASP add-on from 6 percent to 3 percent and would make clear that the WAC add-on would be reduced further as the ASP add-on is reduced.

In addition, as I mentioned already, the text

would provide more detail on principles for binding arbitration under the DVP.

Finally, the text would encourage the Secretary to take steps to ensure the quality of ASP data reported by manufacturers.

So that concludes our presentation. We look forward to your discussion and are happy to answer any questions.

DR. CROSSON: Thank you, Kim and Nancy.

So we'll take clarifying questions. Can I see hands? Let's start with Bill Gradison.

MR. GRADISON: I just want to make sure I understand the role of pre-authorization or a formulary. Am I correct that under Part B today there is no use in traditional Medicare, fee-for-service Medicare, of either formularies or pre-authorization?

MS. NEUMAN: So for Medicare Part B drugs, there is currently not a formulary under Medicare fee-for-service. I believe there might be some experimentation with prior authorization in other types of services in fee-for-service.

MR. GRADISON: I understand, but I'm just talking

about Part B.

MS. NEUMAN: For Part B, no.

MR. GRADISON: Okay. My initial reaction in seeing that was a little bit of belt and suspenders here. Then as I thought more about it -- and there is a question behind this -- it occurred to me that the negotiations, the way I had thought about them, and the ultimate arbitration were focused on price, actually exclusively on price the way I thought about it. But if prior authorization and formularies become an element, as we recommend here, then I could envision the negotiation and possibly arbitration might include those provisions. In other words, part of the deal might be if we negotiate such-and-such a price, it would be in consideration for being at a top tier, or at least not having to have pre-author -- I mean, that would just be a subject for negotiation. I'm not suggesting how it might come out.

So I'm just trying to -- I'm really asking for your help because I have had a little trouble thinking this through, the interrelationship between the price -- I guess we ought to say the price-oriented negotiation and possible arbitration along with these two additional tools. Thank

you.

MS. NEUMAN: Sure. So I would sort of look at it in two pieces. There's sort of the general negotiations that the DVP would have for the drugs that are in the DVP program broadly. And then there's arbitration which might apply to a subset of products that meet certain criteria. So they're kind of in two separate camps.

In general, the idea of including a formulary was to allow vendors where there are multiple products that have similar health effects in the same therapeutic class to be able to go to manufacturers and try to secure discounts for placement on the formulary or for educating providers on which product is less costly and likely to generate savings and so forth. And so the idea was that these management tools would help the vendors to secure discounts from manufacturers where there is competition among products.

With respect to arbitration, as we have said, there would be specific criteria for a product to be even eligible for arbitration, and that would be drugs that are very expensive and that don't have close substitutes, so that any of these tools that we just talked about wouldn't

really be very effective. And so in that situation, there could be a process where it meets those criteria, the drug then goes into an arbitration process, and there is a determination made about an appropriate price through that process. And so there's sort of those two aspects to the design.

MR. GRADISON: I think I understand. Thank you very much for your help [off microphone].

DR. CROSSON: Clarifying -- I'm sorry. Warner, do you want to have a question?

MR. THOMAS: A couple of clarifying questions.

First of all, on the penalties for failure to report, have you thought through what those penalties might look like, or is that to be determined in the future? Is there any recommendation on the penalties?

MS. RAY: I think we envisioned that they should be increased from what the current level of penalties are, but we haven't thought of a specific number.

MR. THOMAS: Was there a consideration of if they do not report, potentially not being able to sell to the program?

MS. NEUMAN: As a condition of Medicare coverage,

they would be required to report this data, and so if they don't report, they could be terminated from coverage ultimately.

MR. THOMAS: Okay. And then on the inflator cap, you had said in further text that will be kind of further vetted, because I know you talked about potentially tying it to provider increases, and then there's, you know, or potentially some type of CPI. I guess my clarifying question is: If it was tied to provider increases, what would that be roughly? Do we have any idea in a range of what that might look like? And if it was tied to the CPI Medicaid number, what would that look like?

MS. NEUMAN: So I can tell you on CPI that we have -- there's a table in the paper that looks at CPI growth on an annual basis over the period that ASP has been in effect, so since 2005. And CPI has been growing at an average rate of about 2 percent per year. My sense is that, in general, market baskets might be a little bit higher than that.

DR. MILLER: I think that's right. I feel like they're running these days above -- market baskets are running about 2, 2-1/2 is sort of what's happening.

There's several of them out there, so it's a little hard to answer.

I would say the other thing that we're trying to say conceptually -- and I don't think we have, you know, an index horse that we're trying to ride per se, and some of what I'm about to say is based on comments that you've made. You probably don't want an index that the price set by the drug manufacturers drives the index because then you have a bit of a circularity problem.

MR. THOMAS: Right.

DR. MILLER: You raised concerns that -- and others, but I remember your voice in particular -- you know, the inflator shouldn't be going up faster than what the person who's purchasing the drug and delivering it to the beneficiaries, that we're sort of saying don't tie yourself to drug prices, be mindful of the fact that the providers' payments are going up. And then within that, we threw out a few indexes, and I think our thinking is that's the guidelines that you want to think of in selecting an index.

Does that all pass your review?

MR. THOMAS: And the last question. You said

there would be a few DVPs. Have you thought about what you think the number might be or how they're selected or anything like that?

MS. NEUMAN: So we haven't hit a specific number. We're cognizant of if there are too many, then we sort of water down any leverage that they have. And at the same time, we would like providers to have a choice, and so you would need at least several, I would think.

MR. THOMAS: Thank you.

MR. PYENSON: On this point?

DR. CROSSON: On this point, Brian and Bruce. Okay. Brian on this point?

MR. PYENSON: Just on the earlier point of the CPI index, I think just a question. Often people default to consumer indices, and whether it makes sense to identify a broader range, such as the producer price index, wholesale medical, as another consideration, just to create the full scope or span of possibilities that are out there.

DR. CROSSON: And I think we are open to adding that as another example in the text.

DR. MILLER: And I think based on what we were saying as kind of the guidelines that we are thinking

about, that does fit into that guideline.

DR. CROSSON: Okay. We are back to clarifying questions. Coming up this way. Pat.

MS. WANG: Again, I apologize that I don't have a voice. I hope you can hear me all right.

Can you say more about how you think shared savings could be calculated? How would that work? What would the benchmark be? How would the benchmark change?

MS. NEUMAN: Sure. So we have some in the paper that talks about the calculation of shared savings, and we have said a couple of things. One is that we would want to look not just at price but at the total cost of Part B drugs, so that we look at both the price and shifts in utilization that might occur in what the overall spend is. And then you would want to compare that to some kind of benchmark, as you note. So perhaps providers that are not enrolled in the DVP program would be one possibility.

And there are other shared savings approaches that occur within other aspects of the Medicare program, and so we could look to that. We haven't gone into detail in saying do it this way or do it that way. We have sort of been at the principle level.

And then another piece that we have in the paper now is sort of shared savings could work by the government, calculating it sort of like we do with some of these other programs and sort of figuring out how much each provider would get, or an alternative would be to identify how much savings is the provider's and vendor's share and then turning that money over to the vendor, who could then allocate it among providers. So there's different ways to sort of distribute it.

DR. CROSSON: David.

DR. NERENZ: Thank you.

Two questions. Both can be related to Slide 13, if you can bring that up.

First one, top line. If you could just clarify – 13 -- high end of the price distribution. Can you just talk in a little more detail? Distribution of what exactly and price to whom exactly, what does that mean? I assume it relates to ASP, but can you tell us what that is?

MS. NEUMAN: Right. So that refers to the provider's acquisition price for the product. So they are buying drugs right now in the market from distributors, wholesalers, and so on at a certain price, and that price

is --

DR. NERENZ: Which could be higher or lower than ASP? That's the point?

MS. NEUMAN: Right. Higher or lower than what Medicare -- yeah -- the ASP Medicare uses to base the payment rate. Yeah.

DR. NERENZ: Okay. That's fine. So if you are on the high end of the distribution and you get paid ASP+6, you still may be losing money on the simplified version, but that's the point?

MS. NEUMAN: Right. Or you may not be making money.

DR. NERENZ: Thank you. Okay. I just wanted to make sure.

The second question, then, is the second bullet, and then this comes up again. In earlier discussions on this -- and I may have been just mistaken -- I thought we were fundamentally talking about moving from ASP+6 to WAC+3, but in the proposal, I see ASP+3 and I see WAC+3. Can you just talk a little bit about the relationship between those two things going forward? When is ASP relevant? When is WAC relevant?

MS. NEUMAN: Okay. There's sort of two pieces. The WAC is used, as Nancy said, when we don't have ASP data. So it is for a very small number of products where the product is really new and we don't have ASP data yet, and right now, we are paying +6, and think that is not an efficient price and we should move to +3.

And then the ASP is what's used the vast majority of the time, and in this case, we are suggesting that in 2022, we start phasing that +6 down.

DR. NERENZ: Okay. So the presumption is that even though another part of this is to require stronger ASP reporting, there still will be specific drugs for which ASP data do not exist, and therefore, WAC+3 -- that is when it applies?

MS. NEUMAN: Right. By definition, new products will always lack ASP --

DR. NERENZ: Yes. Thank you. Okay. Just being sure.

DR. CROSSON: Amy.

MS. BRICKER: So you mentioned inflation or highlighted that there has been a 9 percent growth in spend, half of which was actually due to price, growth, or

inflation. Is that correct? How does that compare to -- so roughly 4 to 5 percent in inflation. How does that compare to Part D? DO you know?

MS. NEUMAN: I am not sure. I can answer that.

DR. MILLER: Can we get one of the D folks up here?

MS. NEUMAN: Yeah. And --

MS. RAY: And it would also be for a different basket of drugs.

MS. BRICKER: I understand. It doesn't actually seem egregious. When you see 9, that is shocking, but when you realize that half of it is utilization, I think it is going to come out to be much less than what we see in Part D. But I just wanted to confirm that assumption.

DR. MILLER: All right.

MS. BRICKER: Do you have mix? Brand versus generic?

MS. NEUMAN: On that? For Part B? Do you want the percentage or the price change?

MS. BRICKER: The percentage of brand versus generic.

MS. NEUMAN: Okay. So under Part B, only 25

percent of the spend is on drugs, and of that, about 15 percent are drugs that are single source and so have no opportunities for competition.

The remaining 10 percent are for products where there is competition between brand and generic, but we don't know from our data how many units of generic are being used versus brand. We only know that drugs with generic competition account for 10 percent of total spend.

MS. BRICKER: I am trying to figure out, again, in comparison to Part D space, is this predominantly generic products that are being utilized here. So, as we look at inflation in this case, we're looking at a very small subset of manufacturers that are branded manufacturers that are highlighted potentially on page 26 of our reading material that are driving that ultimate 4 to 5 percent inflation, or is that not the assumption? The mix is generally similar, B and D, and therefore, the inflation is being held at a lower rate compared to D for some other reason. And that's where I'm headed. I need some help with that, though.

MS. SUZUKI: So for the Part D program, including the generic substitution, since 2006, the prices have grown

by about 8 percent, so this is cumulative. But when you look at single-source drugs, it's grown by 240 percent, according to our price index analysis.

MS. RAY: That's cumulative.

MS. SUZUKI: It's cumulative too.

MS. BRICKER: And you're saying just inflation, not actual utilization?

MS. SUZUKI: Right. This is just price --

MS. BRICKER: So 8 percent versus 4 to 5 percent? Is that right here?

MS. NEUMAN: It is, but it is a different time period, and it's also a different mix of products. The 4 to 5 percent represents the whole portfolio under B.

MS. BRICKER: Okay. Thank you, Shinobu. I didn't mean to start a fire drill.

You mention in the reading material that as a DVP, the worst that a DVP vendor could do is ASP. Yeah. Okay.

So then when you think about there's going to be some -- you mentioned some add-on, a professional service fee or some sort of add-on to the prescriber. If you assume ASP as the backstop, how does ASP plus a

professional service fee compare to ASP+3 or 6 percent?

MS. NEUMAN: So that administrative service fee would be paid to both people who are in the buy-and-bill payment system and people who are in the DVP. It would be the amount that is paid under the physician fee schedule or outpatient prospective payment system.

Under the buy-and-bill, you would get ASP+3 eventually, and under the DVP, you'd get the DVP price, which would be no higher than ASP, but it would be exactly what you acquired the product for.

MS. BRICKER: There is no add-on?

MS. NEUMAN: There is no drug add-on. Correct.

MS. BRICKER: Fee add, like for the administration?

MS. NEUMAN: There is this fee for drug administration services under the fee schedules, and that goes to providers, regardless of which system they are in.

MS. BRICKER: Okay. I didn't understand that.

So, in the buy-and-bill, you get ASP+6 plus the administration fee?

DR. MILLER: Correct.

MS. BRICKER: Gotcha. Okay. So future, worst

case, ASP plus the administration fee. Gotcha.

DR. MILLER: Yeah. But if they can negotiate something down below ASP, then they get that piece.

MS. BRICKER: Okay.

Last question. You mentioned on the savings -- I was shocked that it's so small, 1 percent, $250 million, first year.

MS. NEUMAN: Okay. Mm-hmm.

MS. BRICKER: Is that just ASP reduction, or what is that?

MS. NEUMAN: So the first year of the policy would be the four ASP provisions that Nancy discussed.

MS. RAY: So it would be the consolidated billing, the inflation rebate, the moving from WAC+6 to WAC+3 and improved data reporting.

MS. BRICKER: I was just surprised that all of that reform, we would just see a 1 percent savings in plan year one. Am I missing something?

DR. CROSSON: Well, I think it is the fact that the expectation is that it would take time to develop the DVP, and that whole mechanism is further out in that 5-year window. I think that's the issue.

MS. BRICKER: Yeah. All the other things, absent DVP, I was just surprised it would only result in a 1 percent savings.

DR. MILLER: Well, the other thing I just want to get across is that the numbers that are in the piece of paper that you have in front of us are a range. We are required to do that because we don't do point estimates. CBO has to do the point estimates. So it could be higher than the 250, which is the lower end of that range. But you're right. It's not huge.

And I think some of it also is that the inflation index is one of the components, and of course, that's something that would play out over time. So when you look at that first year, you're probably not getting much out of that, would be my on-the-fly response, and so what you're really probably looking at there is the WAC+3 and the consolidated billing. And to the extent that that relates to biosimilars, it's going to affect just that group of drugs.

MS. BRICKER: One last thing. I just noticed on our reading material, 6, the number one drug in spend took zero inflation since its launch in '13. Is that right?

MS. NEUMAN: Yes.

MS. BRICKER: Thank you.

DR. CROSSON: Clarifying questions?

Jack.

DR. HOADLEY: So I have a couple that are kind of down in the weeds. One was I was just struck by Amy's comment. It seems like we discussed this once. The inflation adjustment, are we basically going to only look at -- proposing only to look at inflation from essentially the enactment of this new policy forward, or is it sort of retroactive to inflation that is historical?

MS. NEUMAN: It would largely be from the policy going forward, although you might set it a couple quarters back so that you avoid opportunities for gaming.

DR. HOADLEY: Yeah. Okay. Or even from enactment of the law or something like that. So, I mean, that would be part of why the savings wouldn't be as great, as if we were sort of recapturing sort of historical inflation.

In the reading materials on pages 36 and 37, this may have been in previous rounds, but I missed it. This one had to do with the footnote where you talk about what

happens to the consolidated billing code at the front end when the new biosimilar enters the market, and you say there that the payment rate, until there is an ASP for the biosimilar, would be based solely on the ASP for the old drug.

In looking at the two examples that we have in the case of Zarxio, that will cost us a little bit in the sense that Zarxio came in with a WAC that is below the competing drug, but in the case of the Remicade and Inflectra, the biosimilars come in 20 percent higher. I guess I am just sort of wondering about -- would there be other -- would it be worth sort of mentioning there might be other ways to think about that, whether we would want to sort of use the WAC for those first couple of quarters as part of setting that consolidated billing code? And sort of regardless of that, it does seem like probably that should be -- that policy point should be more than just showing up in the footnote because it seems like it's actually potentially fairly important.

MS. RAY: We can reflect your comment in the chapter. Yes.

DR. HOADLEY: And my other question comes up in

the reading material on the DVP arbitration, and it was sort of triggered by Bill's comment, which is whether each of the DVPs would do a separate arbitration.

I know in the material, you do sort of speak to that as one of the questions to be resolved, but it sounds like in the way that you phrased it there that you are sort of concluding that the only logical way from sort of an administrative point of view is to have them do it collectively. I just wondered if you had any more to say.

With Bill's sort of idea that that could potentially include some discussion over formulary placement, that would be a reason why sort of separate arbitrations could make sense. So I just wondered if you had any more thinking about sort of separate versus collective.

MS. NEUMAN: So from an administrative perspective, what you said about anticipating just one arbitration for a product in a time period was the thinking, and the paper sort of discussed the arbitration potentially being quite narrow, so just price or something like that. And in that case, there wouldn't necessarily be issues if a group of DVPs were represented by a single

arbitration. So you might have to narrow your scope to sort of make it work.

DR. HOADLEY: So it might just be worth kind of putting that elaboration in.

DR. CROSSON: Questions. Alice.

DR. COOMBS: So say a provider goes with a DVP program. Admin costs before and after changes, or is it fixed, and what percentage? The administrative costs.

MS. NEUMAN: Could you say a little more?

DR. COOMBS: So what is the baseline administrative cost prior to the DVP program currently?

MS. NEUMAN: So how much are we spending on drug administration? I'd have to look. We had it in our chapter. Yeah, I think it's in a footnote. We can find that for you.

DR. COOMBS: Okay.

DR. MILLER: But the fundamental answer, though, to her question is -- and I think this came up in Amy's question -- is what they get through the fee schedule for the administration doesn't change if they're in the buy-and-bill or in the DVP.

DR. COOMBS: Right, right. Okay.

DR. MILLER: So whatever the number is, it can remain --

DR. COOMBS: Do going into the DVP does not change that at all in the big picture?

DR. MILLER: No.

DR. COOMBS: Okay.

DR. MILLER: But I also don't want anybody to miss this. What is changing is what is paid for the drug.

DR. COOMBS: Right.

DR. MILLER: You stay in the buy-and-bill. Buy-and-bill starts to move to 103, and then if you go into the DVP, it is the negotiated price. And then if you have savings, you share in those savings, but the admin underlying fee to the physician for the administration of the drug stays constant between the two settings -- or I mean two payment systems.

Dr. COOMBS: Right, right.

And have we thought anything about provider-owned DVPs in terms of if that were to occur?

MS. NEUMAN: So that is not something that we have contemplated.

DR. MILLER: I was going to say the direct answer

is no. I hadn't thought of it until this moment.

Do you have a concern or a set of issues there?

DR. COOMBS: Well, I would just encourage us to kind of maybe spend some time thinking about it.

DR. CROSSON: Bill.

DR. HALL: Thank you.

The third or fourth time around, I think I am starting to get this. I really appreciate the detail that you have been able to provide.

I have just a question about the potential of adding another way of payment. Very heavy on negotiation, arbitration when necessary. There is very little mention of the value, clinical value of the products that we are talking about, and I think Alice is going to lead us into a discussion about low-value products.

So I introduce a new drug into the marketplace. The arbitration for pricing on that is based solely on things that don't really relate to what we will know about the drug 2 or 3 years later or maybe 10 years later, where it has inherently low value. Is there any way that this new system could be manipulated by manufacturers who put kind of a bum product on the market? What level does that

take place, and can we get more value, clinical value in addition to financial cost for a rectification?

MS. NEUMAN: So if a product comes on the market and it doesn't have any clinically meaningful improvement over other products that are already on the market --

DR. HALL: Yeah. All we know about it is it has a different -mab at the end of its name.

MS. NEUMAN: And so --

[Laughter.]

MS. NEUMAN: So, in that case, if there is a sense that the products are similar, that one is not better than the other, then some of these tools that the DVP vendor have would permit it to potentially secure discounts through formulary and other kinds of management tools.

And if the product is not any better than other things on the market, then it wouldn't necessarily be a candidate for arbitration because those other tools that we have been talking about would be put to use, and it wouldn't probably meet the criteria for arbitration.

DR. HALL: Just a thought that as we modify and develop this, this might be an added opportunity associated with this new structure to take a look at value-added as

opposed to value-diminished when we introduce new products that don't work.

DR. CROSSON: Clarifying questions?

Bruce.

MR. PYENSON: Thank you.

There's a footnote, Kim or Nancy, on page 8 on how ASP is calculated, and there's some words there that sound legalese, as though they're taken from a legal document of what does not affect average sales price and its bona fide service fees; for example, fees paid by the manufacturer to entities such as wholesalers and so forth. And I've got a couple of questions about that, which perhaps you could help me with.

One is, are we talking about 3 percent, 5 percent, 50 percent? Is there any view of how big those payments could be or are in the real world?

Another is that condition of what's characterized as a bona fide service fee, is that fee -- there are some conditions listed there. One is that the fee is not passed on in whole or part to the customers of the entity, meaning the customers of wholesalers. And how that's administered; that is, is that a rule imposed on the manufacturer and not

-- it's not a rule imposed on the wholesaler, presumably, or is the manufacturer required to have that -- those terms in its contract with wholesalers? So how would that rule be enforced downstream from the -- and I know this is pretty esoteric, but if you could shed any light on that, that would be great, or perhaps these are topics for future.

MS. NEUMAN: So a couple of responses. The definition that you have in that footnote is the definition that CMS came up with through regulation, and that is what they tell manufacturers is okay to exclude from the ASP calculation. So it is legalese because that is sort of what is in the regulation.

We ourselves don't have a good window on sort of what the size of these fees are and sort of how they are being implemented on the ground. We hear anecdotally that there may be some vagueness to some of them, and there could potentially be use for more guidance. And so we have tried to reflect that. You brought it up in the last meeting, and we've tried to reflect that in this draft, this idea that there might be a role for more guidance to sort of improve the quality and precision of the ASP data

that's reported.

MR. PYENSON: Thank you.

The other question I have is on the terms of the fee not be passed on from the wholesaler to the wholesaler's customer. How would a manufacturer know, or how would a manufacturer enforce that?

MS. NEUMAN: I can't speak to that currently. We could look into it further for you.

MR. PYENSON: Thank you.

DR. CROSSON: Kathy.

MS. BUTO: I wonder if you could help me understand how the inflation rebate approach would be updated each year. In other words, I can understand how it would be applied the first year that a drug price rises above -- or the increase rises above the inflation limit. How would you, going forward, update that?

MS. NEUMAN: So we sort of borrowed here from the concept that Medicaid uses, and they sort of a cumulative approach. So they have some base period, and then they look at how much the consumer price index for urban consumers has increased between the current quarter that they are looking at and that base period. And they look at

the cumulative change, and then they compare it to the cumulative change in the reported price for the drug over that same period. And so, in that way, as you continue further quarter after quarter, you get a new cumulative number, and that's how it gets updated.

MS. BUTO: Okay, okay.

Just a couple of sort of almost editorial comments. On page 11, you discuss some of the non-Medicare issues that affect drug pricing, including patent and data exclusivity, and I think it's helpful for the reader to explain the differences there and why you think -- why those are related to price, that patent life really starts are a much earlier stage, and then it depends on FDA approval times, and then date exclusivity is a different deal. But both of those have an impact, and I think it's helpful, rather than just throwing them out, to explain that a little bit more.

On page 43, I think you were giving some examples of some drugs where -- really to talk about consolidated billing codes, where price increase differences really didn't seem to be affected. There wasn't effective competition, if you will. And I found it -- the examples

were useful, but using percentage increases wasn't that helpful. In one case, I think it was -- I can't remember which one -- one of the examples you used, a combination of actual absolute price for one drug in the two you were comparing, and the other was the increase in prices percentagewise for the other one. I mean, I think it would be useful to have both the absolute prices and the increases just for clarity, because I think it makes the point more precisely.

And then the last point is really related to, I think, what Bill Gradison and Jack have touched on, and it has to do with the VBP and the use of arbitration. I listened to the presentation, and when, Kim, you were talking about it, you alluded to the fact that the binding arbitration might serve as a propped -- or incentive for manufacturers to sit down and negotiate. And I don't think that these other options for single-source drugs or new drugs comes across as well as it should. In other words, arbitration is one tool, but it actually might provide incentives for other arrangements that might achieve the same goal, and that really gets to Jack's point of different VBPs might have greater or lesser leverage in one

respect or another, including demanding better data on the first years of a new drug, et cetera.

So I would just try to beef that up a little bit. It's certainly implied in the write-up and in the recommendation, but it comes across more as, you know, binding arbitration is the way to deal with these. But I think you meant there would be greater flexibility.

DR. CROSSON: Thank you.

Questions? Brian.

DR. CROSSON: Thank you. Questions? Brian.

DR. DeBUSK: I wanted to revisit the footnote that Bruce mentioned back on page 8 on the ASP calculation. I understand we need to dig a little bit more into, you know, what is a bona fide fee paid from the manufacturer to the GPO or to the distributor. But could you help me understand how that would work within the context? Some of these wholesaler agreements to the providers actually have negative distribution margins. I mean, you will see a pharmacy distribution contract at, say, cost minus 7. Could you help me understand how that would work if you had a negative distribution margin but then these other fees were coming in? How would all that work to alter the ASP?

And, by the way, Bruce, to your question earlier about would they know, yes, wholesalers do give sales tracings, what they are called is "sales tracings," back to who they sold those drugs to.

MS. NEUMAN: So I understand your question, and I don't think I can speak to it at this point. I do think it's something that we need to do a little bit more digging on and think through and come back at a later time.

DR. MILLER: And the two questions that I've heard come up on this is: Do we know what this number is? And I'm worried that we're not going to have a lot of line of sight on that, so just -- my job is always to lower expectations. And then I think the second question which maybe we could bring something to is: Well, if you were to enforce this or how you would know, you know, either from a manufacturer, a wholesaler, or program point of view, maybe we can bring something to bear there. But I'm not optimistic that we're going to be able to know what these numbers are. I'm not sure how we would know.

DR. DeBUSK: If I could follow up on that, I would just be curious to see how a negative distribution markup would actually allow a higher price to be sold --

you know, the ASP recorded to the wholesaler would be higher, but then you would provide it to the hospital or to the provider at a negative -- say a minus 7 markup. But then these other fees would come back in. I'm just trying to figure -- it seems like that would artificially inflate the ASP, you know, possibly double digits. So any work there would be appreciated.

DR. MILLER: Yeah, and it might be that we could put together a hypothetical example about how if somebody were to do X, you know, how does it trace through to the ASP as opposed to what's actually gone on, which I think we would have a hard time getting into. But I think I see your point. If I were to do X, how would that play through to the rest of the ASP. We may be able to mock up something like that. I guess.

[Laughter.]

DR. MILLER: I just got the look from Kim that was like, "We're going to talk about this."

DR. CROSSON: Okay. Thank you. Good questions.

We're going to proceed to comments and then proceed to the vote. What I thought I would do in terms of starting the comment period is to make a few remarks, I

think which will be understood by the Commissioners, but I think for the benefit of guests -- and we have a bunch here today -- who have not been present over the last two years or so as we have worked on this issue, to provide some context.

The Commission has been working on this issue for two years or so. Why? Because we felt that it is our obligation to deal with the escalation of the cost of drugs, including in this case those that are paid through Medicare Part B, for the benefit of the long-term solvency of the Medicare program and also for the growing cost burden that is borne by Medicare beneficiaries, many of whom are financially vulnerable. That is, in fact, those two aspects -- solvency of the Medicare program and the benefit of beneficiaries -- are our primary duties.

That said, this is and has been a complex undertaking because, first of all, Medicare does not directly pay drug manufacturers or distributors; and, secondly, Medicare does not set the prices it will pay for drugs either in Part B or Part D, but it does that for almost everything else it pays for. So we fundamentally have been dealing with a different situation than we do in

most areas of Medicare expenditures, which has added to the complexity, really, of coming up with a set of recommendations or a recommendation with multiple parts.

So that said, we have come up with a recommendation, and it consists necessarily of a set of parts which we believe are balanced in a number of ways.

First of all, we understand -- again, referencing Part B Medicare drugs -- that physicians should not have to be in the position of providing Part B drugs at a financial loss. However, the current 6 percent add-on payment overpays many physicians at institutions and is inherently a cost-inefficient payment system for the Medicare program. Therefore, an additional better option is needed both for Medicare, for the beneficiaries, but also for physicians.

Second point: The problem of escalating Part B drug costs consists of both very high priced single-source drugs, including newly launched drugs, and an unsustainable and seemingly inexorable annual price increase for many other drugs, where in theory competitive market forces should be more effective than they appear to be. Our recommendation, we feel, addresses both of these cost issues.

In summary, our recommendation contains elements which are intended to do three things: to strengthen market dynamics for Part B drugs by creating more equilibrium between the buyer and the seller than currently exists; to provide physicians who administer Part B drugs with an alternative reimbursement system through which they can more broadly participate in lowering overall drug costs for their patients, while preserving quality and then share with Medicare in the results of that success; and, lastly, to ask Congress to provide the Secretary with certain administrative tools designed to supplement market forces where that's necessary.

So now we will proceed with comments and proceed to a vote. Could I see hands for those who wish to make comments? We'll start over here with Paul.

DR. GINSBURG: Sure. Well, you know, what guides my thinking in this Part B drug area is thinking that Medicare as a large third-party payer, you know, always needs to take steps to make sure it's paying the right amount, and usually what we guide ourselves is that the right amount would be something like the outcome of a market that we can't have because of third-party payments.

Now, when I look at these proposals, I am particularly enthusiastic about the DVP proposal because this proposal actually promises to create a competitive market. It really is proposing to do something that is analogous -- it's certainly not identical -- to what the design of Medicare Part D has done of engaging private plans to establish formularies and use other practices to get closer to what a competitive solution would be. The difference, of course, is that the decisionmakers in Part B are much more the physicians than they are in Part D where beneficiaries are going to pharmacies.

Now, it is not often the case that we have an opportunity to actually foster competition in markets that are important to Medicare. In that case, we tend to turn to trying to simulate markets, and I think one of our crudest things but I think an important thing is the inflation cap. The inflation cap clearly is not a market force. But I think the basis of the inflation cap is saying that these price increases we're seeing are not the true outcomes of a cost-driven marketplace, but really the outcomes of a change in the demand side of the marketplace that have made the equilibrium prices of drugs much higher

than they were before, and I've always seen these continual price increases as an adjustment to a market that is far more favorable to the manufacturers because of expansion of insurance coverage than was the case before.

So for that reason, I think there is a good rationale, even though it's crude, to have these inflation caps.

DR. CROSSON: Kathy.

MS. BUTO: So I support the Chairman's recommendations. I continue to -- let me start with the WAC add-on. On that one, I would just suggest -- and I think Bill Gradison actually suggested this last time -- that we may want to leave ourselves a little room to take a rebate approach on this similar to the rebate approach we're suggesting on the ASP inflation limit. In other words, base the reduction on the actual drop in ASP after the first two quarters. That has more of a feel, if you will, of letting the market, you know, tell us what that discount should be rather than an arbitrary just reduction.

I continue to see some asymmetry between the way we're thinking about the inflation rebate approach and the consolidated coding approach, which is that, if I

understand this correctly, the rebate approach requires CMS to adjust the beneficiary co-pays down. The provider payment actually has to go up to compensate for the lower beneficiary co-pay. And the 6 percent add-on has to be adjusted down. So a lot of adjustments to make this work. And, in essence, the underlying thinking there is we don't want the provider to have to bear the risk. We'd rather have the manufacturer bear the risk of that limit.

On the other hand, with the consolidated coding approach where we're consolidating, in the case of the recommendation, biosimilars with the originator biologic, there if the physician feels from a clinical perspective that a drug that is higher priced than, say, the weighted average payment rate, the provider has to bear that entirely, that cost entirely. I think the beneficiary is protected, as I recall.

But, anyway, to me there's a little bit of asymmetry there in our thinking about wanting to be very protective on the ASP inflation limit, protecting them from price increases, while, you know, on a clinical perspective, if there's a judgment there, they're really kind of more exposed. So, again, I support the

recommendations, but I see that as a little bit of an asymmetry in our thinking.

And as I mentioned in the prior round, I think that to the extent you can elaborate more on the use of arbitration and other alternatives, I think that's helpful in thinking through something which has never really been used in Medicare before, which is binding arbitration. I just see it as a difficult thing to execute, but it might be a helpful bit of leverage in order to get other things done.

DR. CROSSON: Bruce.

MR. PYENSON: Thank you. I support the Chairman's recommendation, and without going into a lot of detail, I think the changes will have ripple beneficial impact through the health care system, on the commercial side as well. So I think there's a lot of richness in the suggestions that will have other beneficial effects beyond Medicare.

DR. CROSSON: Bill.

DR. HALL: I support the recommendations enthusiastically. I think we're going to learn a lot from this.

DR. CROSSON: Comments? Alice.

DR. COOMBS: I support the recommendations and, first and foremost, I am happy to say that cost sharing for the beneficiaries is one piece that has been addressed by that.

In terms of the provider side, several things have come up in my mind and others' regarding the providers having changes that might occur in the midst of a contract period with formulary changes, and that's one thing that I think what we don't know is how that's going to impact providers. I think providers that are in smaller practices may be a little bit more fragile and susceptible to changes within formularies, changes with the manufacturers, changes in the price. So that's what we don't know in terms of how a DVP might work in the setting of abrupt changes, whether or not there is a product that is not included as a part of the negotiations and may be required. How easy will that be for the provider to acquire something that's not on formulary in a timely fashion? So those are some concerns I have.

What we don't know is eradicating the 6 percent and is it going to be adequately replaced by the shared

savings? That's unclear. But I think the golden nugget of this whole family of recommendations is the inflation rebate, and I think that -- and I said this from the very beginning, that all the other health care industries are held to a very different type of benchmark in terms of rate of increase, and I think that this should be internally consistent with what we've done for the other health care industries, such as hospitals and providers.

And so, going forward, my key concern would be how providers will adjust to acute changes within the manufacturer's price or the contract or the DVP program, and whether or not the DVP program would have differential negotiations with different groups. That may become problematic as well.

So those are some of the issues that I think we should kind of describe going forward in terms of these are the things that we don't know in terms of how providers will deal with it, but the cost savings that accrue to the beneficiaries I think is a key part of this.

DR. CROSSON: Jack.

DR. HOADLEY: So to start with, I really want to note how pleased I am with all the great staff work and

research that has gone into this over the two years of this effort. Kim and Nancy and all the others have done a great job in both explaining this stuff to us as well as bringing us a lot of really relevant data. And I think our own evolution from just raising this issue a couple years ago to getting to the point where we now have a nice package of recommendations, maybe we should pat ourselves on the back for that as well.

Like many of us, I've got some parts of this that I'm more optimistic about than others. I remain somewhat skeptical about some aspects of the DVP. It has grown on me a bit over the discussions, and I do think we've evolved a good model for it, a big improvement over the old CAP, and so it is definitely something that will be worth trying.

I'm maybe more optimistic about some of the other measures, including reducing the ASP add-on and even thinking back to getting it away from the percentage add-on that we talked about a year ago, the inflation adjustment, the consolidated billing, which I think, you know, may be very important towards -- movement towards biosimilars, which, you know, right now is just a couple of drugs out

there on the market in the U.S. but is likely to be a lot more over the next few years. And I continue to hear others outside of this group who like this kind of a notion of some kind of way to use a consolidated billing approach to move us more quickly towards biosimilars.

And then the last thing I would say is just to note that, as we have noted all along in these discussions, there are other important steps that are outside of our scope that I think are just important to point again to. One is that the FDA's process of approving biosimilars as well as some of the rules that they operate under mean that we're much behind Europe in getting a lot of biosimilars approved for the market, and hopefully that will change, and we'll get more of these out of the FDA in the near future. We're definitely going to need better understanding about substitutions for biosimilars. Part of that is getting the FDA to settle on its interchangeability policy, but it goes beyond that. And, again, what can we learn from the European experiences in where some of these that are maybe not ending up deemed interchangeable by the FDA, still are considered by the research record to be good substitutes? And we just need to understand that more.

And then it goes beyond the biosimilars, you know, and I think it's good that we're raising the issue of continuing to look at the consolidated billing options outside of the biosimilars. They will be more difficult undoubtedly, and so part of that is the need to understand better the comparative effectiveness and the cost effectiveness of the competing products for rheumatoid arthritis, for macular degeneration, for multiple sclerosis, and a lot of these other conditions that have very expensive drugs so that we can, you know, get the system -- get Medicare to move to the less expensive effective alternatives where that's possible.

Thank you.

DR. CROSSON: Comments? Amy.

MS. BRICKER: Again, thank you so much for all of the work. These issues are so complex, and I would say that I am in support of about 80 percent of the Chairman's recommendation.

You know, three things have really been for me hard to rationalize and support wildly, and those being -- and this is consistent with prior comments I've made, but I would like to go back through it.

So consolidated billing. I understand why the Commission wants to get in front of, you know, biosimilars and biologics and the pricing associated. You know, the comments that Shinobu made around novel products and single-source branded products and the gross price increases that the system has incurred, I mean, you would want to then put something in place today so that you could potentially head off, you know, a future path. I understand that.

My concerns remain around biosimilars have so much headwind. There has been so much regulation already put before that's naming -- and in the chapter around Part D, we go through this, right? So this is the least of my concerns, but I could get there. I understand why we want to do it. I just still fear, given the infancy of biosimilars, why would we not encourage more manufacturers to market. So that aside.

Inflation cap, I mentioned this, and the reason for my questions around the inflation cap were really to better understand what's driving the inflation. I am concerned that if it's not generics, if generics are actually deflating -- I don't know. That's just a

question. If generics are deflating and yet we encourage an inflation cap, do we, in fact, cause the generic deflation to reverse to inflation, if that's, in fact, happen. I don't know.

I would encourage us to not have the government set inflation protection. So in the Part D space, it's in your Part D materials, too. This is very common for private entities to negotiate with manufacturers around inflation protection. But it is a matter of private contract. And so if there's a way to do this as part of the DVP, I would be more enthusiastic about it versus just setting a blanket you're going to only inflate by X percent.

Which brings me to my last point. So I was really encouraged, like others have already mentioned, around embracing more of what is working today in Part D and in fostering a free market sort of approach. DVP, while wildly complex, while creating an entity that does not exist today, there are so many tentacles with respect to how this will operate. I am in support of us attempting to get there.

I am absolutely opposed to arbitration because

the message that the Commission is sending is that we believe in free market, but then we don't. The free market today would allow for many of the things that we're attempting to do with the DVP. But then to say unless the free market can't do it, then we have this other solution.

So the things I think are still worth considering, and I fear we haven't had enough discussion around what does arbitration do, how does it play out, is that I go back to if -- and this is Part D, but just so -- because everyone is aware of what happened with hep C. But if arbitration existed when hep C products came to market, and the manufacturer said, "I want $100,000," and the DVP would say -- I'm just making this up -- $75,000, how would we have ever gotten to $40,000, which is where we are today? You have an outside entity that's saying, "I think $75,000 is fair."

So as competition comes to market and you have more entrants, why would they go to 40? They would stick at, "Okay, I'll got at 70, I'll go at 68." I don't think that arbitration ultimately results in lowering the pricing. I don't. I think the way also the DVPs are structured, we have to solve for then how are they not

colluding. So I have a competitor, two, three, how am I going to tell my competitor, "I can't get a deal done. Can you?" "No." "Okay. Let's go to arbitration."

This is counter to the free market and in fostering competition. So for me, it's a bridge too far. I understand why, again, the Commission wants to do this, because we see and we feel paralyzed by drug pricing and practices, but there is a way for us, I believe, to foster competition, to bring value to the market without adopting something as drastic as this.

Thanks.

DR. CROSSON: Comments? David.

DR. NERENZ: Yeah, thanks. I do in general support the package. I share some of the concerns that others have raised, and I would just for my own part emphasize again the need, as this rolls forward, if it does, past our recommendation, to create the strongest possible shared savings incentives in the DVP. I think we have seen other examples in other CMS programs about shared savings that are quite weak. In my judgment, they don't affect provider behavior. They don't move the policy world in a direction, and so I think particularly if we want that

to be the main pulling factor to get physicians or physician groups into this, I just think -- but I think we've made our statement here. It's then up to Congress and CMS to act.

I would say in response to and respect for Amy's concerns, I think also about process, you know, we've arrived at this point. We have a recommendation on the table. It's sort of a package. I will support it. But I think also it's good to have those concerns on the record. So as this does move forward, there may be room in the regulatory space to do something more about arbitration. So I do hear and respect those concerns.

DR. CROSSON: Comments? Rita.

DR. REDBERG: I just want to speak in support of the Chairman's recommendation. I think a lot of the Commissioners, Jack and Kathy, and certainly I think shared savings is important, and I really appreciate the work that Kim and Nancy and others put into this because it took -- you know, it was clearly a big issue, a big problem, when we haven't really looked at except for the last few years, and then it was really thoughtful, and I think a framework that is very useful here and may be useful for other things

that we're going to talk about. So thank you.

DR. CROSSON: Comments? Warner.

DR. GINSBURG: I would like to make a comment [off microphone].

DR. CROSSON: Do you want to make a comment on that comment or a separate comment?

DR. GINSBURG: On Amy's comments [off microphone].

DR. CROSSON: Okay. Go ahead, Paul.

DR. GINSBURG: I think Amy's concerns about arbitration are well taken, particularly bringing up the dynamic aspect of arbitration, that there may be no close substitutes today for a drug, but there might be tomorrow. And it really got me thinking about the fact that we probably should include a mechanism where the ability to go to arbitration about a price is withdrawn once substitutes enter the market, should that happen, because I am concerned about the dynamic of it that she mentioned. I think we could probably design a way to address at least some of that risk.

MR. GRADISON: On that point, may I?

DR. CROSSON: Can I just -- that is the

intention, Paul. I believe it's in the text. If it's not, it should be. Bill.

MR. GRADISON: Exactly. I mean, my understanding is the arbitration approach would only be used if there were sole-source, and if you have a competitor, it's not sole-source. It would fall down to the inflation category and be considered under a different pricing mechanism.

MS. BRICKER: Just to clarify, if I may [off microphone].

DR. CROSSON: Yeah.

MS. BRICKER: My concern isn't that you're going to go to arbitration when there's competition. It's that an arbitrator has essentially determine what is "the fair price." And so you don't have leverage -- your leverage is reduced in the future, I fear, that if an arbitration has said the fair price is $75,000, in my example, how do you ever get to something far less? You have an outside force that's already declaring it's been fair. So that's my concern.

DR. CROSSON: I think, Amy, if I could respond there, I think the intention -- and perhaps it's not laid out exactly -- although I can't remember exactly, but the

intention here is that were arbitration actually to be triggered -- and, again, I think we have heard the comments that particularly based on the design of the arbitration, it would be a very unusual phenomenon. But once it's triggered and let's say the arbiter finds for a particular price, that doesn't mean that that is the price forever. What it means is that's the most that can be charged. And, therefore, in the event that a second drug or a third drug comes on the market and now we have a competitive dynamic that we didn't have before, that negotiation process that would take place based on that competitive dynamic could very well drive the price lower.

MS. BUTO: But, Jay, I think Amy's earlier point, which I really see, is that the shadow pricing that goes on with the second and third and fourth drug, there will be -- there could be some sluggishness in price reductions because there is an established price. In other words, the willingness to go a lot below that may slow down, and I think -- I'm trying to think of the example, but there have been examples in Medicare where the regulated price really can interfere with, if you will, market forces. So I think that was the point I got from your comment, which I hadn't

thought about before but I think is worth at least noting in the text, that this is a concern, and that's why you'd want to use it rarely.

DR. CROSSON: Okay. Fair enough. Thank you.

DR. REDBERG: Can I just --

DR. CROSSON: I'm lost now. Where am I? You.

DR. REDBERG: I understand your concern, but I don't actually share it, and I have not been impressed that market forces work very well at all in drug pricing or that arbitration could not work better than where we are now.

DR. CROSSON: Okay. I think we had Warner last.

MR. THOMAS: Thanks. First of all, I want to applaud the work that has been done, and I think that this is certainly a step in the right direction.

I guess my view is that, given the magnitude of the issue, I still wish the Commission was going further from a pricing perspective. I believe in the fair -- you know, a competitive market, but I would agree with Rita that I don't think that a competitive market has worked in pharmaceutical pricing. I'm not big on setting pricing, but we do it in every other area of Medicare, and that's just the reality of how the system works today.

My preference would be seeing us move to more of a price-setting model for pharmaceuticals given the magnitude of them and given the fact that -- I mean, we were just talking about Part D, which I believe is more of a fair market model, that I think we heard is running a price increase of 8 to 9 percent and a cumulative increase of 200 percent over a pretty extended period of time. So it would appear that that fair market model has not necessarily worked to create the right pricing competition and to control pricing over time.

With that being said, I think the inflator is a good model to help control that going forward. I would encourage us to look at the market basket for providers less any sort of rollbacks or adjustments that are applied to them, because I think that is applicable so that we get a net amount of that.

I think the last comment I would make is that I would hope -- I know the DVP would be put in place by 2022. My hope would be that that could potentially be accelerated given the magnitude of this issue. But once again, I would like to see us go further given the seriousness of the cost increase here.

I also would ask in the chapter if there could be -- I know there was a paragraph put in related to the profitability of this industry. I would ask to see more information of what's available out there because, once again, when we do this in other components of the programs, inpatient, home health, physicians, et cetera, we have a pretty robust discussion of this area. And I think that's an important background context of how we set all this policy going forward.

But, with that being said, I would applaud the fact that there is information in there that I think is helpful as we make this decision.

Thank you.

DR. CROSSON: Brian.

DR. DeBUSK: I enthusiastically support the Chairman's recommendation as written. I think the Drug Value Program has a lot of really good thinking that's been placed in it, particularly around some of the agency issues and the way that there are different tiers. You know, it's a complete tool set for working with manufacturers.

I also want to take just a moment and comment on the proposed improvements to the ASP system, because,

unfortunately, we've been saddled with a system particularly for single-source drugs that is designed to increase prices. I mean, if you look at a system where the more you -- the more expensive it is, the more you make, I mean, it's just -- I mean, the system's working as intended. And I know in the text, particularly in the introduction, you know, we talk about -- I think the word we use is maybe "concerns" exist. Well, it's beyond concerns. I mean, it's obvious, and that we've wired a system to work a particular way, so we shouldn't act surprised when it works the way we wired it to work.

So my comment on these improvements to the ASP system, to me this is -- and I share Warner's concern. I don't know that we've gone far enough. I mean, I would describe what we're doing as a gentle tapping of the brakes on a system that's designed to go faster and faster.

So I see these as very reasonable recommendations, and, again, I enthusiastically support the recommendation as written.

DR. CROSSON: Seeing no further -- seeing one further comment.

MR. THOMAS: Sorry. And I do support the

recommendation, by the way. I think the other comment that I would have, getting back to ASP, is that it still does come back to essentially pharmaceutical companies setting their own pricing. And I think the other thing that -- and this may, you know, not be a popular view, but I think the other thing is that this is a domestic price. It would be interesting to see what ASP or the WAC looked like if you looked at a global price versus a domestic price. I know that that's probably outside of the realm of this, but I think just from a competitor perspective, it could be an interesting thing to look at, and it may reset people's views of how they look at pricing overall.

So, anyway, with that being said, I'll end there, Jay. Sorry.

DR. CROSSON: Okay. Thank you. And we have come to an expiration of the time, so we'll proceed to the vote. The recommendation is before you. Can I see the hands of all Commissioners voting in favor of the recommendation?

[Show of hands.]

DR. CROSSON: Okay. Thank you. All those opposed?

[No response.]

DR. CROSSON: All those abstaining from voting?

[No response.]

DR. CROSSON: Okay. We have reached an end of this. Again, Kim, Nancy, thank you so much for so much work and perseverance and imagination and helping us get here.

Just for the record, we have one Commissioner, I will say, who has been detained. We will record his vote later in the day provided he is able to make the meeting before we adjourn this evening.

[Pause.]

DR. CROSSON: Okay. I think we can sit down now and get back to work.

Now I think we are going to move on to a much easier issue.

[Laughter.]

DR. CROSSON: Eric, did we give you any medal or formal recommendation -- or recognition for the chapter?

MR. ROLLINS: No.

DR. CROSSON: I can't remember. Okay. But you do realize you have set a personal record here.

MR. ROLLINS: I can't take credit for myself.

This is a --

DR. CROSSON: A group effort. All right.

Seriously, we are proceeding to the construction of a chapter on premium support, at least from the perspective of were Congress to decide to go in this direction, what it might do, and we are going to pick up, I think, the last piece here, which has to do with, were this to take place, how would we deal with the problem of low-income beneficiaries, and Eric is going to take us through that. And I hope I haven't given your intro again, but go ahead.

MR. ROLLINS: Thank you. Good morning.

Today, I am going to summarize he work that the Commission has done over the course of this meeting cycle on using premium support in Medicare.

The Commission's work often focuses on improving provider incentives, but beneficiary incentives can play an important role as well, and the Commission has been interested in premium support because it would give beneficiaries an incentive to use lower-cost forms of coverage.

Under a premium support model, Medicare would

make a fixed payment for each beneficiary's Part A and Part B coverage, regardless of whether the beneficiary enrolls in fee-for-service or a managed care plan.

The beneficiary premium for each coverage option would reflect the difference between its total cost and the Medicare contribution, which means that higher-cost plans would have higher premiums and lower-cost plans would have lower premiums.

I would like to begin by giving you a brief overview of the presentation. I will start by summarizing the main points of the draft chapter on premium support that will appear in the Commission's June 2017 report to the Congress. This chapter lays out some of the key issues that would need to be addressed if policymakers chose to use premium support in Medicare.

After that, I will review some new material that we have included in the draft chapter on the issue of providing premium subsidies to low-income beneficiaries. I will then raise some possible topics for discussion. It would be especially helpful for us if the discussion could focus on the new material.

Moving now to Slide 3, the draft chapter is the

culmination of work that the Commission has been doing on premium support since 2012. The Commission has included a chapter dealing with some aspect of premium support in its last four June reports and has devoted four sessions to this issue over the course of the current meeting cycle.

Our work during this cycle has very much been a team effort. In October, Ledia and Carlos discussed how quality could be measured and rewarded in a premium support environment.

In November, I gave a presentation that examined how benchmarks and beneficiary premiums could be calculated and explored how policymakers could mitigate large increases in beneficiary premiums.

At last month's meeting, Carlos gave a presentation on standardizing various elements of a premium support system, while Amy, Scott, and I discussed the potential effects that premium support might have on beneficiaries and managed care plans.

The draft chapter that you received as part of your mailing materials consolidates the material from these sessions into a single document and reflects comments that Commissioners made during their discussions.

I will now briefly review the main points from those earlier sessions before turning to the new material on premium subsidies.

The first key issue discussed in the draft chapter is the role of the fee-for-service program, which covers about 70 percent of beneficiaries. In the draft chapter, we suggest that, under premium support, the fee-for-service program should remain available and be treated like a competing plan. Under this approach, fee-for-service would operate much as it does now, but CMS would develop a bid for the expected costs of fee-for-service coverage, and this bid would be compared to the bids submitted by managed care plans to determine how much beneficiaries would pay for fee-for-service coverage.

This approach has several benefits, such as ensuring that Medicare coverage is available in areas without managed care plans and helping plans negotiate payment rates with providers that are close to fee-for-service levels.

Next, the draft chapter examines how much the coverage options that would be available under premium support should be standardized to make them easier for

beneficiaries to understand. We suggest that all plans should be required to cover the same benefits as fee-for-service, as they are now in the MA program.

Policymakers may also want to consider reforming the fee-for-service benefit structure to make it more similar to the benefit structures now used by MA plans, as the Commission recommended in 2012. Managed care plans would have the flexibility to use alternate forms of cost sharing and offer extra benefits, although beneficiaries would not be required to buy them, and those that do would pay premiums that reflect their full incremental cost.

Beneficiaries would also need better decision support tools to understand their coverage options and make an informed choice about the coverage that best meets their preferences.

Moving now to Slide 5, the draft chapter also examines how benchmarks and beneficiary premiums should be calculated under premium support. The benchmark would serve as a reference point for the cost of providing Part A and Part B benefits and would have two components: the Medicare subsidy and a base beneficiary premium.

For any given coverage option, beneficiaries

would pay an amount that equals the base premium plus the difference between the plan's bid and the benchmark.

Premium support proposals typically assume that competitive bidding would be used to determine the benchmarks. In the draft chapter, we discuss two possible ways to do this. The first option would use the lower of the fee-for-service bid or the median plan bid as the benchmark, while the second would use the weighted average of all bids. Both options are appealing because they would produce benchmarks that fall somewhere in the middle of the distribution of bids, instead of using something like the lowest or second-lowest bid.

The bidding process should also use bidding areas that reflect local health care markets. This would result in benchmarks that vary across areas due to the geographic variation in Medicare spending, and would provide some protection against higher premiums to beneficiaries who live in high-cost areas.

The base beneficiary premium should be similar to the Part B premium and equal, about 13 percent of total Part A and Part B costs.

Some proposals to use premium support would limit

the growth of the Medicare subsidy over time to ensure that the federal government saves money. The Commission maintains that this type of limit would not be desirable because beneficiaries would bear the risk of paying higher premiums without being able to take actions that lower their premiums in a meaningful way.

An alternate approach would be to have the benchmark, Medicare subsidy, and base beneficiary premium all grow in tandem with plan bids, as they do now in Part D, and see if competition among managed care plans can achieve savings.

Under premium support, some beneficiaries would see the premiums for their existing coverage increase significantly. The kinds of beneficiaries that would be affected would vary across areas. In some areas, the higher premiums would mainly affect fee-for-service enrollees, while in other areas, they would mainly affect managed care enrollees. Beneficiaries could avoid paying higher premiums by switching to lower-cost forms of coverage, but there would also be numerous ways for policymakers to mitigate large increases in premiums, such as phasing in the higher premiums over time.

The draft chapter also discusses how high-quality care could be rewarded in a premium support system. To do this, CMS would need to measure quality for both fee-for-service and the managed care plans within each market area, preferably using a limited number of outcomes measures. Policymakers would require managed care plans to meet minimum quality standards and would publicly report quality data for both fee-for-service and plans.

High-quality plans, which could include fee-for-service, could also be rewarded financially by increasing their Medicare contribution, which would allow them to charge lower beneficiary premiums.

Finally, the draft chapter discusses some potential effects that premium support could have on beneficiaries and plans. Premium support is based on the notion that beneficiaries will be willing to switch plans to lower their premiums. There is some evidence that this type of switching occurs in MA, but it is difficult to know how responsive beneficiaries would be under premium support, where the changes in premiums could be much larger than what we have seen in MA. In some areas, we would likely see fee-for-service enrollees switching to managed

care plans, while in other areas, we would likely see managed care enrollees switching to fee-for-service.

The effects on managed care plans are also difficult to predict. Plans would need to reassess which markets they serve, which could lead them to enter new markets and exit existing markets. The greater focus on price competition under premium support would also likely encourage plans to submit somewhat lower bids than they do now in MA. The overall effects of using premium support would vary across areas and would depend heavily on the specific features of the proposal.

Up to this point, I focused on reviewing the issues that we have discussed during our earlier sessions on premium support. Now I would like to switch gears and discuss the new material in the draft chapter on premium subsidies for low-income beneficiaries.

As I mentioned earlier, the Commission has been interested in premium support as a way to encourage beneficiaries to use lower-cost forms of coverage. At the same time, though, policymakers would need to make sure that low-income beneficiaries can afford to buy coverage. Premium subsidies are a way to balance these competing

goals.

Medicare and Medicaid already provide significant premium subsidies under current law. Medicaid covers Part B premiums through what are known as the Medicare Savings Programs, or MSPs, while Medicare covers Part D premiums through the Part D low-income subsidy, or LIS.

Premium support would effectively change how the Part B premium is calculated, so the MSPs would be a logical starting point for providing premium subsidies. However, under premium support, policymakers may want to reassess the role of the MSPs, which could include incorporating some features from the LIS, which I'll discuss shortly.

As part of that reassessment, policymakers would need address three major issues: first, which beneficiaries would be eligible for subsidies; second, what kind of subsidy they would receive; and third, how those subsidies would be financed by the federal government and the states.

We will now look at each issue in more detail.

Moving to Slide 8, we start with the eligibility rules for premium subsidies. The MSPs and the LIS both

require beneficiaries to have low income and low assets to qualify for benefits. The MSPs have somewhat lower eligibility limits than the LIS. For example, the MSPs limit eligibility to individuals with income below 135 percent of the poverty level, while the LIS has a limit of 150 percent.

In 2008, the Commission recommended aligning the eligibility rules for the two programs by raising the MSP limits to match the LIS.

Policymakers would need to weigh a number of factors when setting the eligibility limits for premium subsidies under a premium support system. For example, they would need to consider the income distribution of the Medicare population and the number of beneficiaries that would qualify under various eligibility limits.

About 15 percent of Medicare beneficiaries are enrolled in the MSPs, but the share that are eligible is larger because not all of those who are eligible participate.

Policymakers would also need to consider how much beneficiaries at different income levels might spend on premiums. The method for calculating the Medicare subsidy

and beneficiary premiums would be an important factor here. For example, a premium support system with a lower Medicare subsidy would have higher beneficiary premiums, which could be an argument for using higher eligibility limits. Conversely, the existing MSP limits might be considered sufficient under a system that has a higher Medicare subsidy and lower beneficiary premiums.

In addition to the eligibility rules themselves, policymakers would also need to determine how people would enroll in the subsidy. Policies such as automatic enrollment for certain beneficiaries, like dual eligibles, and allowing beneficiaries to enroll through the Social Security Administration would likely result in higher participation rates among those who are eligible.

In particular, allowing beneficiaries to enroll through SSA would be consistent with a recommendation that the Commission made in 2008 that would require SSA to determine if LIS applicants were also eligible for the MSPs and to enroll those who qualify.

The next issue to consider would be the amount of the subsidy. The MSPs cover the entire Part B premium, but this approach would not be desirable under a premium

support system, where premiums would vary based on their underlying costs. If the subsidy covered the entire premium, regardless of the coverage option, low-income beneficiaries would not have an incentive to enroll in lower-cost coverage.

Policymakers faced a similar issue when they created the Part D program, which uses a premium support model. Their solution was placing a dollar limit on the LIS premium subsidy. Under this approach, the LIS covers the entire premium for any plan that has a premium below this limit, which is commonly known as a zero-premium plan.

Beneficiaries that enroll in more expensive plans pay the difference between the plan's premium and the LIS limit. For example, if the limit is $30, an LIS beneficiary who enrolls in a plan with a $25 premium will pay nothing, while an LIS beneficiary who enrolls in a plan with a $40 premium will pay $10. This approach ensures that LIS enrollees can enroll in some plans without paying a premium but also gives them an incentive to avoid higher-cost plans.

This approach could also be used in a premium support system for Part A and Part B, but policymakers

would need to decide what the limit on the subsidy should be. Higher limits would give the beneficiaries who receive the subsidy a broader choice of zero-premium plans but would also increase the costs of the premium subsidy.

Policymakers may also want to ensure that the subsidy is large enough to ensure that a certain number of zero-premium plans are always available. For example, the LIS limit is determined using a formula that ensures at least one zero-premium plan is always available. If policymakers did put a dollar limit on the premium subsidy, the fee-for-service program would probably not qualify as a zero-premium plan in many areas because it would be one of the more expensive options.

The last major issue to address is how the premium subsidies would be financed by the federal government and the states. Broadly speaking, the premium subsidies could be part of either the Medicaid program, like the MSPs, or the Medicare program, like the LIS.

The simplest way to provide premium subsidies would likely be to build on the existing MSPs and modify them as needed. Since the subsidies would be a Medicaid benefit, their costs would be shared by the federal

government and the states.

The federal share for most Medicaid expenditures is determined by a formula and varies from state to state based on their per-capita income.

Across all states, the federal government currently pays about 61 percent of the cost of the MSPs' premium subsidies, with the states paying the rest. However, policymakers could change the match rate for the MSPs if they wanted the federal government to pay a larger or smaller share of the costs under a premium support system. This decision would have significant budgetary implications for the federal government and the states. For example, if the MSP eligibility limits were increased, the federal government could pay a larger share of the costs for the newly eligible population. This would be similar to the approach that the Congress used in 1997 when it last expanded eligibility for the MSPs.

Under premium support, if the premium subsidies were a Medicaid benefit, states would naturally be concerned about the potential for higher costs. However, the overall impact on state Medicaid spending is difficult to estimate because it would depend heavily on the type of

premium support that was used. For example, a system that has both low benchmarks and generous premium subsidies might be more likely to increase state costs, particularly in states where a large share of MSP enrollees have fee-for-service coverage.

Instead of a Medicaid-based approach, policymakers could also consider replacing the MSPs with a system of premium subsidies that are part of Medicare. Since the states now pay part of the costs of the MSPs, shifting this responsibility from Medicaid to Medicare would ordinarily increase federal spending and reduce state spending. However, the higher federal spending could be at least partly offset if states were required to make maintenance-of-effort payments that approximate what they now spend on the MSPs. These payments would be similar in nature to the so-called "clawback" payments that states now make to the federal government as part of the Part D program.

This presentation has focused on the MSPs' role in covering the Part B premium, but they also cover Part A and Part B cost sharing for many low-income beneficiaries. If the MSPs' premium subsidies were converted into a

Medicare benefit, policymakers would need to decide if the cost-sharing subsidies would be federalized as well, and if so, how much of the cost sharing Medicare would pay. This decision would have significant cost implications because states are allowed to limit their spending on MSP cost sharing, and almost all states do so.

Prior Commission research has estimated that states only pay about 35 percent of the cost sharing for eligible MSP beneficiaries. As a result, if Medicare covered the full amount of the cost sharing, there would be additional federal costs that could not be offset by state maintenance-of-effort payments. Furthermore, full coverage of cost sharing could create inequities across states because the states that now spend the least on MSP cost sharing would benefit the most.

Moving now to the last slide, I would like to close with some potential topics for discussion. First, we would like to know if you have any comments on portions of the draft chapter that summarize our earlier sessions on premium support.

Second, we would like to get your reactions to the new material on low-income premium subsidies that we

have presented here today, focusing on the three key issues of eligibility, the amount of the subsidy, and financing.

Finally, we would like to hear suggestions for future Commission work on the topic of premium support.

That concludes my presentation. I will now be happy to take your questions.

DR. CROSSON: Thank you, Eric.

So we will do clarifying questions. Can I see hands for questions?

We will start over here with Brian.

DR. DeBUSK: I had a question, and I guess it is derived from the footnote on page 76.

You know, it is very novel, the way you are taking that LIPSA approach to low-income subsidies for premium support, and in the footnote, you mention that in Part D, once the plan's premium drops below the LIPSA, basically there is no incremental benefit to the beneficiary to choosing a plan that is even lower cost, and that that somehow sets almost an artificial floor for how plans would want to bid in D.

The text sort of talks around it, but have we modeled or would we consider modeling what to do with that

extra money, maybe to set that money aside for some other health care spending for the beneficiary? I mean, in theory, would a negative premium, if the LIPSA exceeded the premium -- could we model out other things to do with that money that would be beneficial to the beneficiary?

MR. ROLLINS: By the extra money, do you mean the difference between that amount and --

DR. DeBUSK: The LIPSA amount and the premium --

MR. ROLLINS: -- the premium that is lower than that.

DR. DeBUSK: -- for plans that are below that.

MR. ROLLINS: It is not something that we have modeled out. You could certainly think about strengthening the incentive for beneficiaries to pick one of the cheaper plans of the zero-premium ones that are available by saying you will get some portion of this difference yourself. That would be one option.

In the Part D world, one thing that is a factor in affecting the behavior of plans not having an incentive to go much below the low-income benchmark, is the fact that of the plans that are zero premium, CMS auto-enrolls a lot of low-income beneficiaries to Part D plans and does so

equally among the plans that are sort of below that threshold.

So one concern that has been raised is that there is no additional reward, as you know, but one option you could at least consider is sort of changing the assignment mechanism that is used for plans that are below that threshold and saying the lower you bid, the more beneficiaries you could expect to get.

DR. DeBUSK: That is a great idea too. Thank you.

DR. CROSSON: Questions. Bruce.

MR. PYENSON: Thank you very much, Eric. This is really very well done.

A question on page 83 of the material on implications for beneficiaries. You identify experience, looking for precedence, experiences in the movement of consumers for MA plans and Part D premiums -- Part D program experiences on the packet exchanges. I am wondering if you think the experiences of mandatory managed Medicaid, the implementation of that has lessons for premium support. Under those programs, states rolled out mandatory enrollment in a variety of different ways. Is

that something that might be helpful?

MR. ROLLINS: Potentially helpful, I think, in certain respects, although Medicaid managed care is very different, of course, because there is no premium for beneficiaries. So it is a very different dynamic than what you would have on a premium support system for Medicare.

But I think one area where you could think about sort of drawing on the Medicaid experience is -- one option that is sort of raised in the paper is one way that you could mitigate the impact of higher premiums on beneficiaries would be to sort of the default assignment in a particular -- it could be whatever is the lower-cost option in that area. So if fee-for-service is the cheaper option in your area, the default option for new enrollment would remain fee-for-service, which is what we have today. But if you live in an area where managed care is cheaper, your default assignment would be to a managed care plan, and I think in that context, that is getting a little closer to sort of what you see in Medicaid. And what Medicaid typically does in those cases is, once you have been sort of assigned to a plan, if you take no action, they will send you a letter saying you are in Plan XYZ.

Beneficiaries usually have about a 60- or 90-day period once they are enrolled in the plan to sort of then change to another plan, and after that, they are sort of locked into the plan until the next open enrollment window. So I think that would be an element that you could think about incorporating.

MR. PYENSON: A follow-on question. But the auto, that kind of enrollment for dual eligibles, where there would be no premium, would that be an analogy also to the Medicaid mandatory managed care?

MR. ROLLINS: Potentially, yes. I mean, I think that's what the low-income subsidy does in Part D is the dual eligibles are sort of -- we don't want them to pay a premium, and so they are default -- assigned into a zero-premium plan.

DR. CROSSON: Kathy.

MS. BUTO: I have a couple of questions. One is, since Part D is essentially a premium support model, are there any lessons in terms of what LIS beneficiaries have done? In other words, have they all migrated where they auto-enrolled in the lowest-cost plans?

And then, secondly, what do we see in terms of

switching based on cost, switching behavior by beneficiaries more generally? Do we have a sense of that from Part D? Which actually I would think would be easier to switch than a health care plan, but --

MR. ROLLINS: Right.

So in terms of the overall switching, we do have some figures in there about the switching that we see in the Part D world, and I think in the years we looked at, roughly 15 percent of your non-LIS population switched from one plan to another. And we had sort of broke out the LIS population, looked at it separately from the non-LIS because the dynamics are so different. The non-LIS population is only going to move to another plan if they affirmatively choose, "I don't want to be in Plan A. I want to be in Plan B."

MS. BUTO: Right, right.

MR. ROLLINS: And within that subset, we see roughly 15 percent of beneficiaries switching in a given year.

MS. BUTO: Okay.

MR. ROLLINS: In the LIS segment, you have this additional feature of -- Part D auto-assigns you --

MS. BUTO: Right.

MR. ROLLINS: -- to a plan when you first join, and then if your plan's premium goes above this sort of subsidy limit --

MS. BUTO: They auto-assign you again.

MR. ROLLINS: -- you are assigned to a new plan. So you see a lot more switching in the LIS segment, but a lot of that is a function of sort of --

MS. BUTO: The algorithm or --

MR. ROLLINS: -- the assignment that goes on.

MS. BUTO: Yeah. It's involuntary, not voluntary.

MR. ROLLINS: Right.

But there is still a substantial segment, and Jack has looked at this. A substantial segment of your LIS population has picked a plan on their own. I think I want to say it's something like 40 percent.

MS. BUTO: Okay. The second --

DR. CROSSON: Wait. Sorry.

MS. BUTO: Sorry.

DR. CROSSON: Shinobu, did you want to weigh in or not?

DR. MILLER: I asked her to go because she --

MS. BUTO: She was his backup.

DR. CROSSON: Oh, okay.

DR. MILLER: -- made a run-in through with stuff that she had done.

MS. BUTO: Okay.

DR. CROSSON: Sorry.

MS. BUTO: The other question I had was on page 9. I am puzzling through this. It is the first bullet on -- if providers negotiated Medicare payment rates with managed care plans that were comparable to commercial payment rates, then costs for premium support could be higher than, I guess, current law or current program. So that caused me to think of two questions. One was provider consolidation is affecting costs, anyway, right? Both in fee-for-service and probably in managed care as well, so that is one.

So does this somehow -- is this related to the fact that we don't imagine managed care plans would be able to default back to fee-for-service payment rates, like DRGs and -- if they can't negotiate a better deal? What are we thinking in terms of commercial rates affecting the overall

cost of the program?

MR. ROLLINS: So I think a lot of that is driven by the feature that you have now in the MA program, which is plans, when they are negotiating rates with the providers, have by law the authority to say, "If you are not in my network, I will pay you the fee-for-service rate," and so that greatly strengthens the plan's leverage in negotiating with providers. And the available research suggests that MA plans pay providers rates that are roughly similar to what you see in fee-for-service, and so I think the concern would be if you created a premium support system that doesn't have that requirement in there, the plan's negotiating leverage would be a lot weaker than it is today, and then sort of the dynamics that you're seeing with provider consolidation could have more of an impact.

DR. MILLER: And just today, CBO came out with a report where they did some analysis looking at it and sort of arrived at the same point that we were making a while back, that the managed care plans tend to end up paying around fee-for-service, and it is something that we've talked about repeatedly. What you wouldn't want to do is import those prices that are the product of consolidation

into Medicare because you basically make premium support make Medicare more expensive.

DR. CROSSON: Questions. Around the horn, are there questions?

[No response.]

DR. CROSSON: Okay. So we will start with comments, and I see Bill Gradison.

Oh, I'm sorry. I did it again. Jack is going to kick it off.

DR. HOADLEY: Okay. So thank you, Eric. I think this is a really important topic and it also raises some concerning issues, in terms of sort of how the low-income beneficiaries are going to fare should such a system go forward. And I will talk about sort of each of the thee themes that you raised, in terms of the low-income population, and I think most of these are points that you've got but I want to sort of focus in on certain of them.

So on the eligibility level, you know, I think there's -- there are all the issues that you raised about sort of what's the right level and sort of what are the implications for spending, and some of that kind of stuff,

but I think -- and you raise this, but I think there are major issues around sort of the complexity of eligibility and the whole application process, and we've addressed some of that in the past with the notion, and you raised it again here, that Social Security Administration can be a more natural place for people trying to get their eligibility.

A couple of points. One is that it does seem, and the literature seems to suggest that the asset test is something that may discourage some people from applying, not because they necessarily have a lot of assets but because it makes the paperwork that they're required to go through much more extensive. There's all these, you know, issues of what's accepted, what are the exceptions to the assets, and so forth, and it leads to the paperwork for qualifying being more complex, and even raises some issues for people about sort of a reluctance to have to disclose, you know, the values of their assets. And so I think there is evidence there that sort of raises that, and I think that's something that we should, you know, at least raise as an issue.

You talked some about take-up rates. I think

there might be worth sort of indicating some of the levels of take-up that we have today for Medicaid Savings Program and for the LIS, and I know those data are difficult to have, you know, clean numbers on, and certainly on the LIS side we have lacked the ability to say. But we do have a sense that among the LIS they're not automatically enrolled through being dual eligibles. The ones that have to go through an application process, there's some suggestion that more than half of those eligible are not enrolled, and I think the evidence suggests it's even worse on the MSP numbers. And so that's just part of the context, and I think that becomes more important here because the consequences of not getting the subsidy that you're entitled to, I think, will be greater in this system than under the current system.

There are some studies out there. There was an analysis a few years ago, a Health Affairs article that, in particular, the Hispanic population has lower Part D enrollment attributed to lower take-up of the subsidies there. So again, there may be some factors that suggest some of the ways that we could improve it, and I think it would be useful to try to raise some of those issues.

So turning to the amount of the premium subsidy, you know, I think this discussion sometimes takes a -- when people talk about this, sometimes get into almost a sense of blaming low-income people for not being better shoppers, because of how we've structured incentives, and they end up sounding like they're at fault for not saving the government money, and I think we really need to dig deeper into sort of what's going on for this population.

You know I was looking at -- well, two points. One is that the choice of plan under a premium support model, the choice of Medicaid Advantage versus traditional Medicare, is probably going to be a much bigger deal than in the Part D world, where, you know, it's pretty much just all a financial transaction. Most pharmacies are in most networks. You know, there are some potential issues there. But for the most part you go, you pay, you get the copayment that you're entitled to. And so if you switch from one plan to another, it may have financial implications but for the most part we are shielding the low-income beneficiaries from some of those.

In the Part C world, in the Medicare Advantage world, there's a lot bigger issues about provider networks,

and I think, you know, if we're going to have the kind of situation where we're creating either strong incentives or automatic assignment of low-income folks into Medicare Advantage plans, we better make sure that we're looking at whether those Medicare Advantage plans have networks that serve the communities the low-income people live in adequately, and that they're open and available to those kinds of folks, before we start looking at that as something that either is the only way you can get Medicare without paying a premium, or whether it's something where you're being automatically assigned.

And then the other piece of it is the amounts, and I was looking at some of the charts you had in the mailing materials, and in some of your hypotheticals there, it would be something like a $120 premium, even after the subsidy, for somebody who wants to either stay in traditional Medicare or perhaps pick some of the particular MA plans in their given market.

And sort of looking at that next to the table on the income levels that we're talking about, we're talking about something that is, you know, 10 percent of the person's income, and, in fact, since the income levels for

people at the federal poverty level, and since those income levels are lower for couples but the premiums aren't, if two people in a family are both trying to sign up for traditional Medicare in an area where it's $120 a month, it's going to be 15 percent of their combined income, if they're at the federal poverty level.

And I think we really need to think hard about what that means, if we're in a kind of situation where the networks and the way the particular Medicare Advantage plans are organized, are not going to be satisfactory for those kinds of people, and they really do need to be in traditional Medicare, we're asking them to pay a pretty large percentage of their income, which is probably not affordable.

One option around this might be to think about, effectively, what's been done in some parts of Part D, where, you know, it's not just that the dollar value -- and you pay the entire extra amount -- but maybe we scale down the add-on for low-income populations, so that they still face the financial differential but it's not that full differential that gets up to levels where you're dealing with an amount of income that's prohibitive.

So what we are really saying to somebody who's a middle-income person, okay, you have financial incentives to pick among the various options, we've tried to change the way those are structured to encourage you to do certain things, but they're all things you can afford to do. You can choose not to do them, but if you want the advantages of traditional Medicare, it's affordable to you. For this population, we're putting that at a price that basically is unaffordable, and I think we really need to think about what that means.

And then, on the third -- oh, and there are other issues, and I don't want to take too much more time around the sort of passive enrollment and reassignment issues that we've seen. You know, you talked about some of the Part D evidence where a lot of people now are paying premiums they shouldn't have to because they don't switch. You know, it's fine to sort of think of the first year going into this, and you sort of get everybody put in something that works, but as things change, you know, sort of what are we going to be doing? And there is -- and Bruce mentioned the experiences in Medicaid managed care there's some good experiences there but there's some pretty bad experiences

there, that haven't worked well.

But going on to the third issue in your list of topics, how the Federal Government and the states would finance the subsidies, I'm increasingly concerned about keeping the financing of the support for Medicare in the Medicaid program, and as the policy discussions in Washington go a lot more towards -- on the Medicaid side, go a lot more towards per capita caps or block grants, I think the funding for the Medicare part of Medicaid, the support for the dual eligibles, the support for the Medicare Savings Program, could be subject to significant rollbacks by states who were put in those situations, or we're going to put them in situations where they're trading off the interest of our Medicaid population, where those of us who are sitting on a commission like this worried about Medicare aren't part of that conversation, or the other Medicare policy folks, this becomes -- we turn this over to the states to make decisions.

And so I think we either have to think about, pretty seriously, about moving the financing of this to the Medicare side, with all the implications you raise, or if we want to leave it on the Medicaid side, thinking about

provisions that would protect Medicare beneficiaries from decisions that states make, should policy on the Medicaid side shift in some of the directions that have been talked about lately, and maybe that's -- you know, again, since all of that is subject to new law, there's really not anything we can do to permanently sort of protect that. So, to me, it makes sense to really think hard about bringing the financing of this back into the Medicare side.

Thank you.

DR. CROSSON: Thank you. Jack, go ahead.

DR. MILLER: So this is your second point, okay, and you made your point about, you know, if you're going to set up plans that the LIS are encouraged to go into, you should be really sure that the provider networks are complete. I'm with you on that. So assume, for the moment, that you have accomplished that. Did I also hear you saying, though, in the end of your comment, but the person should have the option of going into fee-for-service, even if it ended up -- even if it wasn't the lower-cost option?

DR. HOADLEY: So, I mean, personally, that's

where I would go. I would like to preserve for these beneficiaries a good traditional Medicare option. Within the framework of the kinds of structure we're talking about, what I'm trying to think about is to make it a -- so to make it a choice that does cost them something different but not with the size of the differential that results. So basically, in Eric's table, in one of the examples it's zero dollars in MA versus $120 in traditional Medicare. Obviously there are other examples and other situations.

But, you know, that dollar difference, which, to me, is a choice I can opt to make and I can afford to make it, to this person who is at exactly the poverty level, where we're talking about 10, or for a couple, up to 15 percent of their income, it seems like we just made that a non-viable option, and I want to, at the very least, keep it a viable option by figuring out a way to scale back that differential. So maybe we say there's a differential. It's not 0 versus 120. It's 0 versus 30, or 0 -- you know, something. I haven't thought through what the numbers would be.

I would be happy to keep it in a situation where we guarantee that person has access to traditional Medicare

without additional cost, but, you know, there's less interest in that approach, so I'm trying to offer something that's within more of the context that we're raising here for this -- and again, we're not making recommendations, so it's options.

DR. MILLER: But just to make sure I follow your thinking, above whatever the income level was, you wouldn't do that.

DR. HOADLEY: Again, personally, I would like to set benchmarks for the broader premium support system to maintain better access to traditional Medicare than a lot of our examples do, but here I'm particularly focusing on the low income.

DR. CROSSON: Well, and maybe I wasn't -- so you would not -- having just said that then, you would not be looking at some sort of graduated payment scale, for this population, but you might be looking at a graduated payment scale for a larger population.

DR. HOADLEY: Well, I mean, the premium support -- so I'm working from the framework that we're laying out here, and so what we've laid out is something that would, depending on the cost in a particular geographic area --

and again, the tables, they're not on a slide so you can't pull them up here -- would say, for the non-low-income beneficiary you're going to pay these various amounts if you want to stay in fee-for-service, and you're in an area where that's the most expensive option you're going to pay more.

What I'm suggesting is potentially, rather than just put in a fixed sort of premium subsidy is create that kind of a graduated system for the low-income, if we are otherwise doing what we're talking about in this proposal.

DR. CROSSON: Right. So it would be --

DR. HOADLEY: Do something that's more graduated, yes.

DR. CROSSON: Okay. So let's go back to comments -- I'm sorry -- comments. Bill Gradison.

MR. GRADISON: First off, I think this is extremely valuable. I look forward to the time when it can be transmitted through one of our future reports, maybe in June, because I think it would be very helpful to people who have been thinking about premium support, because it gives them an analytical framework at a depth that they may not have had the benefit of in the past.

I also, however, wanted to say that I think that this represents, potentially -- and I know we're not making a recommendation. I've got that. But this whole concept really goes to the heart of the deal that was struck in 1965, which, in my simplistic view, was we'd have a uniform national program for the elderly, and later the disabled were added, and for others of low income there would be variation from state to state, which is kind of what we have today.

Now I appreciate the Medicare program is not as uniform as perhaps it was originally intended, and I'm -- it's where, I guess, anybody around the table -- of some of the variations. But this would go a lot further, in terms of changing what that deal was, because of the reality that, in a sense it would take away the option that's always been there, to stay with fee-for-service medicine if that's what you want to do, which is what 70 percent still do. So it's not exactly like it's a minority.

I don't -- what I'm going to say now is not an analytical point, and I know that, but I don't think it's just a political point either. I think it's more a question of trying to decide what we mean by fairness. How

do you explain to somebody who moves from, say, Minneapolis to Miami. They're going to have to pay a very substantial amount just to have the same kind of arrangement they had back home, for reasons they can't control at all. That is the environment. The prices are not the same. The cost of living is not the same in Manhattan and Mississippi. I mean, there are variations around this country.

So the paper is great, but I think the fundamental issue here is one that we have to, I think, really make sure that we highlight effectively. I don't want to simply close by saying that this very same issue is being discussed -- I don't know how seriously discussed -- but in terms of a potential replacement for the ACA.

And there are a lot of changes there, but one of the fundamental changes would be to move from a subsidy that's based on income, related to what the premiums would be -- in other words, a subsidy adequate regardless of income, to permit you to buy something at the second-lowest silver plan level or whatever, to a plan, which some have recommended, which would be based upon using the income tax system on a subsidy that's based upon age. But it's not related to what it costs to buy the insurance, and would

mean that in some parts of the country, it would be quite adequate to some, or someplace, I guess, to buy a plan. For others it would be totally out of the question.

And so I think there's a very direct parallel between those two issues, the fundamental one that's underlying here, which is are you going to be able to continue to get a fee-for-service plan without paying a premium for it, in some parts of the country, and the question of, in the case of the ACA, is not only should there be a subsidy but how should that subsidy relate to what it costs to buy insurance.

DR. CROSSON: Thank you, Bill.

Comments? Coming up this way. Pat.

MS. WANG: I just want to commend you for the amount of work and thought that went into this. It's phenomenally complicated, and as you concluded the chapter, if people want to really consider this seriously they have a lot of really complicated decisions to work through.

I just want to focus on the notion of auto-assignment based on lowest cost option. I think that that is a very dangerous and not desirable principle, if there is going to be some sort of direction for folks with LIS

and SP, because low cost -- and I echo some of the comments that have been made, Part D is one benefit. It's one benefit. It's just drugs. Parts A, B, and C, it's your doctor, it's your specialist. You might be in the middle of a care plan. It's far more complicated and there's much more at stake. There might be a reason that a plan is low cost, because they've got a really skinny network, or they've really put together their package of benefits in a different way. In the Medicaid managed care space those tend to be -- really, they're just sort of identical benefits, you know, very strict regulation of networks, administered pricing that is determined by the state. I don't know exactly how it works in states that bid, but there's much more uniformity, I think, in the benefits package and also the way that the network looks. So I wouldn't use that as a complete sort of template example, precedent for the wisdom here.

Personally, I think that there are other approaches to encourage enrollment in the best option, but it might not be the lowest cost option. So, for example, for duals who -- I mean, most Medicaid folks these days are in some sort of mandatory managed care program and as they

age in and seamless enrollment, if that plan has a Medicare option within an opt-out, it might be a first step that is better because they're in that network and they're in that sort of care plan, care management environment. Beyond that, though, I really think that we have to be very careful about this idea of going to the "efficient plan," because there could be very significant differences for beneficiaries in what that means.

One of the things that I wondered was whether it would make any sense to take a closer look at the experience of some of the duals demos, which did try to do some sort of passive enrollment, I think, in some cases, more effectively than others, and sort of reasons for the opt-out rates, which I think would underscore the issue about mismatch and provider networks and so forth, and how important that is.

To Jack's point about the sensitivity of the population, the LIS population, to small amounts of money, I can attest. You know, a lot of these folks are just -- they've just got a few bucks more income than somebody who qualifies to be a full dual, and, candidly, even just, you know, ensuring med adherence for somebody who's got a $3

copay is very, very hard. The sensitivity, the income sensitivity of the population is tremendous and I don't think we should kind of underestimate that.

The final thing is that I realize I should have raised this during the question period, but I just wonder whether, Eric, you've kind of thought about sort of the next phase, in the thinking about Medicare potentially taking over MSP, et cetera, what are the implications of that for integrated care? And when you start getting into the long-term care benefit or behavioral health benefits and those kinds of wraparounds, you know, it might be something to think about, because I think it's a very important policy goal for the country to get to, to have a better system of integrated care for folks with Medicaid and Medicare who need long-term care services. So I'm not really quite sure how premium support would interact with that.

DR. CROSSON: Comments? David.

DR. MILLER: Can I ask just --

DR. CROSSON: Oh.

DR. MILLER: In the midst of that, Eric, we are going to be going back out to the dual eligible

demonstrations again. Did you want to say anything about the middle part of her question there and what we're going to be looking at?

MR. ROLLINS: So we have been doing a series of -- so we did an initial round of site visits to the duals demonstrations, sort of the year before you came onto the Commission, and we had a chapter on the demonstrations in last June's report, but we have sort of a second round going on now. We've gone to Massachusetts and California and we're going to go to Ohio at the end of the month.

So the use of passive enrollment and how people are getting assigned to plans and how that's working out is definitely an issue that we have focused on.

DR. CROSSON: David.

DR. NERENZ: Just a couple of things. A little bit off of the low-income part, but in the chapter. It's interesting, by page count, to me, that of the 100-and-so pages we've identified I think there 2 about quality measures and sort of the role of quality in consumer choice. That's probably not a bad reflection, actually, of the way it works now, meaning that, you know, in a lot of studies publicly reported quality measures don't drive

choice very much, and I don't know that anything we're envisioning here is going to change that very much. But that's an observation.

But then from that, I'm curious, Eric, what your thoughts are about, then, the neighbor concept of narrow networks. If consumers are going to make choice, beneficiaries make choice, they're going to make choice on something. Now, clearly the premium, or their total payment requirements would be one. But in almost all areas of plan choice, whether it's Medicare Advantage, commercial, or whatever, the question is, is my doctor in this plan? Can I see my doctor?

I'm thinking that a lot of what we have here will create a set of dynamics that push, perhaps, even more strongly in the direction of narrow networks. A plan can become more attractive through the bid and the premium process by having a tight network. It's sort of where the networks come from now.

I don't think that's necessarily bad, but as I look at the diagram that's on page 60, that's really illustrating a quality choice, or actually it's an additional payment dynamic, I was trying to think, what

does this look like in practice? If I choose a plan, am I also essentially choosing a distinct provider network, or am I just choosing a plan as one of several means of getting to the provider I want to see anyway? I don't know if there's a right or wrong answer.

I think, Pat -- and there's an empirical question underneath that might be, to what extent are providers currently tightly aligned, say, with just one plan, or in a given area, are providers typically contracting with all plans and working in fee-for-service so that you can get to the provider through any of these means?

MR. ROLLINS: One element in particular to comment on, the idea of narrow networks. We do see that, obviously, in sectors like the ACA exchanges. It's a little unclear to me how much of that would go on in a premium support system for Medicare because a lot of the negotiations in other sectors are driven by a tradeoff of volume for getting a better price.

And what I was talking about earlier with Cathy, that is sort of this backstop on MA plans that, you know, they're able to essentially get fee-for-service rates, to some extent that's a double-edged sword. The providers are

also able to make sure they don't get less than fee-for-service.

So it's unclear that plans in this context would be able to sort of strike that same kind of bargain that you see in other sectors, so I don't know if we would have quite the same dynamic that we do now. There could still be -- you know, when we work more closely with specific providers we think quality is better, or outcomes, or things like that, but I think the dynamic would be a little bit different than what we've seen in some other programs.

DR. NERENZ: Just to clarify, that feature that you just mentioned, the ability to trade off, say, a lower per unit reimbursement against volume, that's not part of what's being put on the table here, at least not explicitly.

MR. ROLLINS: No, not explicitly.

DR. NERENZ: Is it forbidden?

MR. ROLLINS: I'm sorry?

DR. NERENZ: Is it forbidden?

MR. ROLLINS: You mean is it open for discussion?

DR. NERENZ: Well, I --

MR. ROLLINS: I mean --

DR. NERENZ: -- I mean, it's too late in the game. I'm not trying to open this up, and I'll --

MR. ROLLINS: I mean, that would be one of the things to consider in a larger discussion of, you know, to what extent are you going to sort of let plans use fee-for-service rates as a backstop.

DR. CROSSON: Jon.

DR. CHRISTIANSON: I just want to go on the record as saying I think it's okay we went over 100 pages for a proposal that turns the Medicare program on its ear, like Bill was saying. And I also think what you've done here is really important. As the data that you provided and other data that we've seen underscores, we've got almost half the Medicare population that's below 200 percent of the poverty level, in terms of income. I don't know what you want to call low income, but that's low income in my book.

So we are talking about half of the beneficiaries, that this discussion applies to, at least. So if we want to add even more pages, I think we need to continue to develop and address a lot of the details and issues that Jack has brought up, because it affects so much

of the program and so many beneficiaries. So I think I would encourage anything you could do to continue to address some of these issues. I know, again, as David said, it's kind of late in the game for the June chapter, but --

And the other thing I would comment on is I haven't seen a discussion as structured and detailed -- and Jack, maybe you would know more about this -- around how low-income people are going to be addressed in a premium support system. So that, alone, is going to be a major and very important contribution to the ongoing policy discussion. So I'm really, really pleased that you tackled this topic because I think it's so important for premium support.

DR. CROSSON: Comments? Bruce.

MR. PYENSON: Just a couple of comments or suggestions. One, it seems as though we should consider having a roll-out of premium support initially for dual eligibles as a manageable -- potentially more manageable approach to the concept of premium support, rather than having it roll out for everybody, at least initially.

In terms of the issue that Pat correctly raised

about how instability, in effect, in bids could result in shifting enrollment from one plan to another plan for a vulnerable population, I am thinking that having multi-year bids or rate guarantees would be a way to help manage that issue. It's also a way to help manage other issues in the MAPD world. The annual bid cycle is taxing and the short-term basis of that is a -- there's potentially better ways to do that, rather than an annual cycle.

And, finally, in terms of the impact of the states, you know, states with the Part B buy-in, in effect, I've heard that explained as a state is paying roughly 25 percent of the cost of Part B and in exchange for that the state's community, the state's local economy gets 100 percent of Part B back, a net of 75.

And I'm wondering how that might change states' motivations here. One way that MA plans are less expensive than fee-for-service is that they pay less for Parts A and Part B, for those services. So, in effect, states may not just be saving what it's buy-in is but have an impact on the revenue coming to a community of providers in the state.

So I think there might be something -- some

useful thinking or modeling around that issue.

DR. MILLER: Can I just get two sentences on why you would think the rollout first to dual eligibles?

MR. PYENSON: It's not everybody. It's easier to do this in pieces. But it's also potentially a savings to states whose, as I understand, contribution for the Part B buy-in would be less expensive for -- in a couple of ways. One is that to the extent MA plans are lower priced and more efficient, if a state is paying for cost sharing, for the Part A deductible, Part B coinsurance, those would presumably be less expensive for the state. And the other reason is that the state's buy-in would be less expensive than it currently is.

DR. CROSSON: Okay. Kathy and then Paul and then Brian.

MS. BUTO: I think that would complicate the rollout enormously. I guess I'm thinking from a plan perspective when you're bidding, only to be bidding to cover the dual eligibles just seems to me to be really complicating the rollout and actually making it maybe less attractive.

But my concern -- and I think this goes to --

this does go to supporting Jack's concern about beneficiaries' ability to absorb costs, is I worry about Medicare becoming too much of an income-related program, which would undermine the whole point to me of social insurance at some level when you -- if we create a situation where low-income beneficiaries can really just afford to go to the lowest-cost plan or something very low on the spectrum and don't have the same choices because of cost, we sort of create -- we are creating a two-tiered system in Medicare that we will -- we've started down that road already, but I worry that this will make it even more of an issue. And I think leaving cost-sharing subsidies in Medicaid also exacerbates that issue.

So as we go into the next go-round, I hope we'll really think about, you know, what's the tipping point for creating a situation that's really pretty untenable for the lowest-income populations.

DR. GINSBURG: I just wanted to mention that I think the work that has been done this year, that Eric has presented, and the work that MedPAC has done in prior years on this premium support issue I think has been so valuable because so far the way that Congress has approached this

topic has been with poorly thought out proposals. It has been very ideological. It has become a "toxic" that some people aren't allowed to advocate it, and I don't know when the situation will change. But I think that if Congress ever does, you know, address this in a more serious way than it has before, I think MedPAC's contribution will really make for much better policymaking.

DR. DeBUSK: First of all, I want to thank you for a very well written chapter. Don't let anyone give you a hard time of the length. Write as much as you want. We'll read it all. This is very important work, and, again, I really do appreciate the time and the effort and the thinking that you've put into this.

You know, I had been concerned that when we started talking about how to deal with low-income people, that we were going to hit a wall. And to see what you did with the LIPSA-derived approach, I think that's a wonderful place to start. So, again, thank you.

The other thing I noticed, a couple times we talked about, you know, how do you get to the benchmark? Do you do bids? Do you do weighted averages? I hope we could give weighted averages a lot of consideration just

because I think by weighting it on the number of enrollees, you're going to get an inherent stabilization over time, because populations only shift at a certain rate, so you'll -- I think that will have an inherent stabilizing effect on local markets.

And then the final thing I wanted to touch on was something Pat said earlier, which I -- you know, as soon as you said it, I thought this is a fantastic idea. You were talking about people who were in Medicaid aging into Medicare. If you're already in a managed Medicaid program, if we could reach out to those plans and say if you will build a compatible dual MA plan so that these people could seamlessly move into this new plan, you could do some auto-enrollment and provide some individuals to create this seamless on ramp for Medicaid into a dual-eligible MA plan. And I could get excited about that because that's really pre-premium support. You know, that would be a nice way to test some of these ideas, and it would be a test in a way that would err to the side of the beneficiary, because these would be the doctors and the networks that they're used to and, you know, the EOBs would look the same. You know, it would have that continuous feel.

So, again, Pat, I think that is a wonderful idea, and I like the fact that we could do something like that on a fairly short term.

DR. MILLER: On that point, I'm looking for an MA person, and seeing none, I think I might be -- oh, there he is. Okay. Because I was going to be free to operate entirely without facts.

This issue of, you know, kind of rolling a patient -- or, sorry, a beneficiary over, you know, if they're in a commercial managed care plan and then they come up to eligibility, and then you were saying but if they are in Medicaid managed care, this issue has come up in our conversations multiple times, and there is something on the books that allows this. But my sense is it doesn't go on as much as you might guess given -- and I would suspect that some people may have views on this, and I wonder if this is an issue we should unpack separately, even just as it relates to MA, as it relates to premium support, continuity for the beneficiary, just almost on a stand-alone basis and make sure -- because I don't feel like I understand exactly what is allowable and isn't and why things don't go on more than they do, because on its

face -- all right. I'll stop.

MR. ROLLINS: So the option in Medicare Advantage is sometimes referred to as "seamless conversion," where you can go from -- you're not in Medicare yet, but you're in a Medicaid plan or an ACA plan or just commercial insurance, and you're given 60 days' advance notice that, you know, unless you take action, you'll be enrolled in this company's MA product when you reach 65.

The use had been very limited, and CMS for a long time had not put out much information at all about to what extent this was getting used. And then they finally did put out some information -- I want to say at the end of 2015? -- but they've also put sort of a hold on sort of new applications to do this. There was starting to be a lot of interest from insurers offering ACA plans in terms of using this, and I think there was some uncertainty about -- CMS has rules saying you need to do this equally for people who are disabled coming into Medicare and aged coming into Medicare, and it was unclear that they were able to implement it uniformly given that it is hard to know when the disabled are going to qualify for Medicare.

But one point that is worth flagging is you do

see this used in a few limited cases with Medicaid managed care. For example, the State of Arizona, which has done a lot of work to integrate Medicaid and Medicare using D-SNPs as a requirement for all of its D-SNPs -- I'm sorry, for its Medicaid managed care products, that they have to offer a D-SNP, and they have to get permission from CMS to use this seamless conversion so that this situation of somebody who's Medicaid only and then graduates into becoming a dual sort of can stay in the same sort of environment.

DR. MILLER: So what I heard is you volunteering to take this --

[Laughter.]

MR. ROLLINS: I was volunteering Carlos and Scott.

DR. MILLER: Oh, Carlos, okay. For the record then, Carlos.

DR. CROSSON: Yes, Pat, do you want to elaborate?

MS. WANG: So they described the current state very clearly. The point that I do think is important to make, though, the seamless conversion might not be the lowest-cost option in a premium support. That was the point that I was trying to make from, I think -- I'm a

little biased here, but I think from a member/beneficiary perspective, it's like a pretty good option because they're already in the plan, they're already using those providers. They're actually in the Part D, you know, like the pharmacy benefit part of it. But it might -- so from that perspective, it might be a good thing for the person with an opt-out, but it might not be the lowest-cost option.

DR. CROSSON: Okay. Very good discussion. Jack?

DR. HOADLEY: On this point, I know there are some issues from the beneficiary advocacy community on some of the seamless conversion, so I can connect to people that they can provide more of that.

I just want to make sort of a last comment since I focused my initial comments kind of narrowly on this new section of the chapter and tried to think about how within the context of our chapter and the proposals that we lay out there, how we could address the low-income issues in some different ways.

But I also want to come back to the broader focus of this chapter. I think to me the discussion over low-income just highlights and emphasizes some of the broader concerns I have, and some of those came out in the exchange

I had with Mark about some of the consequences. And I'm really taken, for example, by John's point, which I hadn't quite thought of this way, but the point that 50 percent of Medicare beneficiaries are under 200 percent of the poverty level is really something we should keep in mind, that, you know, we're focusing on low-income help at, you know, 100 or 135 or 150 typically; 200 isn't very far away from that. They would be fully exposed as sort of the rules are laid out now to some of these financial consequences and ones that they wouldn't be able to afford.

And to Bill's initial comment about really, you know, how fundamentally this goes back to change the initial premise of Medicare, and Kathy's comment about, you know, changing the social insurance nature of this program, I think, you know, one of the real strengths of Medicare over the years that it's been social insurance available to everybody, regardless of income, that has been its source of political support, that has been its source of just broad societal support. And the more we sort of mess around with that premise and we turn this into something -- obviously, we want to be able to find ways to help the low-income people to be able to afford the same things that

everybody else can. But we've got to make sure we're doing that in a way that really doesn't turn this into a much more income-related program.

And so I think this whole exercise with the chapter, the work on it has been terrific. It does help to frame -- you know, as Paul noted, it helps to frame the issues in a way that people can see some of the complexities, the issues, and in my mind some of the liabilities of going down this path. So I think, you know, this chapter is going to be of real service, but, you know, from a policy perspective, I'm concerned about some of the directions for those who want to really go in this kind of policy.

DR. CROSSON: So just a couple of closing comments.

First of all, Eric, thank you and those who have helped you. Just to reinforce the comments that have already been made, this is a tremendous piece of work, well thought through, well presented as well.

I would also suggest that you never let anybody, particularly the Chairman, kid you about the length of the chapter because I realize that you've just set a new bar,

and it's one that we will work with, no question about it.

Also, I think just a comment for the public to reinforce some other comments that have been made here, because not everybody who is sitting here may have been participating in all of our conversations on this topic.

What we have done here -- and this has been a year's or so worth of work, perhaps more thinking well before that -- is to try to provide guidance and advice and facts when they're available to those who are thinking about premium support or something like that as a model for Medicare for the future.

Going in that direction is not the position of the Commission. We simply have attempted to say, based on the fact that others have been thinking about this and that our responsibility is to provide facts and advice when we can, that we would do that service. But we have not taken a position on the Commission either for or against moving from traditional Medicare to this model or a combination of the models.

So, with that, thank you, Eric, and we will now open to public comment. Those of you who are interested in making public comment, I'd ask you to please come to the

microphone.

Seeing then none -- oh, I'm sorry. Got you there. What I would like to say is I'm going to ask you to identify yourself and your organization. Limit your comment to two minutes. When this light, which I will turn off, goes back on, that is the two minutes. And just to re-emphasize that there are other ways to provide input to the Commission through the staff. But you're free to make comments right now. Go right ahead.

DR. DUPREE: Great. Thanks. My name is Jim Dupree. I'm a urologist with the American Urological Association. I thank everyone for the very engaging discussion this morning, especially about the Part D spending. I have one quick question for consideration as the report goes out and then one comment, if I may.

The question is just to add some clarification about how the Drug Value Program would interact with alternative payment models like the oncology care model that already exists and in which there's a lot of Part B spending and in which there are already shared savings incentives. Just for some clarification on how those two programs would interact.

The comment, also about the Drug Value Program, actually reflects back to the first clarifying question that was asked about the precedent of having prior authorizations and other managerial tools in a Part B program. As a practicing clinician, I don't actually prescribe Part B drugs ever, but I do interact with patients often who are faced with the patient side, the beneficiary side, of many of those managerial tools. And as we put forward a report that recommends some of those tools in Part B, I would just ask that a lot of consideration be given for the beneficiary's perspective on what it's like to experience care when there are prior authorizations, limited formularies, and other managerial tools in place.

I think, you know, from my experience caring for patients, it is often at times a frustrating experience for them having to deal with those sort of tools, and I would just ask for careful consideration, informed by what we know from the commercial market, informed by what we may know from Part B, about what it's like for a beneficiary to face those types of managerial tools.

Thanks very much.

DR. CROSSON: Thank you.

We are now adjourned until 1 o'clock, so we'll be back at 1 o'clock for a busy afternoon. Thanks very much.

[Whereupon, at 12:05 p.m., the meeting was recessed, to reconvene at 1:00 p.m. this same day.]

AFTERNOON SESSION

[1:02 p.m.]

DR. CROSSON: Okay. I think if we could sit down, we'll get going.

We have a very busy afternoon in front of us. We have four important items to deal with, each in an hour. So I am going to ask Commissioners, both in terms of your questions and comments, to be judicious, so we don't fall behind, and as we get close to the end of the hour, I'll get increasingly grumpy, and you can tell without even looking at your watch. How's that?

That said, we have one order of business pending. Dr. Samitt, was, as I said earlier, detained. Apparently, he's now out of detention.

[Laughter.]

DR. CROSSON: And he is here, and so we have put up the recommendation on Part B drugs. Craig has been a part of our discussion, one of the leaders in helping us do this work, and therefore, I would ask Craig to raise your hand if you're voting in favor of the recommendation.

DR. SAMITT: [Raises hand.]

DR. CROSSON: Opposed?

[No response.]

DR. SAMITT: Abstentions?

[No response.]

DR. CROSSON: All right. Thank you very much.

DR. SAMITT: I noticed you didn't give me the opportunity to comment.

DR. CROSSON: Right.

[Laughter.]

DR. SAMITT: But I vote in favor of the recommendation.

DR. CROSSON: All right. For the record, the vote on Point B is completed.

Now we'll turn to a final discussion, maybe, final discussion on unified PAC for post-acute care, a unified payment system for post-acute care.

Carol Carter is back with us. All yours.

DR. CARTER: Okay. Good afternoon.

Last month, we reviewed the Commission's past work on a prospective payment system to span the four post-acute care settings -- skilled nursing facilities, inpatient rehab facilities, long-term care hospitals, and home health agencies -- and discussed implementation issues

that will be a chapter in this year's June report. This month's presentation will be brief, but the complete analysis is in the paper.

For new folks in the audience, Medicare pays for post-acute care using four separate payment systems that can result in considerably different payments for similar patients. The idea of a PAC PPS is to have one payment system to establish payments for patients treated in any one of the four PAC settings, basing payments on patient characteristics rather than the setting where they were treated.

The Commission's initial design would eliminate the existing biases in the home health and SNF payment systems that favor treating some types of cases over others.

Although the IMPACT Act of 2014 requires reports on a PAC PPS, including the mandated report the Commission completed last summer, it does not require implementing a unified payment system. The timetable for these reports makes it unlikely that a PAC PPS would be proposed before 2024 for implementation sometime later.

MedPAC's conclusions. In its mandated report,

the Commission concluded that a PAC PPS was feasible using currently available data and therefore could be implemented sooner than the timetable laid out in the IMPACT ACT. Functional assessment information should be included in the risk adjustment when these data become available. To create a level playing field for providers, the Secretary would need to begin to align the setting-specific regulatory requirements.

In terms of impacts, the Commission's design would redistribute payments from stays with high amounts of therapy that are unrelated to patient characteristics to medical stays. With that redistribution, the equity of payments would increase across different clinical conditions, by narrowing the differences in their relative profitability. As a result, compared to current policy, providers would be less likely to prefer to treat some types of patients over others.

The Commission has discussed three implementation issues. The first is whether to include a transition when implementing the new payment system. A transition would blend new and current setting-specific rates, thereby dampening changes to payments during the phase-in period.

It would extend the current inequities in the home health and SNF payment systems but would give providers time to adjust their costs and mix of patients.

The size and the variation in the changes in payments suggest the need for only a short transition. Providers could be given the option to bypass the transition and move directly to PAC PPS rates.

The second issue is whether the level of payments should be lowered when the PAC PPS is implemented. We estimated that in 2017, the average payment is 14 percent higher than the average cost of stays.

Given the Commission's long-standing update recommendations for PAC, the level of PAC spending should be lowered when the PAC PPS is implemented, if Congress has not already done so. Because MA and Medicare payment reforms are based on fee-for-service, a PAC PPS and its level of payments will also influence these payments.

We found that even with 5 percent reduction, the average payment across all stays would remain 9 percent higher than the average cost of stays.

And for most of the 30 patient groups we examined, the average payments would be in the 7 to 9

percent range, higher than average cost of stays.

The last implementation issue that we will be discussing is the required maintenance of any payment system. As with prior payment policy changes, we expect providers to change their costs, their patient mix, and practice patterns to maintain or increase their profitability. Therefore, the Secretary will need to periodically refine the payment system to keep payments aligned with the cost of care. These refinements include revising the relative payments across different types of stays and rebasing the level of payments for all stays.

Both types of refinements are part of any ongoing maintenance system, and the Secretary will need the authority to do both.

We conclude that a PAC PPS could be implemented as soon as 2021. When uniform assessment data, functional assessment data becomes available, it should be incorporated into the risk adjustment method.

The implementation should include a short transition.

The level of PAC spending should be lowered, and concurrent with the implementation of the PAC PPS, the

Secretary will need to begin the process of aligning setting-specific regulatory requirements and will need the authority to do so. The Secretary will also need the authority to revise and rebase payments.

This leads us to the draft recommendation, which is identical to the one you discussed in March with one exception. At the March meeting, there was a consensus to lower the spending by 5 percent when the PPS is implemented. The recommendation reads: "The Congress should direct the Secretary to implement a prospective payment system for post-acute care beginning in 2021 with a three-year transition; lower aggregate payments by 5 percent, absent prior reductions to the level of payments; concurrently, begin to align setting-specific regulatory requirements; and periodically revise and rebase payments, as needed, to keep payments aligned with the cost of care."

The text below the recommendation would note that if the Congress has already lowered payments to PAC providers, the Congress should compare the reduction it has already taken with this recommended amount and make an additional reduction if necessary to reach the 5 percent.

We would also state that providers could be

allowed to bypass the transition, and thus the reduction should be applied once at the beginning of the transition. We would also note that by law, MedPAC will continue to evaluate the PPS every year as part of its update work and continue to monitor beneficiary access to care and provider performance and make subsequent recommendations if necessary.

In terms of implications, for the one-year spending, there will be no change relative to current law. This is because the recommendation does not apply until 2021, which is year four. Over five years, the spending will be lower by between 5- and $10 billion. This score assumes no behavioral changes by providers. We expect provider behavior to change, and I will talk about that in a minute. Savings will depend, in part, on whether providers are allowed to bypass the transition, and if so, how many elect this option.

We expect providers to respond to this major change in payment policy, just as they have done in the past. By rebalancing the financial incentives, the PAC PPS will correct the current inequities in the SNF and home health PPS that favor some types of patients and providers

over others.

For beneficiaries, providers will be more willing to treat all types of patients, and therefore, there should be less selection among different types of patients. Therefore, patients with complex medical care needs should be easier to place at discharge from the hospital.

For providers, the PAC PPS will redistribute payments across providers. The impacts will depend on provider responses and will vary widely depending on each provider's cost, their mix of patients, and their current treatment practices. The changes in payments will result in more equitable payments across different types of patients because the differences in profitability will narrow.

For more than a year, the Commission has discussed that the PAC PPS is within reach and should be implemented sooner than the approach laid out in statute. The recommendation reflects the Commission's concern that payment reforms in PAC settings have been too slow.

Over the coming year, the Commission will continue to work on a PAC PPS, turning its attention to the regulatory alignments across PAC settings.

And with that, I will put up the draft recommendation and turn the discussion back to Jay.

DR. CROSSON: Thank you, Carol.

We are open for clarifying questions.

Jack.

DR. HOADLEY: So I just have one. In the text, you talk a little bit or you elaborate a little more on the regulatory relief aspects. One of the comments there was that in some settings, in some situations, there might be more stringent requirements, and I was trying to make sure I understood. And it looked to me like an example of that would be where there would be patient-specific standards as opposed to setting base standards for things like the need for ventilator care, and so that might turn out to be more stringent in some settings because they don't exist now or because there is less to them. Is that what --

DR. CARTER: Right. So what we had talked about was sort of a short-term and a long-term strategy. The short-term strategy would be to identify when a uniform payment -- when the payments begin to be uniform, which regulatory requirements need to be waived. And then a longer-term process would be aligning the conditions of

participation for, if you will, sort of the institutional PAC provider and probably something slightly different for home health providers.

We had talked about in the paper a longer-term approach would be to develop conditions that are based on patients rather than setting, and so there could be a core set of requirements that every PAC provider would have to meet. And then there would be additional requirements if a provider opts to treat special types of cases; for example, severe wound care or ventilator care. And so those would be focused on special patient populations that we know require both different staffing and equipment, for example.

DR. HOADLEY: And so with some of those latter ones that lead to being more stringent in particular type of provider, if they are going to see a particular type of patient?

DR. CARTER: They would just be additional.

So, for example, if you are going to opt to treat ventilator patients, you obviously need the equipment. You need staff that have been trained to do that, to wean patients, and to manage that kind of care.

So I guess the word "more restrictive" or "more

stringent" --

DR. HOADLEY: Stringent.

DR. CARTER: It is really -- I think of it as being more targeted to the types of patients that providers would --

DR. HOADLEY: And when you use the term "waive" in terms of the short-term strategy, are there some where the Secretary would actually be able to waive a requirement in statute, or does it look like most of those would require --

DR. CARTER: It's a mix. It's a mix.

DR. HOADLEY: It's a mix. Okay.

DR. CARTER: So, for example, the intensive therapy requirement for IRFs is something that CMS has defined. The 25-day length of stay for LTCHs is in statute, so it is a mix.

DR. HOADLEY: And there is no waiver authority, the way you might have in some others, like in a demo situation where the Secretary could waive requirements for purpose of a demo? There wouldn't be any ability to waive even for a temporary basis for --

DR. CARTER: I wouldn't think so, but I haven't

looked at that.

DR. HOADLEY: Yeah. That's what I was thinking too.

DR. CARTER: Yeah.

DR. CROSSON: Pat.

MS. WANG: Can you talk a little bit more about the spending estimate on page 10? No change in year one recommendation does not start until year four.

DR. CARTER: Right.

MS. WANG: So the five-year spending, does that mean year two of implementation?

DR. CARTER: Yes. Right.

MS. WANG: Okay.

DR. CARTER: So when we talk about a one-year and a five-year, that's starting with next year.

MS. WANG: Okay.

DR. CARTER: And so the five-year window only extends into the second year.

MS. WANG: Okay. That's helpful. Thank you.

And so the 5 percent overall reduction that's being recommended in the aggregate funding level accounts for three-plus-billion of this, I assume, $60 billion

program? I am trying to figure out the derivation of the estimate of savings, 5- to $10 billion. A good chunk of that probably is just implementation of the reduction of aggregate payments by 5 percentage points?

DR. CARTER: Right. Yes, yes.

MS. WANG: Okay. Then so the balance of it --

DR. CARTER: That would be all. I guess I am sort of missing your question.

MS. WANG: Okay. I was trying to figure out what --

DR. CARTER: Yes. All the reduction to the level of payments.

MS. WANG: From the overall --

DR. CARTER: Right, the 5 percent --

MS. WANG: Okay.

DR. CARTER: -- aggregate spending, lowering of that.

MS. WANG: And everything else is just re-distributional?

DR. CARTER: Right.

MS. WANG: Got it. Thank you.

DR. CROSSON: Clarifying questions?

Bill.

DR. HALL: So I am very excited about this whole concept, Carol.

I have one kind of visualization problem. I agree that health care providers will adapt to incentives. One of the best examples, probably, is 30-day readmissions, which have shown a very substantial drop, and the main reason is that the providers are no different, but there are penalties involved. And the change occurred very rapidly and universally across the country.

So the visualization issue, I am sure you thought about. It's let's take the average American -- well, no. An American hospital, a general hospital that sees -- maybe has 300 beds. Let's put it that way -- or larger. In one way or another, usually those hospitals are providing or contracting out for each of these services for their patient population. The incentive is to make sure that we don't readmit patients over and over again. This gets you in trouble with quality, financially, and all the rest.

But the hospital has to provide these services in one way or the other. So while I am sure there are some issues of people who are trying to take advantage of the

system and are motivated by different payment streams and which will benefit them more, I think the major problem from at least a practical point that I see is that you have to have these services.

They aren't the same very often. So contracting for home health agency, intensive rehab, they require infrastructure somewhere within the hospital system. So what would the hospital -- as you think about this, what would the hospital look like? I wondered if maybe somebody here who has to deal with this, like Warner, would comment on that. How is this going to work in a practical way?

DR. CARTER: So I'm a little confused because what we're talking about is sort of a more uniform PAC provider, and is that what your -- right. This isn't about hospitals, per se.

DR. HALL: Well, they are services that really have to be provided to run a modern hospital, and strategies have developed that end up with patients being put in various different venues, where it is assumed the service will be provided in a more efficient way, particularly to keep the hospital going. That is where I am having a little bit of trouble understanding from a

practical standpoint how this is going to work.

DR. CARTER: So do --

DR. MILLER: Do you want me to try it, or do you want it? You've got a momentum. Go.

DR. CARTER: Well, so the thing that wouldn't change for a hospital is they still have to have discharge planning staff. That's a requirement to be a hospital, and those requirements wouldn't change, and we're not talking about sort of the hospitals.

If you're talking about an integrated hospital system that has these other entities, is that what you're talking about? Because we are talking about a more uniform PAC provider, and so --

DR. MILLER: I would take this in pieces.

DR. CARTER: Okay. Good.

DR. MILLER: I would start it right -- I would have started right where you did start, which is the first thing I would say is let's say there is a hospital that actually has a relationship with IRFs, has a relationship with SNFs, has a relationship with home health. It would be point of discharge. They would do their normal discharge planning activities, and in a sense, as the

patient hits one of those settings, on the basis of their patient characteristics, all that would have changed. And I don't mean to say that as simple, but just from a perspective of the hospital. All that would have changed as the payment rate and then the regulatory environment that we have been talking about a bit. So the hospital, in a sense, would be conducting its business as business as usual.

Then my mind, as you spoke, went to her second scenario of were you asking about what if the IRF is inside the hospital, what happens there, and there again, the main thing that's changed or the two main things are changing is that the payment rate may go up or down, depending on what kind of patient we're talking about, and the regulatory environment may get somewhat leveled, if you will, across different settings. So if the IRF had a very aggressive regulatory or has this many regulations -- this is a scientific graph -- and that was more leveled down to have more of a common standard across the institutional providers, there may be some change in the regulatory environment for that hospital and say you don't have to have these types of people on your staff.

DR. CARTER: And so for that hospital, if they have an IRF, they would have the flexibility to take patients who currently don't meet IRF requirements for intensive therapy.

DR. HALL: I understand that part.

DR. CARTER: Okay.

DR. MILLER: But was that your question? Is that where you were going?

DR. HALL: No. I mean, the point is there's a lot of shoehorning that goes on now. This patient doesn't really need intensive rehabilitative services, but we need to move him out of the acute hospital setting, and so sometimes that causes probably unnecessary care.

DR. CARTER: I have heard hospitals give talks about their discharge planning tools that help them decide does this patient need it to go to a SNF level of care, does this patient need to go to an IRF level of care. And those decision-making tools under this scenario, where a provider has much broader flexibility about where they send patients, I guess hospitals would then have a broader flexibility to send patients to providers kind of without the label on the front of the building, if you will.

But they still may opt -- I mean, we're reading this in the trade press, that hospitals are much more -- and you started your comment with this -- much more focused on contracting or directing their patients to high-quality providers, and so that would still remain in place, that they would be looking for high-quality providers. It might just not be IRF or SNF, but now would be a PAC provider.

DR. HALL: Okay. I will come back if we have a Round 2.

DR. CROSSON: We are still on questions.

Warner.

MR. THOMAS: I am just going to make a comment to Bill's question. I think the mental model I use on this is just as an acute care hospital, you have an ICU. You have med-surg. You have step-down units. I think the same scenario is here. I mean, you are going to have people who go to a post-acute facility that have -- some are going to have more intensive rehab needs. Some are going to have more -- some may be on vents because more of an LTCH.

I think we have been programmed to think, well, they can only go to a rehab or they can only go to an LTCH or they can only go to a SNF versus they need to go post-

acute. Let's determine the right place for them versus -- and I think if there can be the right regulatory relief and also I think if there can be the right regulatory relief for hospitals to repurpose some of their existing capacity, this could actually be a step-down within a hospital --

DR. HALL: Right.

MR. THOMAS: -- which would actually facilitate this and make it a lot easier, quite frankly, because, you know, with unused capacity, maybe you could have a post-acute entity right in a hospital, so it becomes another component to the step-down versus having to go find -- if I have to find a rehab because of the regulatory issues, this person has to go to a rehab.

Once again, I think this can work. We can't just change the payment model, though. We have to change the regulatory issues to allow people to move amongst the right components, and I think if that's done appropriately, along with a payment model, I think this actually probably works pretty well for folks.

DR. CROSSON: Very well said, Warner.

Does that help answer your question as well, Bill?

DR. HALL: Yeah, it certainly does. I mean, I think we're going in the right direction.

But I see this as an opportunity to improve the quality of care provided to people when they leave the hospital, and I think the systems will be invented enough to do this, but it might take some time.

So when we think about the amount of time we were going to give for transition to this system on the payment side, we probably ought to give the hospitals a little bit more time, rather than less time, to let this creativity actually work.

DR. CROSSON: Okay. Further questions?

[No response.]

DR. CROSSON: Not seeing any, we will move to Commission comments, discussion period.

I will be brief. I would just like to once again congratulate Carol for an outstanding body of work. It started with a very complex analytical process and then into policy development, and it really has helped lead this Commission forward to, first of all, a complete or reasonably complete understanding of the issues, and then you've managed to engender broad support from the

Commission as well.

I would also like to congratulate the Commissioners, many of whom -- I think, Kathy, I would start with -- who have taken this topic to heart, as well as with respect to their intellect, and understood that this is a big deal for Medicare. It's a big deal for beneficiaries, and that these changes, both in terms of the prospective payment system as well as the amount of money that Medicare pays, these changes should occur as quickly as possible. So I think we have, again, a very well-executed piece of policy development and a very good coming together as a Commission, moving things aggressively in the right direction. So thank you for that.

So let's take Commissioner comments, other discussion.

Jack.

DR. HOADLEY: I just really want to second what you just said. I think back to the discussions we were having a year ago in response to the congressional mandate, and as we learned the process, it seems like we really sort of developed this notion of being able to move forward on a more rapid time table, and this has just been a great job

of getting us to that point.

So I am obviously going to support this, and it's an enthusiastic "yes" vote.

DR. CROSSON: Alice.

DR. COOMBS: Thank you very much, and thank you, Carol, for such great work over the past years.

I honestly think that we have gotten to a better place on this, addressing all the concerns. I support the recommendations.

DR. CROSSON: Thank you.

Kathy.

MS. BUTO: I think this is great work. I think we can all be proud of it, but especially, Carol, you and your team.

And I support going forward with it. I'm very excited about the accelerated time frame, and even though it's hard to do some of the other things, like regulatory changes and conditions of participation, it's doable. And having an open-ended implementation with no specific date will only mean this may never get done. So I think it's terrific.

I think all of us need to just be aware of the

fact that as it goes along, we want to keep our eye on patients who might be particularly vulnerable during the transition, whether it's ventilator dependent or wound care patients or whatever, but I think that's all built into the system, so I think we're in good shape here.

DR. CROSSON: Thank you.

Further comments?

Craig.

DR. SAMITT: This is awesome work, and I also endorse the recommendation wholeheartedly. I guess I wanted to ask beyond just the recommendation. I am curious what Carol is going to do next.

[Laughter.]

DR. SAMITT: And the work has been so great, I just wonder whether there are other areas of applicability to similar thinking and whether there's a whole other category of similarly where we're not seeing the right care in the right place at the right cost, and whether it's, you know, pre-acute, urgent care, freestanding ER, ER, I don't presume to know which the right category would be, but I just wondered whether we should be evaluating a similar philosophy and methodology in other areas of care.

DR. CROSSON: I see Warner and David.

MR. THOMAS: I think this is great work as well. I think that the two comments I would make is, one, I really need -- or I would really strongly encourage us to make sure that we're pretty focused in the chapter around the regulatory components of this, because I think it will be difficult to implement if there is not the right flexibility to be able to move patients within these different levels of care and to be aggregating more patients together versus bifurcate them into, you know, LTCH, SNF, rehab, which I think has created a lot of problems, frankly, for providers.

You know, going back to Bill's comment, I think one of the challenges you have when you have a 20-bed SNF or a 20-bed rehab is physician coverage is very challenging, whereas if you have 50 or 60 patients together, physician coverage becomes a lot easier. So that aggregation of patients I think is going to be really important.

I would also make the comment that I would hope that there would be flexibility to create models or pilots between now and 2021 because this is a massive change for

this component of the industry, and although I support the relatively short transition period, I think we can't underestimate the major impact it's going to have. So I hope there's some time in the interim where there can be pilots for organizations that want to be more proactive and engage on this, that they may have the opportunity to do that.

The last comment I would make is, you know, I think the 5 percent reduction, just lowering aggregate payments 5 percent, I think especially in light of other discussions we have had around other components of spending, is pretty significant change. If you look at the amount of savings here compared to, say, the drug discussion we had this morning, which was only, you know, 250 million or what-not, and this is, you know, several billion dollars, it's a pretty significant change in a payment reduction when you're also going through a significant change in a model modification.

So I just think that needs to be or should be referenced in the chapter, that that's a challenge. And maybe that payment change could be implemented over time to allow people to adapt to this new model, which I think is

going to be a challenge for a lot of folks. And I think, frankly, there's going to be some pretty significant winners and losers that go through this. And I think the model change coupled with a pretty significant cut may be challenging to do simultaneously.

DR. NERENZ: Again, thanks to Carol. Wonderful work. I have said it before and repeat it here. It is great stuff.

The term "patient-centered" I think is a trite and overused phrase, and sometimes I can't even tell what it means. But I think it has a tangible meaning here. One of the features I like about this is that it really shifts to a model that is linked much more closely to patient needs and care requirements. I think that's a good thing.

From that then, if this does get accompanied by the appropriate regulatory relief, some of which may be outside of our purview, meaning maybe there are some Joint Commission things that have to go along, what that does is open the door to innovation and creativity so that there may be sites and levels and models of post-acute care that are wonderful that don't even exist right now. And I like that. I think that's a good thing. So I just want to

emphasize that it's -- among many reasons for favoring it, I want to emphasize that one.

DR. CROSSON: Sue.

MS. THOMPSON: I just wanted to take the opportunity, Carol, to say thank you again. Excellent work, and it's been fun to be a part of it. And I want to acknowledge even between last month and this month your incorporation of additional thinking, especially around alternative payment models, and how this will play into bundles, et cetera. So I appreciate that very much.

Thank you.

DR. CROSSON: Okay. Seeing no further comments, then we'll proceed to the vote. You have the draft recommendation before you. All Commissioners in favor, please raise your hand?

[Show of hands.]

DR. CROSSON: Opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: Thank you very much. It passes unanimously. Thank you, Carol, again, and we'll proceed

with the next presentation.

[Pause.]

DR. CROSSON: Okay. Our next order of business is an overview of the medical device industry. We've got Brian and Eric here to take us through this not entirely ground for the Commission, but in relative terms I think so.

Brian, it looks like you're ready to start.

MR. O'DONNELL: Good afternoon. Today we will continue our discussion of the medical device market by examining four topics: unique device identifiers, gainsharing, price transparency, and physician-owned distributorships.

The goal of today's discussion is to receive feedback from the Commission on policies of interest and potential areas of future work related to medical devices.

Before I begin discussing these topics, I would like to thank Sydney McClendon for her assistance with this work and briefly review some background information that Eric presented in September.

First, the term "medical devices" applies to a broad range of products, from very simple medical supplies,

such as latex gloves, to more complex implantable medical devices, or IMDs, such as pacemakers.

The Food and Drug Administration, or FDA, is responsible for regulating medical devices before they enter the market and for monitoring the performance of devices after entrance.

The FDA's premarket requirements vary based on devices' risk. For most low-risk devices, manufacturers must notify the FDA before bringing the product to market, but no FDA review is required. Most moderate-risk devices go through what is referred to as the 510(k) process under which the manufacturer must demonstration that its device is "substantially equivalent" to another device that is already on the market but does not have to submit data proving the device's safety or efficacy. For most high-risk devices, manufacturers must go through a premarket approval process, under which manufacturers submit data to the FDA that demonstrates the device's safety and efficacy.

The FDA cannot fully assess the safety and efficacy of medical devices prior to market entry, so FDA conducts post-market surveillance to detect and address device failures and other quality issues. FDA's

surveillance involves passive methods, such as adverse event reporting by manufacturers, and more active methods, such as analyzing data through its Sentinel System.

While the FDA regulates medical devices, Medicare has a prominent role as a payer. Medicare pays indirectly for medical devices by reimbursing providers when they use medical devices to deliver care. With some exceptions such as durable medical equipment, Medicare generally does not pay for the cost of each device separately and instead makes a single payment that covers all of the inputs that are used to provide a particular service, including any medical devices.

In terms of the size of the device market, recent estimates vary, ranging from $119 billion in 2011 to $172 billion in 2013. In terms of structure, there are over 5,000 U.S. companies that make medical devices. While most are small and narrowly focused, a few large, diversified companies account for most of the industry's overall sales.

The profitability of these companies also vary. Small publicly traded companies are often not profitable. Because these companies are less diversified than large device companies, their success or failure may depend

heavily on a particular device.

In contrast, the large, diversified device manufacturers, which receive a significant portion of their revenues and profits from the sale of IMDs, have consistently had 20 to 30 percent profit margins. For Medicare-covered services, hospitals spent $14 billion on IMDs and $10 billion on medical supplies in 2014.

In addition to representing a larger share of total spending, the rate of growth in spending for IMDs was nearly twice as high as the rate for medical supplies from 2011 through 2014. Medicare also pays for devices in other settings, such as ambulatory surgical centers and physician offices.

Now that I've given some basic background on the device industry, I'll give an overview of each of our four topics, discuss how the topic relates to medical devices, and lay out some policies for the Commission's consideration.

The first topic is unique device identifiers. A unique device identifier, or UDI, is a code that is assigned to only one device by an FDA-accredited issuing agency.

The requirement that devices have UDIs is scheduled to be fully phased in by 2020. However, while manufacturers are required to have UDIs for their devices, there is no mandate that providers use UDIs.

A UDI consists of two parts: the device identifier (which identifies that manufacturer and model of the device) and the production identifier (which identifies more granular information such serial numbers).

While there is broad agreement on the need for UDIs and the inclusion of UDIs in data sources such as electronic health records, stakeholders disagree whether UDIs should be included on administrative claims.

There is currently a draft proposal to add a field for device identifiers for high-risk IMDs in the current round of revisions to physician and hospital claim forms.

Proponents believe that including the device identifier on claims will allow researchers to leverage the scale, availability, and longitudinal nature of claims to improve post-market surveillance and provide the information necessary to better understand the short- and long-term costs and value of devices.

Opponents believe including device identifiers on claims will be costly to implement and are not needed for post-market surveillance.

This next slide lists some possible benefits of the new UDI system if providers consistently use UDIs and UDIs are incorporated in various data sources.

Most prominently, UDIs can improve quality. For example, UDIs can provide critical information to providers at the point of care, which could help reduce medical errors. UDIs can also help the FDA improve its post-market surveillance system and improve its ability to conduct recalls, which have historically been challenging in the device market.

UDIs may also be used by Medicare and others to improve our understanding of the value of specific devices and to reduce costs. For example, adding the device identifier portion of the UDI to administrative claims could help Medicare better understand the downstream costs of failed devices and track required payments under Medicare's device credit policy, which requires a reduced payment to hospitals if manufacturers provide a credit to the hospital for a failed device.

Given the development of UDIs, the second bullet on this slide lists three possible items for the Commission's consideration.

The first two sub-bullets represent efforts to ensure that, once UDIs are fully phased in by manufacturers, they are used throughout the health care system.

For example, the Commission could consider policies to require or encourage hospitals to retain and use UDIs for IMDs in order to facilitate appropriate care and enhance post-market surveillance.

The third bullet discusses requiring manufacturers to pay what we are calling a "device failure penalty" for failed devices or for devices that fail at high rates. This policy responds to the fact that Medicare and beneficiaries currently pay for many failed devices to which the program's device credit policy does not apply, such as devices that do not have a manufacturer warranty. In addition, Medicare and beneficiaries also pay for all the related costs associated with revision procedures and other downstream costs related to failed devices, which can be substantial.

Future work in this area might involve investigating how to structure such a penalty, which devices the penalty should apply to, and how to define a device failure.

The next topic is hospital-physician gainsharing. While gainsharing can take myriad forms, the term generally refers to programs that allow hospitals to share savings with physicians if costs are reduced below a benchmark.

Previous gainsharing programs have focused on reducing device costs. For example, hospitals have shared savings with physicians that resulted from physicians agreeing to limit the number of manufacturers from which they request devices, which in turn allowed hospitals to promise manufacturers more volume and obtain lower prices.

Physicians and hospitals often have misaligned incentives, as physicians have substantial influence over the device used but hospitals bear the costs of such devices. Therefore, physicians often have limited incentives to seek lower-priced devices. Gainsharing aligns physician and hospital incentives by allowing physicians to benefit from reducing costs, generally after meeting some type of quality benchmark.

Some are concerned that such arrangements could harm patients by, for instance, providing an incentive to stint on care, and could enable hospitals to pay physicians for referrals.

Gainsharing can also violate federal laws, such as the anti-kickback statue. Because of the legal risks, providers are hesitant to engage to in gainsharing involving Medicare fee-for-service beneficiaries outside of programs approved through the OIG's Advisory Opinion process or demonstrations that waive certain fraud and abuse laws.

Empirical research on gainsharing, including evaluations of OIG-approved programs and other demonstrations, has largely found that gainsharing leads to cost savings, while improving or not affecting quality. Further, some of the concerns initially raised about gainsharing programs might be mitigated by relatively new quality programs.

For instance, opponents of gainsharing contend that such arrangements could provide an incentive to discharge patients too soon to save costs. However, the Hospital Readmissions Reduction Program, which began in

fiscal year 2013, penalizes hospitals for excess rates of readmissions and could, therefore, discourage such behavior.

In terms of potential policies in this area, the Commission could consider reiterating its 2005 recommendation in support of gainsharing arrangements or combining gainsharing with efforts to improve price transparency, which I discuss on the next slide.

Specifically, the next topic is price transparency for IMDs, which are devices such as pacemakers and knee and hip implants.

Some are concerned that the IMD market has characteristics that lead to high prices. Relative to the market for medical supplies, price competition is limited in the IMD market because manufacturers often compete on differentiated products, and the market is also highly concentrated.

IMDs can also be technologically advanced, which can be a barrier to entry for new competitors, and can be very expensive, accounting for a large share of the costs of certain procedures.

Despite these high costs, IMD prices, net of

rebates and discounts, are not readily accessible. Even when hospitals purchase IMDs, they frequently do not know what other institutions paid for the same devices.

Patients and physicians also frequently have limited knowledge of device prices and limited incentives to seek such information.

Manufacturers have enforced this lack of transparency by inserting confidentiality clauses into their purchasing agreements with hospitals and suing for disclosures.

At least in part due to the opaque nature of IMD pricing, there is wide variation in the prices that providers pay for the same device.

Little empirical research has studied the effects of price transparency on prices in consolidated health care markets similar to the market for IMDs.

Nevertheless, proponents believe price transparency will reduce the variation in prices and improve the ability of hospitals to negotiate lower prices.

Opponents generally believe that price transparency in highly concentrated markets could lead to higher prices.

A policy for the Commission to consider is exploring how to implement a price transparency program for IMDs. Work in this area could involve determining which device prices should be made public, the timing of disclosure, and exact type of pricing data that would be disclosed.

Also, any transparency policy would likely need to be coupled with policies that give hospitals and physicians the tools and incentives to seek lower device prices.

The last of our four topics is physician-owned distributorships, or PODs. PODs are entities that make money from selling devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients.

PODs can be structured in different ways. Under the distributor model, PODs operate as intermediaries between device manufacturers and hospitals that purchase devices -- that is, a device manufacturer sells a device to a POD, and then the POD resells the device to a hospital at a higher price. Under the manufacturer model, a POD might contract with a manufacturer to produce the device and then

sell their devices directly to a hospital. Under the GPO model, physicians form a POD in order to aggregate their purchasing power and get bulk discounts from manufacturers.

Regardless of their structure, PODs create incentives for their physician-owners to perform more and potentially inappropriate surgeries because they directly profit from the use of more devices.

PODs have predominantly been present in the market for spine devices, although some are concerned that the model could be spreading to other areas.

Using data from 2011, OIG found that nearly one in five spinal fusion surgeries used devices acquired through PODs. The OIG also found that growth in spinal surgeries was three times as high at hospitals that used PODs compared to those that didn't and that devices purchased through PODs were either equal to or more expensive than those not purchased through PODs.

The OIG also put out a Special Fraud Alert in 2013 stating that PODs were inherently suspect under the Medicare anti-kickback statute. The Fraud Alert listed some specific POD characteristics that were particularly troublesome, such as PODs where payments to physicians are

tied to the volume or value of devices used.

In response to the Fraud Alert, some hospitals voluntarily instituted hospital policies that restricted their dealings with PODs. PODs have reportedly shifted to hospitals without such policies.

PODs have also avoided reporting under the Open Payments program. Some PODs may not be required to report or may have changed their structure to avoid reporting. Other PODs may be required to report but fail to do so.

Given this information, the Commission could consider strategies to improve POD reporting under the Open Payments program and requiring hospital-level POD policies.

For PODs that are currently covered by the Open Payments program, better enforcement by CMS could help address non-reporting. However, this does not address PODs that are not required to report or those that have changed their structure to avoid reporting. For such PODs, the Commission could explore a recommendation explicitly requiring PODs to report under the Open Payments program.

The Commission could also consider exploring a requirement that hospitals develop policies requiring PODs to inform hospitals of their physician ownership and limit

their dealings with PODs to those whose structure explicitly complies with the Special Fraud Alert.

While some hospitals have developed similar polices, other hospitals, such as small or rural hospitals, might lack the leverage to voluntarily restrict their dealings with PODs. Also, requiring PODs to report their physician ownership to hospitals could improve transparency, as those reports could be used to improve adherence to the Open Payments program and because the OIG has found that many hospitals that purchased devices from PODs were unaware that they were doing so.

This last slide summarizes the potential policy options that I have mentioned throughout the presentation. As I mentioned earlier, we are interested in feedback from the Commission on these items or other items related to medical devices that the Commission is interested in pursuing.

And with that, I look forward to your comments, and I turn it back to Jay.

DR. CROSSON: Thank you, Brian.

Let's start with questions on this side. Can I see hands for clarifying questions? Let's start on this

side with Warner.

MR. THOMAS: Do we know how many PODs there are out there and where they're more prevalent? Is it simple size facilities or is it --

MR. O'DONNELL: Right. So I think most responses that I have on PODs begin with the fact that no one really knows exactly how many exist. There have been efforts to kind of quantify them, and the best estimate that I've seen was in the Open Payments final rule where CMS estimated that there were 260 PODs that existed in 2013. They acknowledge that was using the Senate Finance's report on PODs and that they were estimating. They didn't know for certain. But that was the best estimate that I've seen out there.

The other thing that you said is that Senate Finance did find that a lot of these were in California, so that's the one geographic thing that I would note.

MR. THOMAS: Thanks.

DR. REDBERG: Thanks. A really interesting report. On Slide 12, you mentioned that POD prosecutions have been limited, even though the OIG suggested they were suspect under the anti-kickback statute. Why is that that

they've been limited?

MR. O'DONNELL: Right. So from what I understand, there are cases ongoing with Dr. Sabit and Apex Medical Technologies, but in my conversations, the anti-kickback statute, which this implies, is an intent-based statute, and so they feel like they need kind of a smoking gun to take this to court and that it's hard to prove that at different times.

MS. BRICKER: I wanted to better understand the comment you made around hospitals often don't know that they're purchasing from a POD. How is that possible?

MR. O'DONNELL: Right, so that comment stems from how the OIG conducted their 2013 study, and essentially what they did was that they surveyed hospitals, and they said, "Are you buying from a POD? Yes or no." And then they verified that with receipts. Right? And so some hospitals said, "Yes, we're buying from PODs," and they listed a name. And then when they went to other hospitals and said, "No, we're not buying from hospitals," and they listed the name, and the names matched someone who bought from a POD. What they found -- and they cleaned the data and did some checking. What they found was that -- I

forget the exact number, but a decent share of hospitals actually didn't know that these entities were PODs.

MS. BRICKER: I would just figure there has to be some sort of due diligence on the part of someone buying something that's going to go in someone's body, like you would know, you know, what is this company?

DR. DeBUSK: Actually, I could follow up on that. I have run into orthopedic practices where the CEO of the practice didn't even realize that they were using a POD, because what happens, you know, they don't call it "Dr. Jones' POD Incorporated." It will say, you know, "Southeast Spinal Concepts, Inc." Well, you don't know who you're buying from or the ownership, and there's some elaborate ways, like there is something called the "40/40 rule" where, if 40 percent of your POD is owned, or less is owned by the referring physicians, and I think 40 percent of your referrals come, there are ways to sort of slip under the radar, and that makes it even more complicated.

MS. BRICKER: I just wonder if there's something we should do. You know, when you're purchasing drugs, you have to ensure a certain pedigree, and you have to know where they're coming from. Right? Like you can't just

contract with Amy's Wholesaler and not do some sort of due diligence. So I was just curious if there's something more here we should do around you've got to know who you're buying from and that it's legitimate and, moreover, identify whether -- you know, their ownership and if they are, in fact, a POD.

DR. DeBUSK: One system -- and I have a copy of the form. Several years ago, one national health care chain had a very, very aggressive anti-POD policy. I mean, it was a multi-page questionnaire. And, originally, when they rolled the rule out, if you read the questionnaire, what it sounded like was even if the physician was part of a POD that didn't take those types of cases to the hospital at all, he just had ownership in some other POD, that they were -- their privileges were revoked. It was a very stringent policy. But from what I understand, I think they've backed off of that just a little bit.

Again, I have a copy of the form. I'll send it.

DR. CHRISTIANSON: [Presiding.] That's very interesting information.

I have a quick question for Brian. This is not on PODs. It's on the identifiers. So most of the stuff

I've seen in the literature, and I think what you are saying in this chapter, is the argument against more information, is that it costs more to collect, and the argument against that is, but there are cost savings if you can avoid adverse events. Is that kind of it in a nutshell, and if it is, is there any way we can get any estimates of what the costs are to collect the information?

MR. O'DONNELL: Right. So I think you are referring to, specifically, the device identifier portion on the claims, and I think the argument against it, just to lay the groundwork, is that, you know, folks who are opposed to that say, yes, we kind of acknowledge the need to put, you know, the full UDI into the EHR and into device registries, but that if you are specifically -- or solely focused on post-market surveillance, they don't believe that just a DI on the claim adds much value. So that's the argument.

In terms of --

DR. CHRISTIANSON: The argument is not based on any additional cost of including that information?

MR. O'DONNELL: No. The bang for the buck isn't there, is essentially the argument, and the only estimate

I've seen is that CMS has come out and said that they will need extra funds to update their legacy computer systems to process claims. I don't know that I've seen any estimates, you know, on the physician side of the house, like what admin burden that adds to them. So then they'd give examples of, you know, the process of getting the UDI or the DI into the claims, you know, they said will involve computer updates on their end but also retraining staff and redoing some of the processes. But I haven't seen a good figure out there.

DR. CHRISTIANSON: Basically we don't know how -- to use a word that Warner uses, material -- how material those costs would actually be.

MR. O'DONNELL: I haven't seen an estimate, no.

DR. COOMBS: Yeah.

DR. HOADLEY: So I also have a question on the UDI. You talked about, in the reading materials, three different agencies that have been authorized to do these and they all have different formats, and I know we have, also, on the NDC codes for drugs, there are differing formats.

Was there a rationale to, you know, allowing this

kind of multi different ways to do this, as opposed to having one uniform format and/or one company doing it? Was there a rationale for this kind of diversity?

MR. O'DONNELL: Yeah. I don't know that I can answer your question specifically but I would note a couple of things, is that there are three different issuing agencies. One specializes in, you know, blood products, so it's kind of a specialty kind of type of entity, and the other two seem to have some overlap in their products. So I'd say at least one, there's some specialization--

DR. HOADLEY: Okay.

MR. O'DONNELL: -- for the agencies, and even though their -- you know, their structures can vary, there are rules and guidelines that the agencies have to abide by, so they can't just make changes, you know, that they want to. So, yes, there are different formats but there are standards that they have to abide by.

DR. HOADLEY: I mean, I know on the NDC, as a researcher, it's just, you know, an annoying extra step to have to go through and make sure that when you are pulling those codes into a database that you're reading the different formats, you know, consistently, and it's a

source of error. So it just -- it seems shortsighted to have allowed things to develop that way.

DR. HOADLEY: Let's just keep going up this row. So that would be you, Bruce.

MR. PYENSON: Thank you very much, Brian. I have a broad question on scope. So I think implantable medical devices, I can understand, and it seems like then there's another level of devices in the scope of this work that are -- require some form of approval, and then there's a whole bunch of other things that hospitals and providers buy. You know, it could be bed sheets, on and on. So it sounds like the scope for this is anything that requires approval. Is that --

MR. O'DONNELL: So, I mean, yes, the scope is broad and I think we focus on some of the higher-end devices, just because, well, there's a lot of money involved in that and there's been some other issues, kind of market-based issues related to them. But, you're right. The scope is -- covered all devices.

MR. PYENSON: So by -- as a follow-up question, the actual food chain, or distributorship sales process, I think often runs through GPOs for any of this, and I'm not

sure if the distinction we're making between things that the health care system buys that Medicare doesn't directly reimburse for, that fit into this bucket, is defined in a way that corresponds to the transactions that occur in the health care system today.

So just as a scoping idea -- I'll try to convert this into a question -- when you think of a hospital and a hospital budget, probably the biggest single chunk is labor, and then there's another chunk that's utilities, energy, things like that, and depreciation, and then there's another chunk that I would say are purchases of stuff. And from that purchasing of stuff, if we had to put a volume on that, I think that would be pretty big, into the, you know -- perhaps a lot bigger than the numbers here. And I'm wondering if you have any sense for that, of that purchasing of stuff, what portion of that is what we're calling medical device industry?

DR. CROSSON: [Presiding.] Let me see if I can understand. So I think, Bruce, what you're asking, for a hospital or a medical office there's a whole bunch of stuff it takes, you know, furniture, light fixtures, you know, you mentioned sheets, things of that nature, some of which,

arguably, have some contact with a patient and some that don't. So are you asking, how do you define what is a medical device versus some other entity that's purchased by a medical facility, that is not a device but is involved in the economic transactions?

MR. PYENSON: So I'm trying to get a scope of what portion of the budget --

DR. CROSSON: -- of the Medicare budget is devices?

MR. PYENSON: Or even a hospital's --

DR. CROSSON: Okay.

MR. PYENSON: -- or a physician office, is devices, and what portion is other stuff --

DR. CROSSON: Other stuff they buy.

MR. PYENSON: -- they buy, because what's behind that is -- my view is that a lot of that all comes through the same deals, and the same middlemen, and the same distributorship.

DR. CROSSON: Okay.

MS. THOMPSON: In response to that question, I think I know where you're headed. In the overall operating budget of a hospital, roughly, what, 40 percent is labor,

and in the materials 15 percent is in supplies. And what's the relevance of that? I think what the relevance of that is what we're experiencing. Medicare isn't buying these devices. The hospital is buying these devices, and if the price goes up, it leaves fewer dollars for labor -- nurses, physicians -- to care for patients. So the beneficiary's response is, you know, he or she is going to get the device the physician chooses, and the hospital is left with fewer dollars to buy the labor, or everything else that it takes to run a health system.

So I think that's a really relevant point that you're making which underscores the relevance of this really complicated chapter, because it's like how do you -- it's a little bit like picking up Jell-O. It's like -- you know, it's pharmacy all over again. And so where do we focus to get some bank for our buck in this discussion, is what I'm trying to get my head around, and I can't quite get there yet because the issue that you raised, Bruce, is right on the money, and the beneficiary is the person who's negatively affected in this discussion.

So that's -- I'm just trying to understand where do -- what do we go after to take a chip at this.

DR. MILLER: So I think there's potentially two questions on the table, which is just a dollar question. How much of some denominator does something represent? But then I think there is a question of, what do we do with this information?

Now, without a lot of consultation with anyone, at either end of the table, the way I would tend to think about this -- and remember, we did get kind of a sweeping request of like, "We've never looked at this. Would you kind of tell us the story?" So, we're trying to -- you know, we're trying to tell the whole story.

For myself, with zero consultation with anyone, and this is not a round one comment, would be that when you get to the stage of talking about policy, if you think about the policies that we're talking about, you know, things like gainsharing, the UDI, I'm going to skip the POD thing for a moment, and, you know, price transparency, my advice would be to focus on the implantable devices. I think those are a big-dollar block. I think when I talk to hospitals, and, you know, Warner is in, I believe, on this too -- he's not here right this moment -- that's the thing that is the physician preference item, and I'm, you know,

saying you're buying this one, even if this one is just as good and it's lower priced. That's the issue.

So if you get to that point in the conversation, my advice would be if you're thinking about supplies and gloves and things like that stuff, I would say direct your attention over to, at least for a starting point, the implantables, and that's said with no consultation whatsoever.

DR. CROSSON: Let me -- we're still on round one, and I want to see if -- Bruce, are you finished? Okay, so we go Kathy.

MS. BUTO: Back to PODs for a second. You had a statement, and it was in the report and you also made it, that PODs can change their structure to avoid reporting. Could you say more about that, like what reporting are we talking about? The relationships, or what exactly?

MR. O'DONNELL: Right. So I was talking about avoiding reporting under the open payments program.

MS. BUTO: Okay.

MR. O'DONNELL: Right.

MS. BUTO: So that's the relationships with physicians and so on.

MR. O'DONNELL: Right. So under the open payments, a lot of PODs, CMS said, should be considered GPOs, but then the PODs allegedly have responded by changing their structure so they don't fit that definition and, therefore, don't have to report.

MS. BUTO: Okay.

The other question I have is how do they get away from Stark, the Stark Laws, physician ownership and reporting, which is, in my experience at CMS, was the most complicated rule we had to develop, in terms of ownership relationships. The real exceptions I can remember were solo physicians, which is an odd exception because it covers a lot of people, and I thought group practices, but nothing like a POD would have been exempt, as I recall, but Ariel knows the answer.

MR. WINTER: So the issue -- well, I'll tell you what I know, which is a little bit dated, but the issue is that the Stark Laws only apply to designated health services, and the devices -- implantable devices or other kinds of devices -- are not considered a designated health service. So, therefore, the way CMS has interpreted the Stark Laws, PODs or other entities that sell devices to

health care providers are not part of Stark.

MS. BUTO: They're not covered by the law.

MR. WINTER: They're not covered by Stark. However, CMS, several years ago, asked for comments. They had received requests from folks that PODs -- that devices should be considered a designated health service because they are used for designated health services -- in other words, hospital services -- and they asked for comment about whether or not these types of entities should be regulated under Stark. And we got comments --

MS. BUTO: So they have the discretion --

MR. WINTER: -- but in the end they said -- they deferred any action.

MS. BUTO: Okay. So somebody thought they had the discretion, because the underlying purpose of Stark was to get at referrals that were driven by self-interest, which is exactly what this is. Okay. Got it.

DR. CROSSON: Okay, Paul.

DR. GINSBURG: You know, we've talked a lot about the potential harm that PODs can do to beneficiaries and the taxpayers and ways to deal with that, but there's a basic question. Is there anything socially redeeming in

PODs?

[Laughter.]

DR. GINSBURG: And if not, should we be thinking about different policies that are far more aggressive?

DR. MILLER: Yeah, Brian.

[Laughter.]

MR. O'DONNELL: Social redemption, I had in my notes.

[Laughter.]

MR. O'DONNELL: Well, I mean, I will say this, and that's the sense of, there are some folks who advocate for PODs, and they say, well, we can save a bunch of money because we, as doctors, can get together and, you know, negotiate better prices for volume and whatnot, and they published a case study that said they reduced prices. And I think my response to that is that it proves that there could be some fat on the bone there, but that, you know, the profits -- you know, there's bad incentives built kind of inherent into the POD. So I think that's the one thing I would say there.

DR. CROSSON: Brian.

DR. DeBUSK: I'm going to save my POD comments

for round two, but I do have a round one question on UDI, particularly the device identifier in claims. If you were dealing with an APM, whether it's an ACO, it's a CJR, or maybe even an APM we haven't even developed yet, if you were trying to measure changes in clinician behavior -- say the devices -- to Mark's point earlier, these implantable medical devices -- if you were trying to track, on a large scale, how being in an APM may or may not have influenced their choices -- say moving to lower-quality devices or something like that -- but for putting the DI on the claims form, what would your Plan B be? What would the alternative be?

MR. O'DONNELL: Right, and I think that's a fair point and I think that, you know, in a perfect world, right, the information from EHRs would be more accessible. But I think in the world that we live in, I think that's the argument for putting on claims, that it's more available to researchers to do those types of analysis.

DR. DeBUSK: So Plan B is that all the HER vendors are going to finally decide to work together and play Kumbaya and interchange data and standardize their dictionaries and all that.

DR. MILLER: You seem skeptical.

[Laughter.]

MR. ROLLINS: You could also envision --

DR. DeBUSK: I'll take the under on that bet.

MR. ROLLINS: You could also envision CMS going at it in a more limited fashion by doing sort of audits and evaluations of certain participants and demos, to sort of profile on a smaller scale what's going on.

DR. MILLER: And just -- there is the kind of analysis that you're talking about, like, you know, in a baseline or benchmark type of way could you see, you know, an effect. But then the other reason I guess people talk about it on a claim is whether you could begin to see faster than some of these other types of oversight, whether you're starting to have a problem from a device.

DR. DeBUSK: But even if you saw, say, a shift in the mix -- let's say I went from buying two-thirds Bo Jackson hips and one-third Medicare hips, and I flipped those percentages, you could see in the aggregate -- and I agree with you, there would be a lag -- but you still wouldn't be able to be -- it wouldn't be actionable data in that I couldn't say, well, oh, here's the orthopedic

practice that's really engaging in the undesirable behavior and here are the guys that are still doing, presumably, the good or the right thing. I think it would be hard to tease that apart unless you dug into each individual EHR, and I think that gets back to --

DR. MILLER: No. I wasn't making an argument for the EHR. I was making an argument for two different uses of the claims data, which is not just to show whether you're -- you know, getting a price effect or a shift in the mix of devices over time. There's also a surveillance function. You might be able, on a national basis, to begin to see a problem emerge. If people were being readmitted because of a device failure, you might be able to also look at the claims data, and more quickly than some of the other surveillance things, without precision, but to know something is up.

DR. DeBUSK: I missed that.

DR. MILLER: I know. I wasn't clear.

DR. CROSSON: Okay. I see no more clarifying questions. We've got this slide up and I'm remembering. But I do want to say a little bit about what we want to do here.

I think we've already heard, in the clarifying question a lot of interest in a lot of different pieces here, but I think what Mark and the staff need -- I think we heard Mark a minute or so ago, say, you know, help us prioritize here. What, among all these different things and different approaches that we've got on the table, should we do first, second, and the like?

So I would ask you to be thinking about that and we'll have Rita lead off the discussion.

DR. REDBERG: Thanks, Jay.

So I think it's a -- I'm really glad that we're talking about this and that Warner brought it up, because, you know, I've been interested in sort of why we have such an expensive health care system and our outcomes lag behind many other countries in the world, and a lot of it, I think, is related to technology because we use -- and of that a lot of that is devices. We use a lot more in this country than anywhere else and we pay a lot more for it. And so, you know, I started, maybe like 10 years ago, looking a little bit into background, medical device approvals, because most of what Medicare is paying for is what FDA has approved. And you did cite our JAMA paper

from 2009, in the chapter.

But basically, I -- and as a cardiologist obviously I've been recommending devices for years before I started looking at the approval process and I was quite shocked to discover that most devices -- and we only looked at high-risk implantable devices, because, you're right, it's Sutton's Law. That's where the money is.

But even in these high-risk devices, most are approved without -- you know, we think for drugs it's two randomized controlled trials. Most devices have one trial, and most of the time it's not a randomized, controlled, blinded trial. You know, they use what they call historical controls, which mean you take controls from some other study. Not -- you know, the reason randomization is such a high-quality study is because you have the same group and you've controlled for everything, and it's impossible to do that without randomizing and blinding.

So I will just say -- and that was for the premarket approval, which, as you said, is only a few percent of all devices. There are other devices that you might think are high risk because they're implanted in your body, like some heart valves, metal-on-metal hips, but

they're not considered high risk, and they don't go through that premarket approval process. So even just looking at the most high risk, you know, the data was a lot less than one would think in order to start putting devices in people, because, remember, these are implantable devices. It's not like a drug, when you discover it's not, you can just remove it -- I mean stop taking it. Now you have something inside someone, and so I come back to that device failure, but it's a big deal to have a device that you find out is not just not effective but harmful, and now it's in you and you have to decide what to do. It's a big problem for beneficiaries.

So after we started looking at premarket, we looked at post-market, and, again, you know, there's a lot of pressure on the FDA, especially since passage of 21st Century Cures a few months ago, to get devices on the market faster. And I think that's a big problem, and it's a big problem that sort of starts with FDA, but then comes back to Medicare, although it's noted in the chapter Medicare doesn't have to cover all FDA-approved devices. But there's a lot of pressure on Medicare to cover FDA-approved devices. So I think part of it is we need FDA to

be more in sync with kind of, you know, standards of reasonable and necessary, and I think the agency is certainly signaling very loudly they're going the other way and trying to get devices on the market faster and not -- which means -- faster generally means without randomized controlled trials, and, you know, the head of the FDA device just had something in the New England Journal yesterday suggesting you did not even need clinical trials for high-risk devices, computer simulations would do. And I think that's kind of a dangerous idea to say that we wouldn't have to study a high-risk device in people that, you know, I don't think anyone would really want to be the test person for a high-risk device that's never been tested but there were computer simulations, because we don't have time but I could give you lots of examples where things look good in simulations and they didn't work so well in people.

So there is a big move now to doing more post-marketing, and I think that's a good idea. But, you know, six years ago, the IOM had a report saying to get rid of 510(k) that the FDA could commission -- and also to improve post-marketing, the FDA proposed and there is talk, but it

is still talk, about this NEST system. But right now, you know, we have very, very poor adverse event reporting, which means that we don't even know how many devices that we're putting in Medicare beneficiaries are failing and are dangerous, I mean, let alone metal hips, which I mentioned, we learned about because Britain and Australia had registries. Like six, seven years ago, we had a California Technology Assessment Forum meeting, and we were reviewing the data on metal-on-metal hips, which the orthopedic surgeons were very excited about, and one who had come to tell us about how great they were and they were putting them in younger and younger people because they were thought to last a long time. And I said, "How can you be so sure when there has never been a randomized controlled trial?" And he looked at me and said, "It would be unethical to do a randomized controlled trial, these are so good." Well, six months later, it was off the market because the data had then come in from other countries that there was like a 40 percent revision rate.

So I think, you know, premarket and post-market could be a lot better, and, you know, as you put in the chapter, we're paying billions of dollars for these devices

in Medicare beneficiaries, and that is good if they're improving outcomes. But we don't have data for most of them that they're improving outcomes. And then they're causing problems.

And I think, Jay, you started with one of our other discussions that our principles were solvency and cost burden of beneficiaries, and these are very expensive devices, which, again, if we have data that they're leading to clinical improvements, that's great. But there are more and more devices getting no the market that we don't have that data for.

So I'll just -- you know, another -- well, I mean, the adverse event reporting right now, it's estimated only a few percent of all adverse events get tracked in the MAUDE database. You mentioned Sentinel, but Sentinel is only for drugs. We don't have Sentinel tracking for devices. There are some individual registries now. The registries are not publicly available, and they're not accessible, and it's not clear how much of the reporting is accurate. But it's hard to know because you can't publicly access the database.

And then we talked a little bit about prices, and

as I said, the prices are way higher in this country. There have been some stories -- I mean, there's not a lot of price transparency, but there have been stories of people that go to Europe to get devices because they're so much cheaper than it is in the U.S.

So I think the idea of the device failures penalty is intriguing because, I mean, like I said some -- you know, metal-on-metal hip, there have been a number of ICD lead recalls. It's estimated there's hundreds of thousands of Americans that have defibrillators, so, you know, these potentially life-saving devices, but when they don't work, they also could kill you. And now once they -- and people now have many -- there have been several recalls on different -- Riata and Fidelis Sprint. And so then you have this person -- it's very hard to track them because we don't right now have device identifiers. Even if you track them, you have the problem of what to do. Should you take it out and put someone through another life-threatening procedure or leave it in with the uncertainty that this may lead to serious outcomes, including death?

One of my colleagues, Zian Tseng, has a study in San Francisco that I think he's now expanding where they do

explants on people that have died with devices in place, defibrillators and pacemakers, and found that there were a number of unexpected deaths that were actually related to the defibrillator or pacemaker due to a misfire. And they would not have been known except that he's doing this autopsy study with the San Francisco Examiner, which he published in JAMA Internal Medicine, and now they're expanding the study, so my point being I think it's the tip of the iceberg in terms of how much we're not -- we don't know how much harm there is from devices, and I just think it's important to understand both the benefits and the harms before we have widespread use. And, unfortunately, with implantable devices, as I said, it's hard to remove them once they're approved. So I do think the standard should be higher, and I'm concerned that the FDA is clearly signaling they're going to lower the evidence standards in order to get these devices on the market more quickly.

I think it's only an advantage to get things on the market quickly if we know they work. It's not an advantage to get dangerous devices on the market more quickly.

So gainsharing reminds me a little bit of

bundling, and, you know, the bundling initiatives, at least in the spine -- and I'm sure Brian can speak more about this - have certainly been successful in lowering the price because it did change the incentive. The incentives are not there, as you explained. Before the bundling arrangements, there was not really much incentive to purchase devices at lower price. I think the main issue people have with bundling is that it still doesn't get at the appropriateness, so if you are going to pay less, you know, you might do more procedures.

And the last thing I'll say -- and you did cover it in the chapter -- is that there are a lot more financial arrangements between device companies and physicians implanting devices, and a lot of those are opaque to patients, so patients don't know when a physician is recommending a device that they actually have a financial interest in the knee or hip that they're recommending, or the cardiac device. You know, the biggest -- it's cardiacs and orthopedists that are the biggest devices. I think that's another area that we could certainly look at and do a lot better at making those relationships transparent at least, because I think it's a big problem.

I'll stop there and hopefully give us more time for discussion.

DR. CROSSON: Okay. Thank you, Rita.

Let's have further discussion and, again, focus on prioritization here. I can't remember where I started last, but let's start with Craig and then Amy.

DR. SAMITT: So I think this has been -- I think all of these topics seem to be very valid. What I'm struggling with is a lot of what Bruce introduced and others, Rita in particular, have mentioned. I have a hard time appreciating which of these potential areas will most support our principles and will help address the challenges and the problems we're trying to solve. I tend to agree with Mark that I think the biggest bang for the buck is an IMD. I also similarly have concerns about PODs. But I can't fully appreciate how material and substantive those policy areas really are, and so I don't know whether it would be helpful to even quantify, either in terms of quality improvement or sustainability and cost, how these all interrelate and which ones truly are material.

For example, UDIs, I just -- when we've studied this at Anthem as well, the cost of implementation for

inclusion in claims form is extraordinarily high, and the question is: Is that cost worth the potential benefit that comes from UDI inclusion on claim forms? It's kind of hard to understand the cost-benefit associated with that.

That aside, I think device failure penalty I would separate out from UDI. I think that's something that I would imagine we could still put in place regardless of UDI on claims forms. So it's hard for me to appreciate the value of each of these distinctly.

The only other thing that I would add is, as I was especially listening to the discussion about price transparency and the PODs, it went back to a lot of our drug discussions and our recommendation for the Drug Value Program. And it made me wonder, should we have a Drug and Device Value Program that has similar requirements that drive transparency and cost competitiveness and avoids some of the POD issue, if we thought of a D-DVR as opposed to just a DVR.

DR. CROSSON: Do you want to --

DR. MILLER: Yeah, let me say -- first, just a real quick clarification, and I know you didn't necessarily mean it. I wasn't advocating for, you know, UDI over any

of these other things. This is for you. I was just trying to agree with Brian that there's EHR and there's UDI, and I was thinking there were some differences there that I want to tease out.

One thing I would say, to the extent -- more directly in trying to respond -- and I agree, we're kind of asking you to do something, you know, where you're like pick, but I don't really know, and we're sort of trying to thrash around, too, at the staff level.

One thing I would put across to you in terms of your DVP point, one of the disconnects in an idea like that, which we could explore and come back to, is that, you know, the hospital is providing the surgery to implant a device, the physician is doing the surgery, and there's a disconnect between those two actors, where the hospital might be saying, "I think this device is just as good as any other, and we could get it at a lower price," and the physician says, "No. I want this particular device." And you can have big arguments whether that's all clinically driven, but then start asking questions about financial relationships. And I'm setting all that complexity up because I want to say gainsharing is intended to try and

get at that, where it says, okay, if you could clear some of the kickback types of underbrush and say you are allowed to share those savings if you as a hospital and you as a physician come together on a price, then the notion of whether it's called a DVP or -- but the idea of negotiating becomes a more aligned function, whereas right now the hospital is saying, "I want a low price," and the physician is saying, "I want this device." And I know that's way simplistic, but I would put that thought in your head if you want to go down the, you know, large quotes, DVP type of road.

DR. CROSSON: Okay. So we've got Warner, Sue, and then David and then Amy. Go ahead, Warner.

MR. THOMAS: Just a couple of comments. I guess, first of all, I would encourage us to take a much harder approach on the PODs. I just don't see how they're helpful for the program or helpful for beneficiaries. And I think going to Mark's point, they certainly could create mixed incentives. And so I would encourage us to be very direct about the challenges with them. At a minimum, I think there ought to be more reporting. Frankly, I think there ought to be a way that we try to do away with them over

time because I just don't find them to be real helpful.

The comment around device failure penalties, I would like to see us understand this in a lot more detail just because I don't think there's a lot of understanding about this in the industry in general. I don't think there's a lot of clarity around it. To me, it's very similar to readmissions or, you know, that whole scenario. So I think we ought to be looking at companies to be very clear about what sort of device failures they have, what are the rates, how does that compare, what's the transparency around that, so I would encourage us to look at that very closely.

You had a comment in the article as well or in the chapter as well indicating that the device or implant cost could range from 30 to 80 percent of the Medicare payment, and I'd also like to just understand a little bit more around what that really looks like for common high-volume types of procedures like joint replacements or cardiac implants, going to Rita's comment. I mean, you know, is that -- I mean, 30 to 80 percent is a wide range, so are there more that are in the 80 percent range or are there more in the 30? I think it would be helpful to

understand that because to me it plays into Medicare pricing.

The last thing I'd like to put on the table for consideration, going to Mark's comment, I think the gainsharing and having gainsharing be easier to do and, once again, with the appropriate transparency, I think it's something that should really be considered.

I also think another concept that ought to be considered is thinking about especially for hospitals that qualify in the 340B area is a 340B type of program for devices and implants. We're doing this in the drug area. It's only available to organizations that have a higher level of indigent or Medicaid patients. You know, I'm not sure why we wouldn't see the device companies that are running, you know, 20 to 30 percent margins, as outlined in the chapter, providing the same type of benefit to organizations that are taking care of a disproportionate amount of patients who are less fortunate in the country.

So I would like to see us explore that concept as well because I think it could be helpful to those organizations that do have a disproportionate share of those folks. And I think it's also a contribution that the

device industry could be making to, you know, indigent and folks that are unfortunate, folks who are in the Medicaid program. So, anyway...

DR. CROSSON: Thank you. Sue passed. David.

DR. NERENZ: I think like others I was particularly interested in the POD part of this chapter, things there that I hadn't been aware of, and clearly the general painting of it is pretty negative.

One of the things I was surprised by is how little effective force there seems to be particularly among hospitals against this. If part of the evil of it is the rising of prices either for particular devices or then sort of the increased use of devices, including cases where they're inappropriate, it would seem like in those examples that there would be, I would have guessed, a lot of strong counter pressure by hospitals.

So, for example, for a set of procedures, use of a POD benefits the physicians, but it results in a higher price, that goes directly to the hospital bottom line in a negative way, and I'm surprised there's not greater pushback.

Now, in the domain of unnecessary procedures

being done, for example, you know, that's an adverse effect at the ACO level, that's an adverse effect at some other -- I'm not sure how MA plans quite play into this because they may be buffered by, you know, DRG-based hospital pricing. But, you know, in general, I guess the observation -- and maybe you can just say more about it if there's anything more to say -- is, you know, why are there not more effective counter forces? But then also looking forward, it would seem like initiatives that we talk about under other headings. Like, for example, bundled episode payment would conceivably have a positive effect if implemented in a stronger form; you know, stronger ACO incentives, for example, might get at it another way. Even when you talk tomorrow about provider consolidation, the dynamics here might be different if the surgeons are employed by the hospital than if they're not.

So I'm just thinking that some of the avenues of approach here may be in other domains of our discussion.

DR. CROSSON: Thank you. Amy.

MS. BRICKER: I just found the chapter to be absolutely fascinating, and really, I am appreciative of all of the work.

I am in absolute support of continuing to explore the notion of unique device identifiers, and what was most interesting to me are the comments that have been made by Rita and others around failure. And to further explore warranties associated with failure, it seems like it would be a tremendous opportunity here. So in order to actually make that work, you'd have to be able to identify the device and the patient.

So is there some cost to it? I would assume yes, but it would be interesting to see if warranties were actually invoked, the savings or the ROI associated with that effort.

I am in support also of price transparency, and in the chapter, it is mentioned that it was -- and in your talking points, you talked about this was a breach of confidentiality for hospitals to share this information with physicians, and so they have now resorted to color-coding the device. I think that is just bizarre. I don't understand exactly why you're -- the person that is actually making a decision shouldn't know the price associated with that decision. That sort of blows my mind, so I am in complete support to price transparency to the

physician, not to other manufacturers, not to put it on a billboard. That's counter to, I think, what then -- essentially raise pricing, but absolutely to the physician and maybe also to the patient.

We don't really talk about that too much, but I think the patient should know the price. I think the patient should know if they have options, and I absolutely think the patient should know if the physician that they're sitting across from has a financial incentive to put that device in your body. I think all those things should be known to the patient.

But fascinating work. Thanks.

DR. CROSSON: Thank you.

Jon.

DR. CHRISTIANSON: So back to the device identifier, I would like to have a better idea, Brian, of how much more valuable information we get from including not only the device identifier but the production identifier and how critical that is to the surveillance activity to have both.

I would also like to know -- Craig says with this, it is going to cost an enormous amount of money. I

would like to know how much of that is a one-time expenditure, in which case we could amortize it over the future.

And I am really worried about the future for the reasons that Rita suggested, which is if we are going to make it easier to get new devices to market, without a lot of testing, then I think it becomes more and more important that we get them off the market quickly if they're not working and if they're causing problems for beneficiaries. And that means, I think, going the claims route right now, because I'm with Brian. I'm not going to sit around and wait for all of the electronic health records people to get together and coordinate things.

Then way back to what Sue said earlier, how do you get your hands around what to do here, for me, the device identifier plays into quality of care for our beneficiaries, and one of the things that we are trying to do as a Commission is improve quality of care.

So, yes, we can't get the devices out of people, necessarily, that have been implanted that have later proved to be a problem, but we can stop continuing to implant those devices in new folks, and that is a quality

issue. So I think that's a very clear thing. Even though we don't pay for medical devices, it's a very clear way that Medicare can connect with medical devices.

DR. CROSSON: Thank you.

We have got about 15 minutes left. Comments?

Jack.

DR. HOADLEY: So one of the things that I am struck by, we have talked, in some cases, here about similarities between some of the things we are hearing about devices with drugs. The big difference -- and I think that point has been made -- is that for the most part, the devices are paid inside payment systems. So Medicare is not making a direct payment, whereas at least on the Part B drugs, Medicare is paying directly.

Now, we've got some Part A drugs with some other issues there too. So it seems like that -- it's all complicated, but that's part of how we have to keep thinking about framing this.

Trying to think about prioritizing, I'm thinking, again, what are the potential benefits versus the cost, but it's both from the system point of view. So if, to Craig's comment, it's expensive to do that, it doesn't mean we

don't do it. It just means we need to think about that.

We've also got to think about it, I think, in terms of our time and effort, both staff and Commissioners, and some of these things take huge research undertakings. That may not be the right payoff or huge amount of time for us to get a handle on, and the payoff in terms of taxpayer dollars or whatever is small.

Those are maybe obvious points, but I thought I'd say them.

I, like a couple of people here, many people here -- the financial incentive issues hit hard. I mean, I was going to ask a comparable version of what's the socially redeeming value of the PODs kind of question. And I think a number of us seem to be trying to understand that. Is there a good reason for these to exist?

So, at the very least, this notion of improving the open payments reporting, maybe that's the kind of thing that we should speak to quickly, so that will help provide the data that might let us see if there's an answer to is there any good purpose for these things, or we can also just go more directly if we really don't think there is.

I would put the same kinds of questions up in

terms of the transparency and gainsharing kinds of issues. To me, my gut reaction is to say, "Yes, more transparency." I may think about it even more broadly than, say, Amy does, but at least we agree on the parts of transparency to the purchasers or to the physicians. And that seems like it could have some important payoff in terms of undertaking financial incentives.

The gainsharing, I just really want to understand, if we are going to go that route, what are all the incentives that are going on, making sure that we do it in a way that doesn't create bad incentives.

And then trying to think about where the sort of low-hanging fruit-type of issues are, again, one of them, I think, is the open payments kind of thing. I don't think we need to do a lot of research or spend a lot of time, and there's not a lot of cost in the system to say, "Yes, that payment, that reporting system should be improved."

Initially, I was going to say that some of these UDI issues felt like low-hanging fruit, but now I am hearing the complexities. Although, like Jon, I think one-time cost versus ongoing costs are part of what we need to understand there, and I hear in other context, "Oh. Well,

that is expensive to do." And I'm saying it is expensive the sense that it disrupts your current routine. Is it actually that much cost as long as we do it on some kind of a time frame where you're revamping systems, anyway? Is there a point at which -- okay, if I tell you to do it and you got to do it in the next six months, yeah, that's really expensive. But if I tell you to do it as you phase in the next round of your systems updates, maybe it's not so. If there is any way to get some insight on that, then maybe we can say, "Oh, it's not really that expensive after all."

DR. CROSSON: Alice.

DR. COOMBS: So I just wanted to speak to a couple of things. One is our role in terms of quality and if there is an intersection in terms of what lane we're in.

I feel like this is a very difficult area to be in and to say that it's directly related because of the setup of the Medicare, how it is processed in terms of Medicare reimbursements.

But I do agree that the device failure penalty is huge, because I have been in the cath lab when you have to take out an AICD that has had a recall. It is a big burden

for the patient, and not to mention, many of them require anesthesia because they go and they test the threshold. They have to be shocked. I mean, first thing, induce refib, and then we shock them. So it's a big deal, and it lasts for a long time. And so many patients, they have the inconvenience of hospitalization, and I don't know what other kind of parameters are there for what they have to pay out of pocket just to have this recall.

Now, it is said that the companies actually cover the recall. I don't know what the logistics of that is, but --

DR. REDBERG: They cover the device, not the hospitalization.

DR. COOMBS: So they may cover just the device, but I actually went down to the lab to talk to an EP chief and ask him, "Do you know how much this device that you're putting in costs?" And he was able to actually tell me that we work this out, and we're actually better than most of the other purchasing companies. So he was very aware of the device.

But I just wanted to speak to one thing, and that's the POD. So believe it or not, the role of a POD

might be that these so-called doctors are usually in the field sometimes. An orthopedic surgeon who no longer does orthopedic surgery will know strategically what to sell and how to promote and how to market to orthopedic surgeons, so that there is a favorable kind of reception to the specialty based on physician helping with the strategy.

Now, they themselves may not go into the operating room. They may have a rep come into the operating room, and they are sitting there. I have been in these cases. They are sitting there the entire time. It is to the degree of the support of how that rep understands the process of putting in the knee or the hip or whatever they are doing. So part of that POD has a lot to do with how successful they are at marketing, and it has a lot to do with physicians having had a part of that.

How do we get at it as MedPAC? And I'm thinking that the best way to consider it is to use the open payment but also to include it in our other chapter, because I think it is going to be hard for us to get at all of these things under the situation we're in right now. So I would say the PODs probably should be included in our open payments chapter and better address it there as opposed to

trying to deal with it solely on this whole notion of DME, because it's conflicted in some regards because I don't see it as the physician who's actually still practicing and actually telling to themselves as a Stark arrangement. I see it as a business venture that is promoted because of a finite knowledge base that the physician who owns that company has, and so that's a very different approach.

I don't see that person as working continually in the field, but having an expertise that actually allows them to be able to sell and to be able to market to a group, I think price transparency is key.

But I think one of the things is if you have an accountable care organization and someone puts -- Dr. X puts in the bad hip every time, has a return to the OR, trust me, the primary care doctor is going to say, "I've had three of my patients who have gone to Dr. X. They have not had a good result." The system will begin to correct itself in terms of referral patterns to low-performing interventionalists, whether it be cardiac, whether it be orthopedic surgeon.

So I think health care reform advancement and to APMs and ACOs will in and of itself correct some of what's

going on with poor performers with procedures.

DR. CROSSON: Thank you.

Bruce, Kathy.

MR. PYENSON: Well, thank you very much for rich material.

I have a couple of suggestions for further research, if I could, on this, and some are easier than others.

One of them is that I believe using the Medicare data, we can identify for some categories, relevant categories, the cases of likely implantable failure. So the case, for example, that Alice had mentioned, we could probably come up with a fair certainty on what we're talking about there.

Now, that's not just interesting from an analytic case, but if we can come up with a reasonable methodology for that using ICD-10s and CPD codes and things of that sort, then we could actually suggest a policy that the hospital is liable for the extra cost, which would induce a market of guarantees from the manufacturer to cover the hospital cost.

So I think there's a direct string from the

analytics, which I think is capable without -- we're able to do that without new coding or anything else for at least a subset of these kinds of conditions.

Another on the cost issue, I think there's a couple of approaches. One, which is probably easy and imprecise is using Medicare cost reports. I believe there's cost centers for some of the kinds of stuff we are talking about and perhaps a cost center base, ratio cost to charges kind of approach that we could use to try to come up with some kinds of estimates of at least what's flowing through the hospital system.

I share Brian's view of electronic medical records, and I am almost at the point of having that view about cost accounting as well, but there are databases, large databases of hospitals that have cost accounting systems and could probably make available their database to MedPAC for this kind of research as well, which would be a more longer-term kind of issue but probably better results, so a couple of thoughts there on ways to move ahead with the guarantee and also the scoping out what sort of dollars we're talking about.

DR. CROSSON: Kathy.

MS. BUTO: Yes. So, first of all, I wouldn't limit this to implantables because imaging and diagnostics are -- I think were -- I don't know if they were are -- the fastest-growing area of medical devices' cost. I don't know if they still are, but I would at least take a look at that, that category.

I was listening carefully to Rita, and I think she identified three important buckets. One is safety and surveillance. The second is the cost of unnecessary care, and the third is just the payment incentives issues, right?

So, on the first one, I do think Medicare has a role, could have a role of gathering more data post-marketing and working more closely with the FDA. So I would encourage us to think about that. I don't think we have to do a lot of work on that, but they have begun on a couple of instances to try to collaborate more with the FDA.

On the cost of unnecessary care, I go back to a comment at the last meeting, which is, I think, generally, we have to tackle this issue of appropriateness of care, whether it's device-related or other drugs, other things. We haven't really taken that on, and I hope we will in the

future.

On the incentives piece -- and I look at -- let me just touch on the items up there. The device failure penalty that I am aware of, actually, when there is a failure can cover the cost of the device, some cost or the hospitalization or partial cost, but also all of the ancillary testing and ambulatory follow-up that goes with that, because it isn't just re-operation.

And I know in the instance of my former company that an offer was made to replace the device, not just with their device, but any device that the hospital chose. So, again, just getting away from the circular, you just replace a defective product with your next-generation product. The hospital was given the freedom to select, and then the company would pay for that device. So there are ways you can structure this that's more than just a penalty but actually covers a lot of the ancillary costs.

On the gainsharing proposal, I think that's certainly worth exploring. I'd also like us to think about -- and I don't know how this would work particularly, but in the ancient past, CMS looked at centers of excellence for bypass surgery and cataract surgery that included not

just the procedure, the device, but also the physician payment. And that got around some of the IG gainsharing concerns because it was really a bundled payment.

What the hospital got in exchange was some designation as a -- it had to meet certain standards, which drove some volume, and there were savings, and quality was as good or better than before the center of excellence demo. But, again, it's ancient history, and maybe the program has moved way beyond that. I just think it is a broader concept and more like bundling that includes a physician payment that tends to incent everybody to try to get the best overall result and do the best -- get the best savings out of it that's possible.

On the POD, I agree with Paul. I don't see any reason -- I think Paul and Warner -- no reason at all for the PD that I can imagine, but at least the open payments reporting. And it seems to me re-raise the question of physician ownership rules and the applicability here because it drives behavior. Even though I am hearing Alice say that it may not be the same physicians who are operating, it does seem to drive greater utilization, so that suggests some interest of some kind.

And I know ownership and referral rules apply to diagnostic tests, so I just wonder why this kind of input wouldn't be covered as well.

I think that was it.

MR. O'DONNELL: Can I just clarity one thing really quickly? And I have heard this from Alice and now Kathy. From what I understand, not all devices have warranties. So what you were saying, that if a device fails, there is a warranty to pay for the replacement device in certain cases, I think that's true in certain cases, but a lot of other cases, there aren't any warranties that exist in the marketplace.

MS. BUTO: Yep.

MR. O'DONNELL: And then also, from what I understand, it is not common to pay for the downstream cost as well.

MS. BUTO: Right. I was just suggesting --

MR. O'DONNELL: Yeah.

MS. BUTO: -- a policy we could consider, not what's out there now.

MR. O'DONNELL: I agree. Yeah.

DR. CROSSON: Okay. Paul.

DR. GINSBURG: Yeah. On --

DR. CROSSON: Sorry. One second, Paul.

DR. GINSBURG: Sure.

DR. CROSSON: Do you want to comment on that?

DR. REDBERG: Well, it's a comment on -- well, it's to thank Kathy for making cohesive my eight years of ramblings on the device industry, but also specifically on FDA and CMS.

It occurred to me, there has been coverage with evidence development that has been a coordinated effort between FDA and CMS, where a device looks promising -- or it could be for anything, but for this case, devices looks promising, but there isn't sufficient data to say that it's reasonable and necessary, that CMS can cover in a limited -- only in the context of a clinical trial, which really only works if you can only get that device in the context of the clinical trial, because otherwise -- like with the atrial septal occluders, people do it off label and get reimbursed, and then you have to say, "Okay. Now we're going to go look. Did it work? Then we'll cover it. If it didn't work, we're not going to cover it." But that, I think, is a really fertile area for FDA and CMS going

forward in terms of gathering data, ensuring access, and working with the evidence to make sure that Medicare beneficiaries are getting reasonable and necessary and safe and effective devices.

DR. CROSSON: Sorry. Paul.

DR. GINSBURG: Sure.

On the price transparency issue, we know that when markets are un-concentrated, price transparency is wonderful. When they are concentrated, especially if one side is concentrated, the other is not, then it is potentially problematic. I think the implantable device market is like that.

And one thing that we might want to explore is whether given the fact that Medicare and the hospitals have very closely aligned interests and the hospitals being able to get good prices on these devices, whether we could have a program where Medicare collective transaction price data and share them carefully on a confidential basis with hospitals who would use it for buying. This would not be released to the public. This would not be public information.

One further thought, Amy brought up the

intriguing thing about should the beneficiaries get the price transparency information, and I would say given the way the Medicare benefit structure is set up, absolutely not, because they pay the same, no matter whether they get the Jack Nicklaus hip or the basic hip. So I can envision all the advertising: "Go for the Jack Nicklaus hip. Tell your doctor that's what you want." Yeah, I don't think we're ready for that.

I was very intrigued with Bruce's idea about making the hospitals, in a sense, requiring a warranty to be given by the hospitals for implanting devices because, in turn, they would, I think, go to the manufacturers, basically get warranties form the manufacturers, and it would be much easier for Medicare to enforce this.

DR. CROSSON: Paul, do you know of a hospital where I could get one of those Jack Nicklaus hips?

[Laughter.]

DR. MILLER: It's the one with the red stick.

DR. CROSSON: Brian.

DR. DeBUSK: First of all, I think Mark earlier in his comments really framed the root cause of a lot of these issues when he talked about the misalignment between

physicians and hospitals or the lack of alignment, which will just go to teach me not to separate my Round 1 and Round 2 comments because that's where I wanted to get it in.

But I do think you framed that really, really well, and I think we as a group, one thing we could do that would be very beneficial is to build a framework for physician-hospital gainsharing, and if we could create -- I know it's a vague concept, but if we could create that clear bright line, so people would know when they're operating and in a compliant way, you could also eliminate -- for example, eliminating things like PDs, just put that on the other side of the line. Just flat out make a POD illegal.

But I think there's a framework here where we could -- for example, we could speak to stenting. We could speak to induction, where you get more procedures simply because of the opportunity. We could speak to vigilance. How are you going to measure the effects of these systems? But I think if you had that framework where we could drop it into any APM -- so if a fee-for-service hospital could operate within that framework, an ACO with BPCI, something

that was almost like a safe harbor for that -- and I'll give you a good example, for I saw something really creative, and I don't know if this was done intentionally or by accident.

But some of the APMs that are out there that do episodic payments, they will cap the physician incentive to 150 percent of the fee schedule. So I might be in, say, a BPCI or something with a hip. Well, my approach may be to rationalize post-acute care. Well, my colleague's approach may be to try to save money on the implant itself. We may all have different ways to try to improve care, but you know you're in a sandbox there where you're not going to go past 150 percent of the fee-for-service.

So I think if we had that very clear framework, so that the physicians who would normally be hesitant -- because that's the other issue. The way we do it now, alignment is really just a series of OIG rulings and guidance and all that. Well, the more conservative physicians don't even want to get close to the line. The bolder physicians -- I mean, there are PODs out there today that are 100 percent owned by one person, where 100 percent of the referrals come from that one person. They are what

we call "100-100 PODs." I mean, it's the doctor paying himself to do cases. There aren't a lot of them, but they're out there.

So you've got this group of very bold people and then this group of people who are very conservative, and what you'd like to do is help us -- I think what we could do as a Commission is help draw that bright line and then try to make that line as applicable to as many different situations as we can. It's almost like a reusable set of principles for physician-provider alignment.

And the final thing I am going to say on that, I think if you had that, it might actually take some of the pressure off around consolidation, because we're going to talk, I think, tomorrow about provider consolidation. Well, as an independent practicing physician, if I thought there was a way that I could align better with my hospital and not necessarily become an employee or basically be forced into a bigger group, I think you'd have some opportunity there too. So you may be able to solve a lot of problems with a very robust set of gainsharing principles.

DR. CROSSON: Okay. Thank you for a very rich

discussion.

I think, in all honesty, it's a little hard to sum up here. I think Mark and Jim have captured all of this input, and so kind of --

[Laughter.]

DR. CROSSON: We may need a little bit of a meta-analysis here, more than I can do at the moment. I did hear a few things, though, I think.

Number one, Mark mentioned let's focus on where the money is, and it's in implantable medical devices. I heard a modest support for that. Not many people were saying, "No. Let's go look at tongue blades and towels and things of that nature," although I think, Kathy, you did add imaging stuff, which I think is fine. We could add that. But I do think there is a sense here that rather than look at the whole realm of devices, that whatever work we do, it ought to be concentrated in some area of high cost or high impact on quality. I think I heard that.

I did hear broad support for some process to track the use of these devices, and then as a derivative of that, things like reimbursing for failure or tracking for unrecognized problems, et cetera, like that. Now, which

particular method of tracking is the best, I think, probably, we could do a little more work on, and I think it ties into the next point, which is as we start to narrow even further here, the notion of bang for the buck is important here, not just from the perspective of how much money could be saved for the Medicare program, but the impact on beneficiaries, in some relative terms. And I think you've done some of that. Perhaps we could do a little bit more of that.

I think particularly with Brian's last comment, but others as well, the notion of trying to bring together potentially conflicting interests that exist now between physicians and whatever support mechanism they've got going on in terms of choosing devices and the interest of the hospital and then the interest of the Medicare program, some process to make some suggestions as to how that might work better. Gainsharing is certainly one of them.

And then I heard a fair number of people essentially questioning the issue of PODs and their existence, and maybe this is one of the easier areas here that we could -- I say that because I don't have to do the work, but essentially say, "Okay. If there is a value,

this is what it is. Here is the whole list of arguments for why there is no value, and here's some suggested interdictions that we could recommend." And that may be a circumscribed area of work.

That's honestly the best I can do at this point, and I think, as I said in the beginning, we need some more work to make sur that that's the right representation of all the great ideas that we've had here.

So, on that notion, thank you very much, Brian and Eric, and we will move on to the next presentation and discussion.

[Pause.]

DR. CROSSON: Okay. So we have, in the past, looked at regional variation in Medicare Part A and Part B spending and service use, and at the request of the Commission, we have asked you to come back and tell us what's happening.

DR. ZABINSKI: All right. There are substantial differences among geographic areas in how much Medicare spends on beneficiaries, and this geographic variation has been an issue of interest among researchers and policymakers. In particular, there is little evidence that

the higher spending and service use result in better health outcomes.

In previous work, the Commission has evaluated geographic differences in program spending and service use among beneficiaries in fee-for-service Medicare. For today, we have largely repeated our previous analysis and will present the results of this new analysis and compare these results to those from our previous work.

An important point to understand is that spending and service use are very different measures. We define spending as monetary outlays by the Medicare program. Geographic variation in spending is affected by geographic differences in prices, special payments such as IME adjustments, service volume, service complexity, and beneficiaries' health status. Variation in service use is affected by only by service volume and service complexity. To obtain service use, we remove the effects of prices, special payments, and health status from spending.

Because service use and spending are so different, we find that areas where spending is high do not always have high service use. For example, New York City has per capita spending that is 26 percent above the

national average but per capita service use is 5 percent below the national average.

Our discussion today includes separate analyses of the variation in Part A and Part B of Medicare for all fee-for-service beneficiaries and variation in Part D among those enrolled in stand-alone prescription drug plans. We also will compare our findings from this analysis to our findings from the Commission's 2011 report on geographic variation.

In our analysis of variation in Part A and Part B, we obtained spending data for 2013 and 2014 from a database that summarizes the spending on Medicare claims into beneficiary-level spending amounts. We then obtained service use by adjusting each beneficiary's spending amounts for differences in prices, which meant removing the spending effects caused by hospital wage indexes and GPCIs, and special payments such as IME adjustments. We also adjusted the spending for differences in demographics and beneficiaries' health. The result is our measure of service use for each beneficiary.

Then, we defined 484 geographic areas that we based on metropolitan statistical areas. For areas that

were not in MSAs, we combined into statewide non-metropolitan areas, and we refer to these as MedPAC areas. We determined per capita spending and service use for each MedPAC area. These per capita amounts are average spending and service use from 2013 and 2014. Differences in service use between areas reflect factors such as providers' practice patterns and beneficiaries' preferences for care.

On this diagram, we show the distribution of Part A and Part B per capita spending and per capita service use over 2013 and 2014 across our 484 MedPAC areas. The green bars represent the distribution of per capita spending and the red bars represent the distribution of per capita service use.

Along the bottom of the diagram, we've placed categories that indicate per capita spending and service use relative to the national average. This ranges from less than 65 percent of the national average on the left to more than 135 percent of the national average on the right.

The vertical bars indicate how many of our MedPAC areas fit into each of the relative spending categories. A vital point is that we weighted each MedPAC area by how many fee-for-service beneficiaries are in that area. For

example, Los Angeles, with its 950,000 beneficiaries, has a much larger presence on this diagram than does Corvallis, Oregon, with its 7,000 beneficiaries.

We think the most important takeaway from this diagram is that the distribution of service use illustrates much less variation than does spending. For example, in the 95 percent to 105 percent category at the very center of the distribution, it indicates that 45 percent of beneficiaries are in MedPAC areas that have per capita service use that is within 5 percent of the national average, but only about 24 percent of beneficiaries are in MedPAC areas that have spending that is within 5 percent of the national average.

We can also see that the green bars indicate that spending is more spread to the ends of the distribution than is service use.

Even though service use has less variation than spending, substantial differences in service use remain among our MedPAC areas. For example, we compared the spending for the beneficiaries in the geographic area at the 90th percentile to the spending for the beneficiaries in the geographic area at the 10th percentile, and we did

the same 90th to 10th percentile comparison for service use. We found the ratio of the 90th percentile to the 10th percentile was 1.47 for spending and 1.24 for service use.

We have evaluated other measures of variation that show much variation in service use but that variation in spending is even higher.

Finally, an interesting result is that, on average, per capita service use is nearly equal in urban and rural areas. We found that urban areas, on average, are 0.1 percent below the national average while rural areas, on average, are 0.2 percent above the national average.

Then we explored what factors underlie the variation in service use. We started by evaluating service use variation in three broad sectors: inpatient, ambulatory, post-acute care, where inpatient combines acute inpatient services with inpatient psychiatric services; ambulatory is physician services and hospital outpatient services; and post-acute care combines SNF, home health, LTCH, and IRF services.

We found that the PAC sector has much more variation than the other two sectors. For example, the

ratio of service use at the 90th percentile to the 10th percentile is 1.88 in the post-acute sector, while the same measure is 1.16 in the inpatient sector and 1.20 in the ambulatory sector.

The high variation in the post-acute sector appears to contribute more to the variation in Part A and Part B services than do the other two sectors. Among our 484 MedPAC areas, we found that the correlation between use of post-acute services and use of all Part A and Part B services is 0.83, while the same measure is 0.65 for the inpatient sector and 0.63 for the ambulatory sector.

Now I will turn things to Shinobu who will discuss variation in Part D of Medicare.

MS. SUZUKI: A subset of fee-for-service beneficiaries get their drug coverage through Part D. In 2014, about 25 million, or 62 percent of fee-for-service beneficiaries, were enrolled in Part D drug plans or stand-alone PDPs. We focused on this subset of fee-for-service beneficiaries because we don't have drug data for the other fee-for-service beneficiaries.

PDP enrollees differ somewhat from the overall fee-for-service population. For example, they are more

likely to be female, disabled beneficiaries under age 65. Among the elderly beneficiaries, they were less likely to be younger cohort between 65 and 69, likely reflecting the recent rise in beneficiaries choosing to enroll in Medicare Advantage plans.

Compared with overall fee-for-service enrollees, PDP enrollees have higher Parts A and B spending on average, and higher prevalence of medical conditions.

Among the PDP enrollees, we found that drug use varies less than drug spending. Similar to the method Dan used to analyze Parts A and B spending, drug use is spending adjusted for variations in prices, demographic characteristics and health status. The dark blue bars show the distribution of drug use relative to the national average. Compared to the gray bars, you can see that it's more concentrated around the middle.

About 51 percent of the beneficiaries were within 5 percent of the national average drug use, compared with 31 percent for drug spending. We also found that drug use in high-use area, or at the 90th percentile, is 21 percent higher than the low-use area, or an area at the 10th percentile area, compared with a 38 percent difference for

drug spending.

Among the PDP population, we found that drug use is somewhat more concentrated than medical service use and that combined medical and drug use varied less than either medical or drug use alone, though the difference was not large.

In general, we do not find a systematic relationship between medical service use and drug use across geographic areas. That is to say that in many areas that have very low or very high medical service use, we do not consistently find correspondingly low or high drug use, and vice versa.

Our regression analysis also did not show statistically significant relationship between drug use and medical use in a given geographic area, in total or when analyzed separately for inpatient, ambulatory, and post-acute care services.

Many of our findings are similar to our previous study. For example, in both studies, we found that areas with high or low spending is often different from those with high or low service use. In the example that Dan gave, the New York region had above average medical

spending, but once the spending was adjusted for differences in prices and demographic characteristics and health status, the average use was lower than the national average.

Service use varies less than spending, but large differences still remain, and for Parts A and B services, much of the variation is due to variation in the use of post-acute care services.

We also continue to find that medical service use is positively correlated between sectors, but does not appear to be correlated with drug use. We also found that medical service use do not differ between urban and rural areas.

There are some findings that are different from our previous study. I'll just highlight a few here, and we can address others on question.

Compared with the previous study, the current study shows slightly lower variation in medical service use. We also found this to be true for post-acute care services, although the variation is still large compared to non-post-acute care services.

Finally, we found lower service use in areas that

had the highest medical services use in our previous study, though their service use is still higher than the national average.

We would like your feedback on the material we covered today and in the paper. Next step for us is to include any revisions based on today's discussion and prepare the paper for a standalone report to be published later this summer.

With that, we are happy to take your questions.

DR. CROSSON: Thank you, Shinobu and Dan. We are open for clarifying questions and I see Craig.

DR. SAMITT: So a two-part question. Great report. Did you analyze service use difference based upon the evolving penetration of CMS ACOs, and what impact the ACO dynamic environment has on evolving service use differences, by geography?

DR. ZABINSKI: We didn't tear it apart down to that level, but I think there is probably some evidence that, you know, that ACOs have had some impact. I think Mark was thinking about McAllen and what happened there. Right? Or do you want me to bring you into this?

DR. MILLER: So you're giving me the opportunity?

Thanks.

DR. SAMITT: Well, and it may be helpful for me to add the second part of my question, because I think it's all interrelated. You know, I think putting on my former provider hat, you know, I think the phenomenon that the provider community is experiencing is this notion of a foot in two canoes. And there's still the volume world and there's the evolving and growing value world.

And I guess the question is, is I would imagine that the progressive value world, wherever that sits, is motivating and evolving change in the way practice occurs, across all payers. And so I'm interested in knowing and studying sort of growing Medicare Advantage, because growing Medicare Advantage could conceivably begin to socialize the provider community with value, or the growing commercial ACO world, CMS aside.

So if I am a provider and more and more of my patients are either in MA programs or in commercial ACOs, I may very well evolve my service use for fee-for-service Medicare. And so I'm curious to know the correlation between a payment for value for the providers and how that's changing, and the spillover effect that would

frankly have in fee-for-service service use.

DR. CROSSON: Amy.

MS. BRICKER: I'm curious. Miami and McAllen, do you have any idea as to why they improved, although still above average?

DR. ZABINSKI: Well, just on nuts and bolts, particularly in Miami, durable medical equipment dropped substantially from the earlier study. They were way above the average. In fact, they were way above the location that was in second place on durable medical equipment, and now they're below average on DME.

McAllen, it primarily looks like a decrease in use of post-acute care, yet, you know, they're still well above the average in post-acute care but much less so now, in particular, the amount of home health dropped by a substantial amount.

MS. BRICKER: So do you think it's like public shaming, or like how did they, like, get in line?

DR. ZABINSKI: Um --

DR. MILLER: Well, I think that's what difficult and in some ways not unrelated to Craig's question. It's hard, at this level, even though it's disaggregating by

market, it's hard, still, to attribute cause. My recollection, in the Miami situation, is there was a specific program integrity effort on this front, wasn't there?

DR. ZABINSKI: I think, you know, it could point to some success in anti-fraud efforts.

DR. MILLER: And so that might -- and whether that falls into your public shaming category, I'll leave it to you to judge. But, you know, also, you know, the second part of that story often is that the people who are engaged in that activity move to different counties, and so I wouldn't be surprised if you see some of this show up elsewhere. But that was one piece of it.

In the McAllen instance, you know, we had this conversation internally, post-acute care went down. There was some sense that an ACO was created there, and if you read -- and again, I want to be really clear that all the following statements are just kind of connecting dots as opposed to real analysis. If you remember kind of the Atul Gawande stuff, where he said, you know, a set of entrepreneurial providers kind of entered the market, changed the dynamic there, and a part of that real change

in dynamic was post-acute care, in a big way, and there were even issues of kickbacks and that type of thing. They then formed -- or some of them have formed an ACO.

Now think about it. You have a giant -- you know, you've kind of got it going up, and now somebody shows up and says, "By the way, I'll reward you if you take it down," so now they're into --potentially into that.

So internally, you know, around the, you know, the lunch room, this is kind of the things. Maybe a program integrity focus, and to some extent, maybe, but not, you know, with a lot of analytical rigor, maybe some effect from, you know, ACO type of activities, in these couple of instances. But also, Dan, some compression in the distribution overall.

DR. ZABINSKI: Yeah.

DR. MILLER: I'm sorry, and I'll stop. I swear. The other thing to keep in mind is the other thing that happened, I think, to data that we used previously and now is also we're getting more of the effect of the slowdown in utilization that started to occur around 2008, 2010, that type of --

DR. ZABINSKI: Yeah, we picked that up as well,

and to the extent that the slowdown was greater at the high ends, you're going to get some compression.

DR. MILLER: Right.

MS. BRICKER: So I know Miami is identified as a heat zone. Is McAllen? Heat -- are you familiar with this?

DR. ZABINSKI: No, I'm not.

MS. BRICKER: No? It's from a program integrity perspective. They identify certain MSAs that have a high propensity for fraud --

DR. ZABINSKI: Okay.

MS. BRICKER: -- so just curious. I know Miami is that but I don't know if the other is.

DR. ZABINSKI: I'm not aware of it.

DR. CROSSON: Okay. Questions? Jack.

DR. HOADLEY: A couple of methodological questions. When you're defining this concept of service use, you're taking the overall spending and you're adjusting out these various factors -- the wage indexes, the add-on payments, and health status measurement, and so forth -- but this is still a dollar measure so it's still incorporating the price of the service?

DR. ZABINSKI: Hm -- I would say --

DR. HOADLEY: Or is it a true volume of service measure?

DR. ZABINSKI: Yeah, it's going to -- Shinobu is whispering. We have intensity yet. Yeah, it's intensity of services. It reflects, you know, like the volume and the intensity of the services with sort of a, you know -- basically, what it does is it says, suppose everyone was paid at the same rate --

DR. HOADLEY: Okay.

DR. ZABINSKI: -- everybody had the same health status. Okay?

DR. HOADLEY: So it does assume everybody is paid at the same rate.

DR. ZABINSKI: Yeah.

DR. HOADLEY: It's not just adjusting out the wage index kind of variation.

DR. ZABINSKI: Right. It adjusts out the effects. Like everybody has a hospital wage index of 1 and GPCIs of 1, is essentially what's going on here. And then what it reflects is idiosyncrasies of the particular areas, you know, like providers' practice styles, beneficiaries'

preferences, and that sort of thing.

DR. HOADLEY: Okay.

DR. MILLER: And the intensity point, which I'm sure you get but just in case anyone else isn't following it, is: Do I have more volume versus do I have more of higher, you know --

DR. HOADLEY: Level 4 visits versus Level 2 or whatever.

DR. MILLER: Yeah, MRI versus, you know, X-ray.

DR. HOADLEY: CT scan. And my second question, in the text you talked about the difference between the A-B analysis and the D analysis is the D includes the cost sharing? Was there a particular logic to that or was that just a byproduct of how you happened to run analyses?

MS. SUZUKI: So because D's benefit, as you know, is very unique, to try to measure use, converting spending to use, I think we had to include all of gross spending to get at the use concept that's comparable to A-B.

DR. HOADLEY: Because of the doughnut hole ad all the --

MS. SUZUKI: Mm-hmm.

DR. HOADLEY: Okay. Thank you.

DR. CROSSON: Jon.

DR. CHRISTIANSON: On page 21 and 22, you talk about the lack of correlation between spending in different sectors. There's a bit of research that has been done on that, on the private sector, often within single employer groups. I think it would be useful to put that context with that discussion, so maybe in the next version of this, you could look at some of that research and compare your findings to what other people have done that have tried to do similar correlations.

DR. CROSSON: Bruce.

MR. PYENSON: Thank you. A question on NBSF. To what extent -- I'm not familiar with NBSF. What do the data fields look like?

DR. ZABINSKI: What do the what [off microphone]?

MR. PYENSON: Data fields. How summarized is it?

DR. ZABINSKI: Let's see. There is -- how summarized. There's a number of ones that would be classified under physician, you know, imaging tests, et cetera, collected all those together, but there's ASC, there's OPD. This is a number of different small categories.

MR. PYENSON: The reason I'm asking is the variation seems tighter than what I recall seeing, say, in Dartmouth Atlas. And I'm wondering if that's -- I believe they're using the 20 percent sample and looking at things like an admission or days per -- you know, more granular. And to what extent is your distribution of function of the compression going on in NBSF?

DR. MILLER: Compression going on in what?

MR. PYENSON: In the data source, NBSF. NBSF is a summarized --

DR. MILLER: Okay.

MS. SUZUKI: It's a beneficiary level file. So if Dartmouth analysis is a bene level -- you know, they may aggregate from the claim, but up to the beneficiary level, whether it's six-month spending use or annual, NBSF is an annual summary file at the bene level, so you have --

MR. PYENSON: But just maybe this is a technical issue. So, for example, I don't know if ER is separate as a line item.

DR. ZABINSKI: It's not, no.

MR. PYENSON: So the variation in ER just by itself would be expected to be bigger than the variation in

OPPS, in --

DR. ZABINSKI: Sure, yes.

MR. PYENSON: That's kind of the question I'm asking.

DR. ZABINSKI: Yeah, I mean, well, you know, we aggregated -- we took everything from the NBSF and put it together into a total for each beneficiary, all the categories, all A and B, and then Shinobu will get Part D with a different data set. So, yeah, there's going to probably be canceling out from the different sectors and get a little tighter distribution.

Perhaps also that, you know, they had a different geographic unit. They use HRRs, and we were using these MSA-based things. But I'm not sure how much that would affect the variation or not.

DR. MILLER: But isn't there a much more -- and I haven't reentered this debate for a while, but I thought the big difference was that what we're adjusting for, we adjust for more than Dartmouth does, and we did that purposely because people were arguing over what the variation represented in the Dartmouth Atlas. And so as I recall the debate, the Dartmouth folks had a number that

was much more like a spending number. They did something very different on their health adjustment. I'm not sure they adjusted for prices, and -- I don't recall that. I will leave that aside. And I don't think they did the special payments thing.

And so we came in and said, look -- and at the time when we did this the first time, there was a raging argument on the Hill over what this data represented, and so we came in and did the risk adjustment, the special payment adjustment, and the price adjustments, the conversation you just had, and said, look, it's imperfect, but this is something that's closer to utilization. And if you're talking about geographic variation, you shouldn't be capturing differences in, you know, payment rates and that type of things and try and get truly to practice variations in terms of the services delivered.

Now, I think Dartmouth's big criticism of our work -- and as always, we're right, they're...

[Laughter.]

DR. MILLER: Right okay. Their big criticism was they're worried about the way we did the risk adjustment. They think that there's a certain circularity between

utilization and getting more codes and, therefore, doing greater adjustment like in the Miami area. And so if anything, I think our error is we've probably understated the variation a bit.

DR. ZABINSKI: That's correct. Yeah, I think so.

DR. MILLER: I think that's more what you're seeing there.

DR. ZABINSKI: Another thing, Dartmouth was -- and they released a number of studies, and I think their studies each have slightly different purposes. And from one study to the next, their approach would be a little different. So for one, you know, you'd have a variation that could like quite wide and another one that would look narrower. So that's probably adding some confusion.

DR. CROSSON: Okay. Questions? Kathy.

MS. BUTO: In 2011, did you put out a MedPAC Atlas?

[Laughter.]

MS. BUTO: In other words, what I'm trying to get at here is whether McAllen knew what its numbers were -- are, and Miami and so on. Was there -- back to Amy's point about shaming, you would only be shamed if you and others

knew what you got, right?

DR. ZABINSKI: Yeah, there's a report 2011 --

MS. BUTO: With a table and --

DR. ZABINSKI: A table, yeah, and, you know, explicitly pointing out your bad -- that sort of thing.

PARTICIPANT: Sad faces.

DR. GINSBURG: I think for the shaming, let's not forget about the role that Atul Gawande played, who may have been using the MedPAC numbers. But whatever he was using -- or maybe he was using Dartmouth numbers.

DR. MILLER: He used ours.

DR. GINSBURG: Yeah, so I think -- you know, so basically you're putting the numbers out, and then, you know, getting the attention of Atul Gawande to put it out. I think that's a big part of the story of why the variation has shrunk somewhat.

DR. CROSSON: Okay. Brian.

DR. DeBUSK: First of all, I want to compliment both of you for taking this issue on. This is a very difficult analysis.

I had more of a methodological question. On Chart 4, where you do your regression, you lay out the

HCCs, and then, for example, community versus institutional, you know, dual versus non-dual, I think disabled versus non-disabled were in the regression, treated as regression variables.

If you look at the way CMS actually calibrates the HCCs for, say, MA risk adjustment, they actually treat those as separate compartments in eight different models.

Just for method consistency, would we want to compartmentalize that just in case maybe you find something down the road and it turns out to just be an artifact?

DR. ZABINSKI: I thought about that a little bit, and I see benefits to both. I think ultimately, you know, why we chose to have just one regression is just sample size. You get, you know, very specific about who's in a particular regression sometimes with CMS' method, and I think on some occasions, you know, they have to do some data massaging to get --

DR. DeBUSK: Just spreading your data too thin.

DR. ZABINSKI: Yeah.

DR. DeBUSK: Okay. Just curious.

DR. ZABINSKI: Yeah.

MS. SUZUKI: One thing we do, though, is to

assume that in each county the demographic characteristics are representative of the national sample. So we're trying to capture what's unique about each of the area. So to the extent that there is more low-income or ESRD in any given county, that shouldn't technically affect our analysis when it's adjusted.

DR. CROSSON: Okay. One more question from Jack, and then Paul.

DR. HOADLEY: Yeah, I had one more methods question. You said you attached everybody's data to their place of residence, not the place where the service was delivered. I know at least anecdotally of cases where people get their official address on file is at, you know, their daughter's address or something like that. I assume that we are basically stuck with using whatever zip code is on file for the person. Has anybody ever looked into how often you get these cases and whether that has any effect on sort of studying these issues?

DR. ZABINSKI: Not that I'm aware of, and that's a really good question. I hadn't even considered that point. But that's a really good question.

DR. HOADLEY: I mean, it comes up because I know

people who -- you know, a person whose father lives in Pittsburgh and the daughter lives here, and the daughter gets all the records. So I assume all the records show up as if that person lives in Washington, D.C. But, you know -- and it seems like it wouldn't be totally rare, but I don't know if there's any way even to study that.

DR. MILLER: You're really bringing the party down here [off microphone].

[Laughter.]

DR. CHRISTIANSON: Let's assume [off microphone].

DR. HOADLEY: Maybe I'll offset it [off microphone].

DR. CROSSON: Okay. We've got the last slide up here. As you can probably see there, we're going to have a standalone chapter published in the summer. The purpose of the discussion now is to help improve the content of that, sharpen it, emphasis, whatever anybody thinks would improve what you've read, that purpose, so we won't be coming back to it again. And Paul's going to start us off.

DR. GINSBURG: Sure. A really good job, and I think it's very useful for MedPAC to be reporting on this geographic variation. I think it goes into -- it's going

to go into policy areas we don't even imagine, you know, like you think about the quartiles that Congress set up for Medicare Advantage benchmarks, that would be probably very well informed by this. I doubt it was when they did it.

And I like your analytic approach of separating out use from spending. And I would be really interested -- and would suggest that you just add a chart to this -- in having something on the variation in health status to just give people some insight into how significant is this in, you know, determining the different resource use in different parts of the country. You know, people talk casually about it, but this would be precise, or as precise as we can do with the data.

You know, I found -- we've talked about the Miami and McAllen results. Fascinating. And, you know, this is not statistical regression to the mean. This is really information getting out and various people in their own ways acting on it, and I think that's a virtue of doing this at a detailed level and getting some of these outliers out.

I was also very surprised by the fact that urban and rural as a group seemed about the same in service use,

and I think that will be a surprise to many people, because I think the impression that many people have is that, well, rural areas, they don't have the specialists, their hospitals aren't capable of doing as much, and, therefore, they have less service use. And, you know, that may not be the case.

DR. MILLER: Can I just -- because I wouldn't have brought this up but he said it. You are right. Everybody walks around with that in their head. The previous geographic analysis that we did a few years ago showed it was relatively comparable. A bunch of work that Jeff and others did on rural issues a few years ago showed it was relatively comparable. And everybody walks around with that perception, that it isn't. And so it -- at least for the Medicare population, because I think sometimes facts in other parts of the population get kind of attributed to Medicare. So I'm glad that you picked upon that. It is something that people miss.

DR. CROSSON: Okay. Further comments? We'll start -- nowhere.

DR. CHRISTIANSON: Sue and Craig.

DR. CROSSON: Okay. We'll start down here again.

Craig. That's where the majority are.

DR. SAMITT: So, again, I thought the analysis was wonderful. I think what I'm curious to understand is: What is actionable now based upon what we've studied and observed? And I think that's why I asked about, you know, looking at ACO penetration, Medicare Advantage penetration. It's why we ask about encounter data, to try to get to the root causes of the differences in service use as opposed to just knowing that there's geographic variation. So it feels like we need to know more about the root causes to truly make some additional policy recommendations, and so I don't know how to go a layer deeper, because I think that would be the natural next step.

MS. THOMPSON: Well, thank you for your work here, because when I saw this chapter, I was really excited, and I just wanted to dig into it. And as soon as I did and started asking -- writing down questions I had, I thought, "Oh, my gosh." I mean, we could go down many, many rabbit holes here, and it felt like I wanted a whole little set of folks just doing nothing but maintaining all these analytics around variation. And, therefore, to your point, I think this is going to be -- as a Commission, I

think it's going to be important for us to be disciplined about -- I mean, we could go -- we could spend all of our time doing nothing but studying variation and really never understand what's the problem we're trying to solve. So that's a point I just kind of like foundationally want to make.

But at the same time, while we, you know, focus on Miami and McAllen, I want to understand who are the best performers and why can it work like that and where are they and what does that look like, and better -- I mean, we tend to kind of want to focus on the negative. But where's the really good work going on?

And then to Kathy's point earlier about at some point in time getting after appropriateness issues, I mean, this does seem like a wonderful set of data to help guide that discussion.

So my comment is thank you. I would love to see a map. I'm looking for a map where we'd overlay where the ACOs are and did that make a difference. But I could send you down 14 rabbit holes pretty quickly. I just think it's going to be important for discipline around how we use this, and, of course, we love this stuff. So thank you.

DR. SAMITT: Fourteen aren't so many.

[Laughter.]

DR. CROSSON: David.

DR. NERENZ: A similar comment. I think this is really good, and last night, actually, on the cover, when I write down things I might say, I had the word "shaming." I thought that was probably what was going on.

But as this moves forward to a report for the summer, not a rabbit hole but you might want to just make some passing mention to the relationship between any of the patterns you see here and what we see on commercial insurance. I'm going to look at Jon here, but it seems like one of the interesting things we've seen in the past is that Minnesota and Wisconsin are typically identified in analyses like these as low cost, low utilization for Medicare. But then you look at commercial insurance, and it's completely reversed. They're up on top.

DR. CHRISTIANSON: On spending.

DR. NERENZ: Spending, yes, thank you. But it seems like a dynamic that at least ought to, you know, get a paragraph or two of mention, and maybe we draw some conclusion from that, maybe we don't, but it's -- because,

otherwise, you look at this, and following on Sue's comment, you say, well, there must be some places that have really good, tight conservative practice patterns, and maybe they actually do, but it's not reflected in commercial insurance spending, and then you have to explain why not.

So not a rabbit hole, just a little tiny hole in the earth.

DR. CROSSON: A burrow.

DR. NERENZ: Not deep. Shallow. A little dig.

DR. CROSSON: Jack.

DR. HOADLEY: So my comments are sort of on this notion of the standalone report and sort of follows on Paul's comments. I mean it really seems like we have some interesting findings, and to the extent that some of them are against what persists as conventional wisdom, you know, I'd really encourage you to try to find a way -- you know, we have our normal sort of fine-print report that looks like a nice MedPAC government report. But I know you also sometimes put things into the blog and so forth, and I think, you know, to be able to have things like five interesting facts we learned from this analysis might be a

really useful way to subtly -- we don't have to hammer the politics of it, but just sort of state that, gee, it turned out that urban and rural have the same usage. And, you know, you can go farther if you want, but if you want to just stop at sort of making the observation. Same thing with McAllen and Miami, to the extent that you've identified this fact and, you know -- then, again, we can't prove what all the reasons are, but to the extent that we can comment on things, we think about why this may have happened, I think that could be really effective in communicating this to people.

The other piece I would say there is think hard about trying to do certain aspects of the methodology in some, you know, much more lay terms. So one of the things that occurred to me after I asked my first clarifying question is that this approach to the methodology kind of works in Medicare because Medicare has a uniform payment system. And for the moment, in my head I was still, you know, thinking about the price variations that you might see in a commercial analysis where you really would worry about the fact that, well, the doctors here just charge more than the doctors there. Oh, but in Medicare they

don't do that because we pay them based on a uniform fee schedule once we take out those adjustments.

So I think if we can make sure that in writing about the methodology, sort of walk it back to some of those simple levels, then, again, you know, this is the kind of document that could get a lot of use by a broader -- not necessarily the general public, but a broader set of journalists and policy folks and people on the Hill, and just making sure that they completely get that we have adjusted out and that might be why we're different than something else you've seen. This really is about service use with intensity and whatever the rights words to use are.

So I would just pay a little more attention to sort of simplifying it for readers and actually defending why this is, in our view, the right way to look at these things.

The only other comment I would make is in sort of looking at the areas like Sue was saying that may be on the low-use end is thinking about is there any possibility in those that we're hitting areas that are underusing services. There's always the issue, if, you know, we tend

to say they're high because they're overused, and when we've controlled for health status and all that, you know, let's look at the low areas, and if there's any way we can think about a question like that, is there any potential this is a low-income area where, you know, maybe there isn't enough providers. That's the argument that people make about rural, but we're able to show there that that doesn't play out that way. So it's just one other little element to think about.

DR. CROSSON: Okay. Kathy.

MS. BUTO: A quick question. I know this doesn't include MA experience, but do we have a sense of how areas with high MA penetration do in terms of both use and spending versus high fee-for-service penetration areas?

DR. ZABINSKI: Haven't done it in this study, but way back, the first time I think we ever did this, it was like 2005, 2006, something like that, we did. And --

MS. BUTO: Is there a difference?

DR. ZABINSKI: There's an effect of -- we found some effect of HMO penetration, yeah.

MS. BUTO: I don't think you can compare spending, really.

DR. ZABINSKI: Right.

MS. BUTO: That's very hard, but use would be interesting.

DR. ZABINSKI: Yeah. There was -- it was a long time ago, but I think it was small but significant in a regression.

DR. GINSBURG: I think what's so hard is that when areas have high use, that attracts HMOs into Medicare Advantage because of the payment. But then the Medicare Advantage probably influences the fee-for-service part through spillover effects. So it's pretty difficult to sort it all out.

DR. CROSSON: Bruce.

MR. PYENSON: Just a thought to follow up on Susan's comment, not about the rabbit holes, but identifying what might be considered best practice or well-managed areas. And that it could well be the case that areas that are well managed for post-acute are not necessarily well managed for inpatient or physician services and so forth. So my recollection is you, in effect, created a total index, use that for variability, and I suspect separating out the major components of that

might -- I think you indicated relatively little co-variance between the different categories.

DR. ZABINSKI: Right. That's correct.

MR. PYENSON: So from the standpoint of a composite best practice, it may not be the same -- it's unusual to find a place that does everything well.

DR. CROSSON: Okay. Good input. Seeing no further comments, thank you, Shinobu and Dan. I look forward to your report.

We'll move on to the final presentation of the day.

[Pause.]

DR. CROSSON: Okay. Ariel is going to take us through a re-look at the issue of low-value care.

MR. WINTER: Good afternoon. I want to begin by thanking Aaron Schwartz and Michael McWilliams of Harvard Medical School, as well as Dan Zabinski, for their help with this work.

Rita originally encouraged us to examine the issue of low-value services, and this is the third year that we will be updating you on our work to measure low-value care. We use this information every year for various

publications, including our data book and March report.

For today's presentation I'll start by defining low-value care and discuss the development of claims-based measures of low-value care. We applied these measures to Medicare claims data from 2012 to 2014. I'll describe the results of our analysis and conclude with some potential policy directions

Researchers define low-value care as services with little or no clinical benefit, or care in which the risk of harm from a service outweighs its potential benefit. In this presentation, we also use the term "overuse" to describe low-value care.

Low value care is a concern for two reasons. First, it has the potential to harm patients, both directly. by exposing them to the risks of injury from the service itself, and indirectly, when the initial service leads to a cascade of additional tests and procedures that contain risks but provide little or no benefit. It may also displace higher value care. And second, it increases health care spending.

I'll say a few words about our motivation for exploring this issue. First, there is a growing literature

on the topic of low-value care. For example, analyses sponsored by the Commission found higher-than-expected rates of repeat diagnostic tests among Medicare beneficiaries. In addition, practitioners are making efforts to identify and reduce low-value services through the Choosing Wisely campaign. Thus far, over 70 medical societies have identified more than 450 tests and procedures that are often overused.

As part of our recommendation in June 2012, on redesigning the Medicare benefit, the Commission supported value-based insurance design, in which the Secretary could alter cost-sharing based on evidence of the value of services. Under this approach, cost sharing would encourage beneficiaries to use high-value services, and discourage the use of low-value services. Therefore, CMS would need information on how to define and measure low-value care. Finally, when we measure quality, it's important to look at overuse of services in addition to underuse.

We have been using 31 claims-based measures of low-value care developed by a group of researchers. These measures were published in JAMA Internal Medicine in

2014 and 2015. The measures are based on Choosing Wisely guidelines, recommendations from the US Preventive Services Task Force, and the medical literature.

The researchers developed two versions of each measure: a broader one with higher sensitivity and lower specificity, and a narrower one with lower sensitivity and higher specificity.

The broader version of a measure captures more potentially inappropriate use, but also is more likely to misclassify some appropriate use as inappropriate. The narrower version of a measure is more conservative. It is less likely to misclassify appropriate use as inappropriate, but is more likely to miss some instances of inappropriate use.

To explain this, I'll describe the measure for inappropriate imaging or patients with nonspecific low back pain.

The broader version of this measure includes all patients who received imaging for low back pain and therefore captures more inappropriate use, but also some appropriate use. The narrower version of this measure excludes patients with certain diagnoses, such as cancer

and trauma, and is limited to imaging provided within the first six weeks of the diagnosis of low back pain. This version identifies fewer cases of inappropriate imaging, but is less likely to misclassify appropriate use as inappropriate.

For the last three years, we have contracted with the authors of the JAMA Internal Medicine articles to obtain their measures and the algorithms to calculate them. In prior years, we applied the 31 measures to 100 percent Medicare fee-for-service claims data from 2012 and 2013, and for the analysis we're presenting today, we added data from 2014.

Here are the aggregate results from our analysis for 2014. Based on the broader versions of the measures, 37 percent of beneficiaries received at least one low-value service. A single beneficiary can receive more than one service, which helps explain why there were 72 low-value services per 100 beneficiaries. Medicare spending for these services was about $6.5 billion.

Based on the narrower versions of each measure, 23 percent of beneficiaries received at least one low-value

service, and there were 34 low-value services per 100 beneficiaries. Total Medicare spending for these services was $2.4 billion.

This table shows the aggregate results for the low-value care measures for 2012 through 2014, and you can see a modest decline in volume and spending during this period. The first three rows show results for the broader version of the measures. Aggregate spending declined from $7.5 billion in 2012 to $6.5 billion in 2014, and the number of services per 100 beneficiaries fell from 74.6 to 72.2.

The bottom three rows have results for the narrower version of the measures, which also show a slight decline. It is important to point out that despite this modest decline, there is still a significant amount of low-value care, which has the potential to harm patients and increase Medicare spending.

We grouped the measures into six larger clinical categories, using same categories as the authors of the JAMA Internal Medicine articles. This table shows which categories accounted for most of the volume and spending, by type of measure.

Under the broader version of the measures, in the first column, imaging and cancer screening accounted for most of the volume of low-value care but cardiovascular tests and procedures, and other surgical procedures, made up most of the spending.

Under the narrower version of the measures, in the second column, imaging and diagnostic and preventive testing accounted for most of the volume, while other surgical procedures and imaging made up most of the spending.

Here are results for some of the individual measures for 2014. Results for all individual measures are in your paper.

The first row on slide shows back imaging for patients with nonspecific low back pain, which I talked about earlier. Based on broader version of measure, there were 12 cases per 100 patients in 2014 and spending was $232 million. Based on narrower version, there were 3.4 cases per 100 patients and spending was $66 million.

The second measure is PSA screening for men age 75 and older. The number of cases per 100 patients ranged from 9 in the broader version of the measure to 5.1 in the

narrower version. These results show that the volume of low-value care that we detected can vary substantially based on the measures' clinical specificity.

Our results probably understate volume and spending on low-value care, and thus they represent a conservative estimate of the actual amount of low-value services, and this is for following reasons. First, there are a limited number of measures of low-value care that can be calculated with claims data. It can be challenging to identify low-value care with claims data because claims may not have enough clinical information to distinguish appropriate use from inappropriate use.

In addition, our spending estimates probably understate actual spending on low-value care because they don't include downstream services that may result from the initial low-value service. For example, a PSA test with an abnormal result can lead to prostate biopsies and prostate cancer treatment.

We looked at a study that estimated Medicare spending on PSA tests and downstream diagnostic services related to the test. For men age 75 or older, average annual spending for the PSA tests and the follow-up

diagnostic tests was $145 million, but PSA tests accounted for only 28% of the $145 million. Half of the cost was related to biopsies and about one-fifth was related to pathology.

New for this year, we examined geographic variation in the use of low-value services. We used a set of geographic areas based on MSAs, and these are the same areas that Dan and Shinobu used in the work they presented earlier. We call these "MedPAC areas." We adjusted for differences in the demographic characteristics and chronic conditions of beneficiaries in each area.

The model estimates the adjusted number of low-value services per 100 beneficiaries in each geographic area. We used the narrower version of the measures for this analysis because they represent a more conservative estimate of low-value care.

We found that, even after adjusting for differences in demographic characteristics and comorbidities, there is still substantial variation in the use of low-value services. The adjusted number of low-value services was 61 percent higher in the area at the 90th percentile than the area at the 10th percentile. At

the extremes, the number was nearly two times greater in the highest area than in the lowest area.

But it is worth noting that there is a substantial amount of low-value care even in areas with relatively less use of such care. For example, the area at the 10th percentile had 25 low-value services per 100 beneficiaries.

We also explored the relationship between use of low-value services and total Medicare service use, which is the measure that Dan and Shinobu discussed earlier. We found a modest positive correlation between the amount of low-value services and total service use.

DR. MILLER: If I can hold you just for a second. There is a little bit of a photocopying issue. You have one copy that's 12 pages long and then you have a second copy that's 16. We are now in the second copy, on page 13. So if you are fumbling around, look at your second copy and pick it up at page 13.

I'm sorry about that but it was Warner's fault.

[Laughter.]

MR. THOMAS: I stapled them in the right spot.

[Laughter.]

DR. MILLER: Sorry about that.

MR. WINTER: Okay. So moving on to Slide 14, we want to give you a sense of which areas provide the most low-value care. This table shows the 10 geographic areas with the highest adjusted number of low-value services per 100 beneficiaries in 2014. As with the prior slide, these are based on the narrower versions of the measures.

By way of comparison, the national mean across all the geographic in our analysis was 32 low-value services, and it is worth nothing that 5 of the top 6 areas are in Florida.

The work we presented today raises the question of whether changes in payment policy and delivery systems can influence use of low-value care. In one of the articles we mentioned earlier, Schwartz and colleagues compared changes in the use of low-value care between beneficiaries in Pioneer ACOs and a control group of other beneficiaries. The study used the same 31 measures that were in our analysis.

The authors found that Pioneer ACOs had a greater reduction in volume and spending on low-value care, relative to the control group. These results suggest that

changing financial incentives at the organizational level can discourage overuse.

I would like to conclude by laying out some potential policy directions for addressing low-value care, for your discussion.

First, you could think about payment and delivery system reforms, such as 2-sided ACOs. Second, quality measurement at the population level could incorporate measures of low-value care. A third issue to consider is Medicare's payment and coverage policy. Kathy and Rita have asked us to look into coverage policy, and we anticipate coming back to you in the fall on this topic.

Finally, you could think about encouraging greater beneficiary engagement through changes in cost sharing or use of shared decision making. In shared decision making, providers communicate with patients about the outcomes and uncertainties of tests or treatment options, and patients discuss their values and the importance they place on risks and benefits.

This concludes my presentation. I would be happy to take questions.

DR. CROSSON: Let me start off with one.

Ariel, were you able to look at the relationship between the use of low-value care and beneficiary age? Does it go up with age? Flat? What?

MR. WINTER: So we haven't looked at it using age directly as a variable. However, what we've done is -- we didn't show the results here or in the paper, but we did segment it for beneficiaries who are over 65 only, and all beneficiaries, whether they were over 65 or under 65. And I think the results show a higher rate of low-value service use for the over 65 population, but that's probably an artifact as well as the way the measures are defined, because some of the measures, for example, several of the cancer-screening measures only apply to older beneficiaries.

DR. CROSSON: Yes.

MR. WINTER: So it's really hard to say. But we can go back and look at that for the future.

DR. CROSSON: Yeah. It might be interesting.

All right. Another question. Jon.

DR. CHRISTIANSON: I'd like to go back to Slide 8. I guess I was more impressed with, just looking at the broader version of the measures with the declines than your

title of the slide implies -- modest. I mean, on the spending it's like 15 percent or so decline in two years, which, you know, any decline in health care spending for a population is notable. Fifteen percent is two years is seriously notable. And that's at the same time -- I think that's not -- that's not a per capita, obviously. So it's also a time when enrollment is going up in the Medicare program, when you would expect to see exactly the opposite happen. And then if you look at the count per beneficiaries, that, of course, went down by not nearly as much percentagewise as the spending.

So I think there is more to be said here about this slide, and I can't, frankly, remember how much you went into the discussion of that in the paper, but it didn't strike me as being modest at all. It struck me as something to really look at.

MR. WINTER: Right. The number that does stand out, and said this in the paper, was the reduction in spending for the broader version of the measures, which was about 13 percent or so, and you don't -- the reduction in counts per the 100 beneficiaries was much smaller in both the broader and narrower versions of the measures. And a

lot of what's driving this was there was a really big reduction in spending for the cardiovascular tests and procedures category.

DR. CHRISTIANSON: It would have to be for high cost --

MR. WINTER: It went down by over $700 million between '12 and '14, so that's driving about 70 percent of the reduction.

The other categories, you know, there were reductions but nothing as significant as that one, where there's a lot of money to begin with. That's the highest-spending category, when you look at it by type of clinical category.

But the thing I want to caution you all about is that we only have three years of data here, so things could change. Things could start going up again in the future. So I want to caution you about drawing too many conclusions from this pretty short trend.

DR. CHRISTIANSON: Right. The only conclusion I'd like you to draw is that it's a pretty big change in two years.

DR. CROSSON: Other questions? Jack.

DR. HOADLEY: So my question relates to your modest positive -- on Slide 13, where you're talking about the positive relationship between the low-value care estimate and the total service use. I'm thinking to the last session. I wonder if there's an ability to sort of say, well, how much of the variation that we were looking at in the last session goes away when -- if everybody achieved the level that, say, the best-performing areas achieved, or something like that. It might be an interesting way to --

MR. WINTER: I can talk to Dan about that. One thing I'll show you -- we have a bonus slide, which Dan created, so Dan gets all the credit. This shows you that -- the simple regression that he ran, between total service use, on the horizontal axis -- I'm sorry, the vertical axis -- and low-value care on the horizontal axis. And you can see that there is a relationship but it's just a lot of unexplained variation between the two variables, and R-square, as you can see, is 0.29. So we've begun to explore this issue but just in the last couple of weeks, so we'll think some more about your suggestion.

DR. HOADLEY: Thank you. You know, just the fact

that your biggest variation is in post-acute care, and I don't know that any of those services are on the low-value list --

MR. WINTER: They're not.

DR. HOADLEY: -- limits the degree of correlation.

MR. WINTER: Right, and as Dan said, that's a much bigger explanatory factor than low-value service use.

DR. CROSSON: Right. But you could remove post-acute care and look at it again. Right?

Sorry.

MR. WINTER: He's nodding, yes.

MR. PYENSON: Just along the lines, I think of this discussion. Looking at this in aggregate from Slide 7, roughly $2 to $6 billion, you know, a higher end, lower end, which corresponds to roughly 1 percent of Medicare spending, or half a percent of Medicare spending. And just to emphasize, I think that this is not the only low-value care around. Right? We expect ACOs, in order to get a bonus, to do much, much better than that. And I think we've looked at other measures, potentially readmissions, potentially preventable admissions, things of that sort.

So I'm wondering how you put this into that context, because just looking at the title, somebody assigned the word "low-value care" to this set of specialty society CPT codes, and there's lots more than that.

I don't know how -- that's sort of a context issue, because I'm concerned that this gets lost.

MR. WINTER: Yeah, those are good points, and one thing I'll point out is that the $6.5 billion that was captured by the broader versions, it's about 2 percent of fee-for-service Medicare spending.

MR. PYENSON: Okay. Two percent of fee-for-service.

MR. WINTER: So not -- it's still not huge. Right, it's pretty small. And we've tried to caution throughout the paper, and perhaps we should have done this more in the presentation, that this is -- we are measuring services that we can -- that could be defined pretty well using claims data, by a group of researchers that have been kind enough to let us use their measures, and it doesn't -- we're not -- we don't intend to capture the entire universe of what might be considered low-value services within Medicare.

And you mentioned PPAs and PPBs, and my colleagues, Lydia and Nancy, have been doing a lot of work in this area. And that, it's a little bit different because they're looking at -- using that to assess the quality of the ambulatory care system, where, was there adequate access and was there adequate coordination to present either ED visits or admissions that could have been prevented. And we are not saying that each one of them could have been prevented but it's more of a relative measure. If you see a region of the country that's twice as high as the national average, that might raise some concerns. Whereas here I think they're trying -- these are meant to be more precise, even though we have -- we definitely have a range, you know, broad versus narrow, but we're drilling down into specific kinds of services that could be considered low-value.

MR. PYENSON: I wonder if we could somehow change the title because it seems like measuring low-value care, you're really measuring a subset of low-value care here, and I think that's an important distinction.

But it's terrific work. I don't want to take away from that.

DR. CROSSON: On this point, David?

DR. NERENZ: Yeah.

I appreciate it, but although I guess I would use the words differently. If somebody has a bad infection and then needs to be admitted, that's high-value care. So I would think the two domains, although in both cases, there are things you might not want to see, they're not sort of a subset and then a remainder subset of the same concept.

The reason I like the term and what's under it is that you're talking about services that either do no good or do harm, but say a preventable admission, the admission itself is of high value presuming --

MR. PYENSON: Well, no, but it --

DR. NERENZ: Yeah. We don't know for sure but at least you don't presume up front that it's not. Here, we do presume up front that it's not.

DR. REDBERG: For this list, I would say this is no-value care or harmful care. It's not even low value.

MR. PYENSON: So I don't want people to say, "Well, if it's not low-value care, then it's high-value care; therefore, we're expecting ACOs to meet their targets by getting rid of high-value care." Right? I think the

words are important.

DR. NERENZ: Well, except the discussion here is not everything we think somebody might want to get rid of. It's a specific thing put out with a label for a specific region, was the point I wanted to make.

DR. CROSSON: I don't know if we need to change the term, but we could modify it in some way, at least in the text, to talk about selected areas, because after all, this is sort of what we can measure, right, as opposed to other areas of low-value care, which just represent individual physician judgment for an individual patient, which is just not the right decision, but it's non-measurable or very difficult to measure.

So selected areas of low-value care, something like that, would that help?

MR. PYENSON: Yep.

MS. BUTO: You might want to add in Medicare fee-for-service, too, because it doesn't include --

DR. CROSSON: Right.

Could you come up with an acronym for all that?

[Laughter.]

DR. CROSSON: Alice, did I see you?

DR. COOMBS: Slowly.

DR. CROSSON: Slowly raise your hand, considering your question.

DR. COOMBS: So this was a claims-based study. It wasn't a medical record review.

MR. WINTER: Correct.

DR. COOMBS: So there's some inherent problems with that, per se.

MR. WINTER: There are always going to be questions about the accuracy of the claims in terms of the diagnoses, procedures, the time frame, yes, and the measure developers have acknowledged that in their publications.

DR. COOMBS: Right.

DR. MILLER: Well, and that's why there's kind of a conservative and less conservative measure.

MR. WINTER: Right.

DR. COOMBS: And I think that's really important, the narrow or broader division.

And then the other question is there are things that I consider maybe not as valuable, but there is another category that I don't think we really dealt with. And I'll give you an example of Lyme disease. There's two different

specialties that are involved in the treatment of Lyme disease. There's a Lyme Disease Society, and then there's ID world, and they have very different ideas about treatment. Some have proposed treating Lyme disease chronically with antibiotics. The other group doesn't believe in that. The cost is absolutely staggering with one of the societies that propose it.

I think that duration of treatment can be low value, so that inappropriate treatment with antibiotics for prolonged periods of time can be low value, and there's certain complications with that. So I think that's one of the areas that I thought about in terms of low value.

I was happy to see that in the original paper, they did discuss the U.S. task force. There's some retraction with some of the recommendations originally in terms of being able to recognize groups that are at risk, i.e., African Americans with PSA monitoring. So I think they did allude to that. I saw a brief statement.

MR. WINTER: Are you saying that the Preventive Services Task Force has retracted its 2012 recommendation against testing?

DR. COOMBS: Well, not so much retract, but there

is a qualifier, because I had talked about this, I think, ever since we brought this up --

MR. WINTER: Yeah.

DR. COOMBS: -- about race being a consideration that in an African American male, PSA is very valuable because they are not going to have the same outcome as a while male who has a positive PSA, just in terms of the mortality by itself and how aggressive disease is.

MR. WINTER: So I've looked at the 2012 recommendation statement, and if there's something more recent, then I'll be happy to look at that as well.

They looked at primarily two randomized trials of PSA testing. In only one of them were African Americans present, and there were too few of them for the task force to draw conclusions about the balance of risks and benefits for that population. If there's more recent information that they've put out, I'd be happy to take a look at it.

DR. REDBERG: I don't know of any data, Alice, that suggests that PSA testing is a value, even in African Americans. If there are some references, I'd be interested to see them.

The task force is doing an update on their PSA

recommendation. I will say the one in here is way -- this one over 75, but as you know, in 2012, the task force said PSA was a grade D for all ages.

MR. WINTER: Right.

DR. REDBERG: So this way underestimates the overspend on PSA because none of it should be done.

MR. WINTER: Right.

DR. REDBERG: And there isn't any data to suggest it's valuable in African Americans, but I suspect we're going to see something on race in the next update because they specifically say they're updating and looking at subgroups, so I think that's what they'll look at, probably.

DR. COOMBS: Just so we keep current with it.

MR. WINTER: One of the reasons we used the earlier -- one reason the researchers who developed the measures used the earlier Preventive Services Task Force recommendation, which is age 75 or above, is because the newer one came out in May 2012, and we're using 2012 data as our baseline. So it wouldn't be fair to hold them to a standard that wasn't yet out until the middle of 2012. So that's why we're using the older recommendation.

DR. CROSSON: Okay. Let's see where we are with the questions. I see no more here. Clarifying questions coming up here?

[No response.]

DR. CROSSON: Okay. So, Rita, I believe you're going to start off.

DR. REDBERG: Well, thanks, Ariel. It was really a great chapter, and I think it's really important work because it's really win-win.

I wasn't joking. This is harmful care. I mean care that has no benefit and it only has harms, and so besides the billions of dollars that Medicare is spending, people are being hurt. I mean, there is nothing -- there is no social redemption in this. It's like POD. There is nothing fun about getting tests that you don't need and aren't going to help you feel better.

And as I said, a lot of these, I think they were pretty conservative because -- which is fine, and PSA was just one example.

I do think -- and you talked about it -- it's hard to separate our current fee-for-service system from what's going on. I have a quote. George Bernard Shaw from

"The Doctor's Dilemma," 1911, said, "Having observed that you could provide for the supply of bread by giving bakers a pecuniary interest in baking, we go on to give a surgeon a pecuniary interest in cutting off your leg." That's essentially the kind of system we have.

I mean, the urologists and the spine surgeons, they all vigorously protest that in their hands, they know these things are better, but there isn't any evidence. And it's very hard for -- it's like you don't ask the barber if you need a haircut. I mean, those are not the groups that should be passing on this, and it should be -- and we know for a fact that your treatment, because -- and the other reason they way underestimated the cost of PSAs, I mean, you showed the data on biopsies. It's not the biopsy. It's the surgery. It's the IMRT, the proton beam therapy.

I mean, there was that new article in the Times last week about some other kind of radiation therapy for prostate cancer. None of it ever has any evidence, and it's always very expensive. And I look at it and I think this has all started because men keep getting PSA testing. Why is Medicare paying for PSA testing at all? We pay for Grade A and B. That's great, but this is harmful, but

Medicare is still paying for it.

If people want to get tests that aren't in your best interest, you can pay out of pocket for them, but I don't see why the program is paying. So it's not the tests or the biopsies. It's all of these treatments. It leads to incontinence, erectile dysfunction. There are a lot of very unpleasant things from PSA.

The other thing here, imaging for non-specific low back pain, I suspect most of the Commissioners, but maybe not a lot of other people remember the Office of -- was it OTA? No. Agency for Health Care Policy and Research, which did the technology assessment looking at back pain, and said that conservative treatment, you did better than with surgery for back pain. But the orthopedic surgeons got very upset with that and got together with Tom DeLay and threatened to zero-fund the agency, and then it sort of went away and came back as AHRQ, which stayed away from making any kind of statements that would have got the medical groups concerned that they would interfere with the practice of medicine, which wasn't, of course, what they were doing. They were stating that there was no evidence.

But there are a lot of -- I see patients every

week who have had spinal surgery, and I feel very badly because I know that there isn't any evidence that they are better off. And a lot of our device discussion was over spinal fusions.

So getting to what we can do, I think certainly changing -- getting away from fee-for-service and getting away from paying for services, I mean, some of these are quite clear. A lot of it is in cancer screening, and you can use billing data because you're just looking at age. I mean, it's not recommended for people over 75 because you need a long lead time in order to see a benefit from cancer screening. So there are a lot of things we could do even without medical records data.

So I think Medicare can -- it takes political will, but not pay for things that are harmful for beneficiaries, that seems pretty reasonable to me.

Moving towards ACOs and alternative payment models that don't reward this is certainly an improvement.

You mentioned quality, because all of our quality measures are -- or towards things we're not doing, but certainly overuse as a quality measure, I think is a very effective mechanism.

And I think -- so those were all, and I want to see if there's anything from the discussion. Quality management, payment and coverage policy, we talked about -- and beneficiary engagement. You know, that's an interesting question. I'm just not sure how much shared decision-making. It's a good idea. I don't think it's actually happening. It's very hard for beneficiaries to understand all the numbers, and I don't think that a lot of doctors are taking the time to explain, especially in the system where people are going through very quickly, and honestly, financially, doctors are rewarded for doing more things, not for explaining to patients why they don't need particular tests.

So while I think shared decision-making should happen, I don't think it's going to be a major factor in decreasing overuse. But I'm glad that we're looking at this work, and I look forward to my fellow Commissioners' comments.

DR. CROSSON: Okay. Thank you, Rita.

So Rita has touched on the four potential policy directions that are up there. It's not the first time we've discussed them.

So what I'd like to do is -- and we can do this fairly -- in a fairly time-efficient manner -- is to say which of these four -- and some have more components, cost sharing, shared decision-making, for example -- where should we be putting our policy development energy over the next year or two? What are your favorites? Which ones do you think are a blind alley? That's the point, I think, we've got here.

I can't remember now. I think I've been going this way every time, so I'm going to start over here. Paul.

DR. GINSBURG: It's really good to put these four options, but even though I suspect that when you think about what Medicare can do well and what Medicare can't do well, probably coverage policy is not a strength of Medicare, just given the political environment it does, and just the difficulty of using well the recommendations that come from the Preventive Services Task Force when Congress gets hold of them. That may not be the area.

To me, payment delivery system reform, in a sense, gets at this indirectly by providing, you know, frameworks and incentives for an organization to act in

this way, which is something that Medicare can do much better, and I think the dollar potential in that one is probably strongest. So this motivates me to work more on delivery system reform payments.

DR. CROSSON: Bruce.

MR. PYENSON: I think one of the things that we could do in this piece that would be helpful is to avoid some of the controversies that are in the health care system. For example, on page 5, there's the statement about the risks of injury from radiation exposure from CT scans. I and others believe that's a myth.

I have a quote from the American Association of Physicists and Medicine to that effect, perhaps not as eloquent as George Bernard Shaw, but it says, "Predictions of hypothetical cancer risks and deaths in patient populations are hypothetical and probably nonexistent and should be avoided because they lead to sensational articles that cause patients and parents to refuse needed medical treatment."

It's the same -- so, in my opinion and others, a safer example would be the harms from -- the well-known harms from, for example, perforation, from optical

colonoscopy, which is somewhere between 1 per 1,000 and 5 per 1,000 -- I'm sorry -- 1 per 1,000 and 1 per 5,000. So I think focusing on really the strong evidence would be helpful.

I heard what Paul said about the challenges with coverage, but perhaps I'm not as pessimistic or as smart. But I would hope for coverage policy changes that would help, in particular, with the relatively focused subject of this paper.

DR. CROSSON: We have a comment on your comment from Rita, and then I'm not sure if Kathy wants to get in on that one too. So, Rita, Kathy, Alice.

DR. REDBERG: Yeah.

DR. CROSSON: You're getting it now. Look out.

DR. REDBERG: I've been practicing medicine for 35 years, and that's the first time I've heard someone say that there was not a cancer risk from radiation. I think there's extensive evidence that links exposure of ionizing radiation to increased risk of cancer. There's diagnostic CT. There is studies showing DNA damage. There's epidemiologic studies. We have all the Hiroshima data. I mean, I could give you just lists.

I wrote a New York Times op-ed on the risks of CT scans, and we published articles in Archives, when it was Archives of Internal Medicine from the National Cancer Institute, estimating there would be 60,000 additional cases of cancer, 30,000 excess deaths just from the CT scans done in 2007 alone. There have been studies and studies. There have been hearings. I have to disagree, that there is definitely a radiation -- there's cancer risk from radiation exposure.

MR. PYENSON: You heard it from me before, but as an actuary, I can calculate the risk of a 10-mile car trip to go to an office visit. I can't extrapolate from the 500 -- the lethal dose at Hiroshima to the kind of millisievert, one millisievert, five millisieverts doses that occur today with modern CT scans.

So I know there's been a lot of things said around that, but frankly, the methodologies aren't something that has been widely accepted, the linear extrapolation.

DR. CROSSON: Okay. It's getting a little radioactive here. Kathy?

[Laughter.]

MS. BUTO: It's the end of the day.

So the first bullet, which is payment delivery system reform, I think we all feel comfortable in that space.

I don't think it works very well, though, without clinical guidelines or some other mechanism to help inform the judgments made by well-meaning payment systems. So I think there is a responsibility or an opportunity there to go forward or to promote a greater role for Medicare in getting -- pulling that information together, whether it's through outside bodies or whatever it is, in order to help inform that decision-making.

I know Paul is pessimistic about coverage policy, but it has been effective in limiting coverage, sometimes after the fact where evidence suggests that a procedure or an approach is not advisable. And it doesn't happen very often, but when it does and claims get pulled or denied as a result, it's pretty effective.

So I think when we get around to looking at coverage policy, maybe in the coming year, one of the issues will be is there a way that it can be a little more nimble in addressing these kinds of questions. It has a

number of problems right now that make it difficult to -- and one of them is trust. A lot of beneficiary groups and other groups do not trust the process. So I think it's got to be looked at and made potentially -- brought up to modern times. But I think there is a potential there.

DR. CROSSON: Alice.

DR. COOMBS: I just wanted to speak to some of the items there, and also to say that -- you know, I think I circulated the article on cancer mortality -- I sent it out to a few people around the table -- in which there is 20 percent reduction in mortality, and in that article in JAMA, January 2017, this year, they allude to the fact that what has happened with colon cancer, how do you get a 20 percent reduction without the identification and the diagnosis? Well, that's for the general broad population, but they do break out age groups in that, and they also look at geographic distribution. Very persuasive article.

So something we're doing is okay with screening, and so I'm not saying that an octogenarian needs to have, you know, the full cart-plus in terms of workups, but there's something we're doing in this country that has resulted in good results for that article, and they allude

to screening. And that's in the Journal of the American Medical Association.

First of all, I agree --

DR. REDBERG: The recommendation is to stop at age 75. It's not --

DR. COOMBS: Yeah, so I just mention I'm not talking about octogenarian, but I am talking about screening tests in general in terms of the individual tumors that they allude to. It's a great article.

So the first part is that I agree with Paul regarding system reform. We are in the midst of MACRA and MIPS. I mean, what do we think we're doing if we're not doing quality and we're not looking at how we're impacting providers, physicians, nurse practitioners, and PAs? And I would think that we need to sit back and consider that we already have something that is actually hopefully changing patterns through the MIPS. And that in and of itself actually addresses some of this in terms of -- and it's looking at cost, it's looking at resource utilization.

So why do we have to layer yet another layer on top of providers for some of the other things? Why don't we wait and see or wait and look at how we best change

patterns of low-value services through what is already on the table? I mean, it sounds like we're trying to -- I mean, I'm okay with saying that it actually deals with all the specific areas that we would like to see in terms of low-value services.

DR. MILLER: But there is one thing on MIPS that I've got to say. There was a lot of discussion over the last few months -- I can't remember the specific months -- where we kind of came back to the MIPS and the APM framework, raised a whole host of issues around the amount of data collection and burden and how much given the precision fact that you choose your own measures, that they're small, and the way the system is designed, whether you're actually going to really be able to distinguish among physician performance, and started to have those questions and started to raise questions about whether you could use more of a population-based approach to it, of which a low-value measure could be slotted into that.

Now, you could do it certainly for an APM or an ACO when you have a population base. And then we talked about the notion of individual physicians saying, "I want to choose the physicians I get measured with" so that

there's enough measurement that you could use a population base for. And it would relieve, you know, the burden and then measure, like I said, on a population basis.

There is a concern that the current methods and the measures that are being collected are not going to really give a lot of information to distinguish the performance of --

DR. COOMBS: And I agree with that, but that argument and discussion, especially around the specialties, the 5 percenters, the radiologists, anesthesiologists, pathologists, and ER physicians, because they didn't have consistent benchmarks, qual. metrics to look at, so they're trying to meander their way through this whole process. But some of these things are more skewed toward primary care, family practice, and, you know, just in terms of the generalists. And I think if you were to analyze any internal medicine practice -- and, Craig, you can say so -- there's inculcated within their practice those quality parameters that people actually look at already.

So I think the point you bring up is very good, but I think right now, for primary care doctors, they're including all of those things, and I'm not sure that having

another layer of yet something else that we're requiring of providers is going to help them in the big picture. I would like to see how this works out first rather than to layer something else on top of providers.

DR. MILLER: The only thing I'll say -- because I don't want to get into an argument -- I do want to get into the CT thing you guys --

[Laughter.]

DR. MILLER: In our approach, this wouldn't be an additional layer. It would be a removal of the current requirements, and then the calculation would be done on a population basis and would remove the burden from the physician entirely. So we can, you know, potentially disagree on what's the right approach, but I do want you to understand we're not proposing this as another layer. That at a minimum I do want to be clear on. But, you know, we may have a different view of -- you know.

DR. CROSSON: Okay. Let me see where we are. Who wants to get in on this point right now? Okay. Paul and Brian. Then, Bill, you have another point?

DR. HALL: Well, yeah [off microphone].

DR. CROSSON: Okay. Let's do Paul and Brian

first.

DR. GINSBURG: When I suggested that payment delivery system reform was perhaps the best way to go, not necessarily the path we're on now, and really reflecting a lot of what I've learned here, I'm not very optimistic about what MACRA is going to accomplish in its current form. I think the ACO model that Medicare has chosen is not the best way to pursue that concept of global payment.

So, basically, the path, which I think has high reward, is also high risk, that we could fall on our face and not accomplish much. So I wouldn't -- in saying that I think that the greatest opportunity is there, I wouldn't to rule out working in other areas. And, you know, coverage policy is something that where there's lower potential, there might be some low-hanging fruit there to get at.

DR. CROSSON: Brian.

DR. DeBUSK: The last time we met, we talked a little bit about reforming MIPS and some of the limitations in PQRS and all that. Could this methodology, if it were packaged and refined, could this produce a virtual PQRS measure, I mean, something that -- it would work like a PQRS measure but it would be passively derived from claims

data, so you wouldn't actually have a physician-reported measure at all. That's to Mark's point earlier.

DR. CROSSON: As I listen to Mark, that's what I thought --

DR. DeBUSK: Yeah, it's a virtual PQRS measure.

DR. CROSSON: Essentially, because we've talked before about getting out of the granular MIPS measurement process because of the burden that that creates for physicians. And yet we have to have something to hold physicians at some level of collective responsibility accountable. But that should be a small number of measures, and it should be, as much as possible, measures that don't require extra work on the part of the physician. So you could imagine just what I think -- that's what I thought it meant. What Brian was saying was you could develop a global measure of the use of low-value services at an aggregate practice level of some sort. It wouldn't require any direct work or reporting by the individual physician but still would represent, you know, for comparison purposes how one practice of collection of physicians is going about the practice of medicine versus another. I think that's -- okay. Bill.

DR. REDBERG: Can I just comment --

DR. CROSSON: You want to comment on this? Okay.

DR. REDBERG: I just wanted to say on the colorectal cancer -- and I agree that with screening between the ages of 50 and stopping at 75, but the article -- and it was Gil Welch's article -- I just pulled it up -- in the new England Journal called "Colorectal Cancer on the" --

DR. COOMBS: It was a JAMA article [off microphone].

DR. REDBERG: I'll just finish my sentence, thanks. "Colorectal Cancer on the Decline: Why Screening Can't Explain It All." And it's just about how the decline started way before we started screening, and it is attributed to changes in American diet, which is a good thing.

DR. CROSSON: Okay. We have gone from radioactive to scatology, and I'm going to now --

[Laughter.]

DR. COOMBS: It was a different article, just so everyone knows [off microphone].

DR. CROSSON: Bill.

DR. HALL: I don't have a solution for this, but just a couple of observations.

Number one, the most important one is that medicine is not a precise science -- and we don't like to admit this very often -- so you're always going to have controversy about screening or therapeutics among well-meaning, well-educated physicians. I think this is very difficult.

The other thing, I haven't mentioned this for a long time, but the very powerful influence of direct-to-consumer advertising that really blew this out of the water, so on my very modest and on-time flight down here yesterday -- it takes one hour -- I went through the American Airlines book that's there, and it talks about Florida vacations and all that sort of thing. I found -- I wasn't looking for it, but I guess I was in a way. I found maybe six or seven ads all related to prostate screening or therapeutics that implied magic. Half of them were put in there by major medical centers in the United States. This wasn't some fly-by-night person doing this.

DR. COOMBS: American Airlines [off microphone]?

DR. HALL: American Airlines, well, yeah, so they

change it every month. So this is a big problem, and I don't think there's going to be one solution. We talked in the presentation about "Choose Wisely," which was a heroic effort by dozens of medical societies. It's almost fallen off the map two years later. You don't hear much about it anymore. So it didn't lead to something that was actionable over a short -- or a long period of time.

So I think it's multifactoral, but I think the one thing that comes out of this is that there's got to be some effective consumer education, and I don't really know how that's going to happen. We went many years about perimenopausal use of estrogens in women. I don't know how many thousands of women were harmed, killed, before we -- it wasn't just overnight that people discovered this. So in terms of high-risk things, I think if we say this is the one thing that's going to do it, MIPS or whatever, I think we're going to be -- we're going to fail.

But a lot of things I think as we go forward in Medicare, at least one approach that might be better is, as much as we can, to have a much higher educated Medicare population. I don't think this is all legislation and knocking on the doors of physicians and saying, "You were a

naughty boy or girl." But this isn't going to go away. I think I's going to get much worse with time -- well, it is getting worse with time.

So I think we should be very careful before we say this is the magic bullet that's going to change this behavior.

DR. CROSSON: Bill, I usually travel on United, and they try to send me on cruises.

[Laughter.]

DR. CROSSON: The other thing is, to your point, I have seen on TV fit testing advertisements with some really interesting graphics, if you are not seeing the commercial. I won't go any further on that.

DR. HALL: Is that right next to the page where you have 30-minute dating for older people [off microphone]?

[Laughter.]

DR. CROSSON: Right. Yeah, well, that's a thing of the past. Who's up next?

DR. REDBERG: Can we please get back to radiation [off microphone]?

[Laughter.]

DR. MILLER: Please change the topic.

MS. BRICKER: I'll be brief. I was going to highlight the importance of thing 4, increase beneficiary engagement. You know, Bill, you said a lot to cover what I was going to reiterate. I don't think it can be done in isolation, but I'm absolutely a proponent of ensuring that folks have, you know, a balanced view. If you believe that you can't ask the barber about the haircut, then we've got to figure out who they can ask about their haircut.

And, you know, I think to your point about estrogen and the harmful effects of, I think it's going to take, you know, quality measures -- right? So when someone comes into the office and says, "I just saw this thing in American Airlines about getting the screening," and you know as a physician that you're going to be dinged from a quality perspective and you're held to a standard that you must educate the beneficiary on that decision, and maybe they share in some of that cost -- I don't know, weaving some of these things together -- maybe then the outcome is different. But to do it not in consultation with the beneficiary I think is a missed opportunity.

DR. CROSSON: Thank you. Jack -- David.

DR. HOADLEY: I do want to get in [off microphone].

[Laughter.]

DR. CROSSON: And I do have eyes in the back of my head.

DR. NERENZ: That's good. I'll also try to be brief. I would, first of all, say that I'm so glad this is on our agenda. I think it's important. I think it's crucial. You've done a really nice job. I've tried to support Rita's interest in this, so I want this to stay in front of us.

You know, when I think broadly about this, I do have this from the heart sense -- and Rita expressed it eloquently -- Medicare shouldn't pay for things that hurt people, and that leads me to the third and fourth bullet there, but then I am cautioned, and appropriately, by Paul's comment that it's okay to say that in this room. But you try to run that through Congress and ultimately out through CMS, and it's a way harder process.

I would by instinct say, well, we should just say Medicare doesn't pay for this, or the cost sharing is kicked up to a high level, so at least Medicare isn't

paying very much for it. But I appreciate the difficulty in implementing that.

So that leaves us with the top two bullets. I think there are things to like there. I'm a little curious on the top one that we highlight ACOs, which I think aside from that one little example of the Pioneers, over on the much larger MSSP program, I don't know of any evidence that they've done much in this space. In fact, they're having trouble saving money in any -- doing anything. So I don't know the answers there, but we didn't talk about MA. And I'm a little surprised because MA has stronger incentives to do this and better tools, and a dollar saved drops right to their bottom line.

Maybe there just aren't examples there to talk about, but at least I'd like to sort of perhaps highlight that a little more.

Do you have a response?

MR. WINTER: Just quickly, we do cite an article in the paper by Culhane and colleagues from 2013 which does say there is low-value care in managed care arrangements in addition to fee-for-service. I don't recall if they were looking at MA specifically or general managed care, but we

can get back to you, get some more details to you about that article. And the low-value care that they were looking at is different than these 31 measures. I don't remember exactly what they were, how they were measuring it, but they were using a different set of metrics.

DR. NERENZ: I imagine there are lessons out there sort of in managed care in general. I just mentioned MA because that's our territory. We could learn from --

MR. WINTER: And if we ever get the full set of encounter data for 2014, which Andy and Jennifer talked about last time, we could try to look at applying some of these 31 measures to the encounter data. We've begun to explore this a little bit within the last year, and it's going to be difficult. So I don't want to get your hopes up too much, but we are continuing to think about that.

As well, there is at least one HEDIS measure that is comparable to one of these measures, which measures on prostate cancer screening using PSA tests. So we're going to see about whether we can make those two measures more comparable so we can compare MA to fee-for-service, at least on that one dimension.

DR. CROSSON: Okay.

DR. NERENZ: And then just quickly, the last thing on the quality measurement, I would like to see us take a favorable stance on moving this into MIPS or perhaps in other quality measurement programs, depending on where we think the accountable entities are. You know, that's, again, easier said than done. Measures have to be developed. They have to go through NQF endorsement. They have to -- you know, it's kind of a long path. But that's there. And I don't think I'll surprise anybody at the head of the table. I don't think what I would do is just make one big global indicator, because I'm not sure the entities that are high on one thing or high on another thing. I'm just afraid by aggregating, you're just going to wash it all out, and nobody's going to be different.

Also, my instinct, as I've said in other meetings and other contexts, would be to try to focus the measurement and its eventual financial implications much more tightly on whichever entities or actors it is that are actually driving these decisions. I would not do it on a region basis. I wouldn't do it on a big global basis. But we just differ in that view, so I'll just -- for the record, I would do it differently. But it's favorable to

this concept. I think the execution in my view would be a little different.

DR. CROSSON: Okay. Comments? I have Warner, Craig, Jack.

MR. THOMAS: I'll be very brief. I just would encourage us -- I know there's a lot of controversy around the issues we've been talking about. I think ultimately changing the payment model in the ACO arena is the way to get folks to be more creative and to look at this in a much more disciplined way. I would encourage us to spend more time looking at how we can continue to refine and improve the ACO model to get more folks into it and to improve the incentives and improve the alignment of those programs.

DR. SAMITT: So I want to go back to the discussion about radiation. Should I be worried about all the air travel that I'm doing?

[Laughter.]

DR. CROSSON: Don't even think about it.

DR. SAMITT: So I'm going to put back on my provider hat as we think about this, and, frankly, of all of these four policy directions, similar to what others have said, I would focus on the first. And I think it's

mostly because I'm not sure the other three are going to be powerful and effective enough. You know, the reality is whether it's CMS is not very good at coverage policy or, frankly, providers aren't incredibly receptive to policy as a means of driving change and adoption of evidence-based medicine, I'm not sure that's so effective.

Shared decisionmaking, you know, I've studied in multiple prior lives, and I think it's still early and it's still even a bit unproven in terms of changing consumer and patient behavior based upon those levers.

And then quality measurement, at least in isolation, has problems as well. As Rita knows, we published a piece in 2015 about "Choosing Wisely" and found that, despite sort of avid measurement and communicating evidence-based best practice, it didn't translate into practice, that communication and reporting on sort of non-adherence to "Choosing Wisely" didn't change prescribing and ordering behaviors.

And so for all these reasons, it feels like the concept of ACOs and delivery system reform, which is to drive accountability at the provider level, is the one that's likely going to generate the most significant

change.

One other thing about quality measurement as well, we talked about -- I'm not opposed to a population health measure for "Choosing Wisely," but we already talked about the fact that we measure too much, and it's kind of hard to follow. What we haven't talked about lately is maybe we should be rewarding cross-cutting measures. So, for example, you know, there are systems out there that are offering "Choosing Wisely" decision support. So, in essence, you're prompted when you're ordering things, whether you're adhering to "Choosing Wisely" guidelines or not. You know, maybe our quality measure is: Do you have a "Choosing Wisely" decision support tool, and are you using it and adhering to it?

And the same would be true of other quality measures, but, you know, assuring that ACOs are using some of these tools is another way of sort of raising all boats.

And then, finally, I think it has already been mentioned, you can sort of extract my comments from the last chapter to this chapter, you know, which is: Have we looked at differences at low-value care deeper beyond just the Pioneer ACO pilot? I'm interested in looking at

commercial ACOs. Commercial ACOs seem to be getting differential results than Medicare ACOs. Do we see differences in low-value care use? Do we see differences in Medicare Advantage? And, remember, not every Medicare Advantage plan looks the same. So when you look at Medicare Advantage plans where the shift of accountability has actually occurred to the provider groups, do you see differences? I'm curious to know that.

And also going back to the last discussion, where do we see the lowest use of low-value care? And what have they done to achieve that performance? Because that could give us the road map in terms of policy directions. If we find that X organization or Y market has very low utilization of low-value services, what levers have they pulled to actually achieve that result? And it may sort of give us -- shine some light on the direction for us as well.

DR. CROSSON: Thank you. On this point?

DR. REDBERG: So I liked almost everything you said, Craig.

About the clinical decision support tools, I think it would be good for companies that make clinical

decision support tools, but we see so many papers on this, and I have seen a lot of literature. Mostly -- maybe people check off they have them. It doesn't really change anything.

And the data that I've seen shows you can put a decision support in, and then people will check the right boxes, but the overall volume of what they're -- so it looks good as what you're supposed to do, like people -- all of a sudden, everyone had acute chest pain instead of no symptoms. But the volume doesn't change at all. So I think it just -- unfortunately, I think there's a lot of gaming. I don't think it changes practice.

DR. SAMITT: And I think what I should say is they kind of go hand in hand. If they're offered within a setting of an ACO, I think you tend to see more appropriate and effective adoptions of these tools as opposed to just teaching to the test. So, to some degree, I could be convinced to say the first and the second together are going to be much more effective than, I would argue, the third and the fourth.

DR. REDBERG: Maybe as part of a big picture, but I also think there's a lot of electronic record fatigue. I

mean, I turn off every -- and most people turn off every alert you get because there are just too many of them.

DR. MILLER: And for future discussions, what I want you to think about is, on those two things, which is the responsibility of the program and which is the responsibility of the entity. So, in a sense, you are saying you can't -- this prompting thing, notwithstanding the disagreement right at the moment, let's just say it does work.

Rita, hang with me.

You know, should the -- or whatever. You know, should the government and Medicare be tracking that and scoring on that basis or saying to, in your example, the ACO or whatever example, you were using, "Look, we're going to judge your performance. You are free to pursue at a disaggregated basis how you get to that performance." If you want to use your prompting and Rita is saying in our group, that just doesn't work, there is some flexibility there.

When we go on with these conversations, I am going to focus you constantly at what's the Medicare role, what do you want to leave as the flexibility for the

organization or the accumulation of physicians.

DR. CROSSON: Okay. Jack.

DR. HOADLEY: So, actually, one of my comments dovetails nicely on this last conversation, which is if we're able to identify by whatever means, ACOs, MA plans, organizations, or whatever that have had some greater success in this, whether we can do that from the data or more from just other kinds of reporting, it seems like there might be value in trying to find out what they think is working for them, if they think anything in particular is.

And it's like your example. Whether it prompts one place or some other device -- and I don't know whether -- if we're able to find that X organization that is MA or X organization that is ACO, do some interviewing, do some qualitative research, and get a sense from them of what they think they are doing, or even if there is no data, to start out and go in, "Do you think you've made any inroads on this, and if so, what have you done? What works?"

And then maybe it's to your question, Mark. Maybe it's more circulating best practices and highlighting some things, especially if there is not an obvious -- if

everybody points to the same thing, then obviously that leads us to a different place than if, well, if this worked here and that worked there, but having some of that kind of dialogue.

I am very much, I think, in agreement with the political challenges of the coverage policy, but I do wonder if there are examples out there, again, sort of trying to build this case study kind of notion. It seems like there are cases where at some point in time, practice changed. So whether it's the estrogen treatments or something like that, you can see certain things where there actually was a big shift in practice on something or other.

And, again, maybe trying to look back -- and this might not be Medicare-specific as much as society-specific -- what changed the dialogue on that? "Choosing Wisely," I think was premised on that notion, that if there's a conversation about some of these things, it will change the dialogue, and then people will think differently. If people are saying that didn't happen all that much, that's one thing.

I mean, I remember, now probably several decades ago, the videos, I think, Jack Wennberg had on "Watchful

Waiting" versus other treatments for prostate, and it seems like that's something that's kind of known out there now is that things like "Watchful Waiting" can be a good alternative for certain things. I don't know if that's right, but, I mean, if there are examples of where the dialogue really did change or the practice really did change, trying to go back and figure out what changed that dialogue -- was it dramatic safety? I mean, obviously, if something went to a black box and it got taken off the market, that's one thing. But in cases where there isn't the case, can we go back and look at? And then that goes to is it going to be only those rare examples where we can intervene with coverage policy.

Same thing with the beneficiary cost sharing. For any of these subjects where the evidence at least is controversial or there is some disagreement, it's a tough thing to go to the beneficiary and say -- even if you politically could get to that point to say, "You're going to get higher cost sharing," because at least some people think that's a bad thing to do. And in many of these cases, the "don't do it" is contingent upon various criteria. Okay. Don't get this if you're in a certain age

group, but there's an exception if you have this kind of medical history or whatever. And if you're going to have to write all that into cost-sharing rules, we're going to go crazy. So, again, that's hard.

The only other thought I was going to throw out is we've now done a nice job, I think, of exploiting this particular analytical tool of these 31 or whatever items it is. Are there other lists out there that we could do similar things with? And I'm wondering whether there are some examples in the drug world, whether it's Part B or Part D drugs, where there are certain drugs that there's fairly strong evidence that moderate use is unnecessary. And, again, it's like your different levels of evidence. It doesn't have to be one where it's absolutely this should never be done, but if there's at least a significant thing and if there's other kind of medical procedures where we do this -- and, again, this is just a matter of doing analysis and saying -- you know, shedding some light on it, and if there is some shaming effect or whatever else is going on that's leading to a change, just identifying this on some other categories of services might be something else where we could do it, which is less fraught with some of the

controversy than some of these other policy solutions that we're talking about.

DR. CROSSON: Just to combine two of your ideas, Jack, that sort of second level could potentially, I think, be derived from that interview process with delivery systems managing population risk, and I would imagine -- I don't know, but I would imagine that you'd find a lot of similarities, particularly if you're looking at ones that have been successful over time. And then that could work as an adjunct here.

I know how the "Choosing Wisely" -- the selection process for the "Choosing Wisely" measurements took place. I would just say -- in not all circumstances. In many circumstances, they were not on the most aggressive end of the spectrum, whereas I think you would find a more balanced spectrum if you actually looked at what clinical guideline processes or other collective physician educational processes were going on in certain organizations that had the incentive to do that.

DR. HOADLEY: I mean, I would wonder, in particular, Group Health Puget Sound. We used to hear Scott talk about some of the kinds of ways. They just saw

medicine differently and now obviously part of Kaiser. What is a place like Kaiser doing? What are some of the other organizations doing? Or if we think there's some successful ACOs out there, ways to target what they might be doing.

DR. CROSSON: Alice.

DR. COOMBS: I just want to say, as Jack was talking, I was thinking about a couple things. One is how certain robust health care systems say, "We want IHI to come in, and we want to implement some of the things that they've done." And even with the changes that I've seen in the ICU, Xigris is a $3,000 drug that was used for sepsis. We stopped using it, and it was a process of several specialty groups saying, "This is no good, and it's a waste of money." But that in and of itself took probably 12 months, 12 to 18 months.

PA lines are not used anymore because people have looked at the literature, as is right now hypothermic protocol for a post-arrest is being assessed, which is really a costly venture. And so it's not proven to help patients.

So I think there are some things that you could

say this is a marker, leap frog coming in saying, "Do you have 24-hour ICU coverage?" and how that makes a difference in the quality.

So I almost think that even an emphasis on high-value care might be as productive as looking at low-value care.

DR. CROSSON: I have Amy and Kathy. Amy?

MS. BRICKER: Just quick, back on your point, Jack, so the Beers List exists, medications you shouldn't use in the elderly, and star ratings look at those certain metrics of MDs. So you are thinking about something beyond that?

DR. HOADLEY: Yeah. I mean, part of this -- I mean, the Beers List goes at sort of a collective measure of the list of drugs. If there are -- I mean, I could imagine things like overprescribing of opioid. Well, opioids may be a special case, but even use of PPIs beyond what they are indicated for cholesterol drugs for people over a certain age. Again, I am not the clinician, so I don't know quite what to put on the list, but it could be individual drugs, like this drug is contraindicated for the age, so that's the sort of Beers List kind of thing, and I

know that's been controversial. What's the right list there?

MS. BRICKER: You're saying more clinical appropriateness?

DR. HOADLEY: Clinical appropriateness. Again, I'm just sort of trying to take this notion that there are things that there was some consensus on that had issues, and can we find some other categories just to sort of push this exercise further?

DR. CROSSON: Kathy.

MS. BUTO: Mine is going to be very short.

Payment policy is hard, and depending on how dramatically we want to tinker with it, it may require legislation.

Coverage policy is hard, but you don't need legislation.

So if we can get our minds around what might be appropriate and a better way to approach low-value care, coverage policy is a definite avenue. If it's clear what you want to do and the criteria are basically accepted, you can go forward more easily.

DR. CROSSON: Okay. Very good comments.

Ariel, I hope you have got some good ideas here. I think there were many, and I think we are finished with this presentation and discussion.

So we now have time for the public comment period.

[Pause.]

DR. CROSSON: I'm just going to wait and see who is lining up here. If you are going to make a public comment please line up so we can see who you are. We've got a couple of individuals here.

So we will -- I think you may remember the admonitions from this morning, but I'll have to repeat them for you colleague behind you, which is we would ask you to state your name and your institution, if any, and then give us your comment. We'd ask you to limit your comment to two minutes, which you will know are up when this red light comes back on again, and then we'd ask you to sum up.

Please begin.

DR. DUPREE: Great. So my name is still Jim Dupree. I work at the University of Michigan.

I wanted to talk a little bit about beneficiary choice -- I mean, it's sort of a foundational principle of

Medicare -- and express some concerns, from my perspective, about the use of sort of broad strokes of federal health policy to influence what are ultimately, in these uncertain situations, admittedly very controversial but also very personal and complicated decisions between a patient and, in the case of PSA, his doctor. PSA got a lot of attention today so I'd like to, if I may, just speak about PSA for a second.

It is absolutely controversial. I think there is a diversity of very well-learned and very well-intentioned opinions on the subject, but it is not a clearly -- and I would respectfully disagree with the statements that were made, that it is universally harmful.

The biology of the disease is very important to consider. Age is not a strict cutoff. The biology of the disease does not recognize age. Instead it recognizes longevity.

So I would like to offer two examples to bring that to people's attention. The first is, for example, a 76-year-old patient with newly found metastatic disease in the lungs, and an exhaustive search needs to be done to find the primary source, to guide further therapy. That

patient might receive a very high-value PSA and diagnostic biopsy to find out if these are metastatic prostate cancer nodes in the chest.

Another example would be a very health and fit 76-year-old, who has a longevity of at least 15 years, for whom PSA screening would absolutely offer a benefit.

Since the introduction of PSA screening there has been about a 40 percent reduction in mortality for the disease. Certainly not for patients with short life expectancies, but I think using strict ages and cutoffs really risks removing choice from patients for whom this would be quite beneficial.

That being said, there are absolutely inappropriate surgeries that are being done for prostate cancer. There are urologists who are as offended and appalled by the advertisements in American Airlines, as you certainly expressed. And there were several comments, I believe from Craig and Jack, who asked about case studies, about places where we can find examples of how care is being improved, and I would offer to invite you to come to Michigan. There is the Michigan Urologic Surgery Improvement Collaborative, a group of empowered physicians,

together with patient advocates, who are working on reducing low-value services.

So please come to Michigan. Please come and see another way, other than sort of broad strokes of federal policy to empower physicians and empower patients to make these complicated decisions together.

Thank you.

DR. CROSSON: Thank you.

MR. MAY: Hi. Thank you. Don May with the Advanced Medical Technology Association. We represented medical technology companies, device manufacturers, and diagnostic manufacturers.

I really appreciate the discussion today on medical technologies. It's a really important issue and glad that you're taking it up. I really enjoyed hearing the conversation and the dialog here today.

I wanted to highlight a couple of things that I think are important to remember. One is that technology has got to be part of the solution as we look forward into the policies that we want to think about, our policies that should be about making sure that patients have access to new innovations, have access to technologies that will

improve care.

If we look at the changes in health care that have occurred over the last several years, whether that's less invasive care or precision medicine, we are able to be able to target lower costs and improve care, because of what technology is allowing physicians and hospitals and caregivers to do.

You've talked about a lot of important policies, whether that's how to collect information using UDI, which is really important. You had a lot of good discussion about the benefits and costs, and what is the best way of getting that information for safety and surveillance issues. We'd really like to engage with you on that. We've got some ideas and we can reach out to you.

On gainsharing, that's another issue I think that's real important. But as you were talking here in this last discussion, in particular, about the changes to the payment system, and incentives that have already brought physicians and hospitals together, you know, I think a lot of focus around gainsharing should really be around how do you improve quality, how do you reduce costs, how do you make sure that there's appropriate use. And

technology can be a part of that but a lot of that's happening already, through these payment mechanisms that have been in place in APMs.

On the PODs issue, I absolutely agree with you. There are a lot of issues there to be concerned about.

And then I think I just wanted to highlight another policy option for you to consider, finally, and that is this whole idea of risk contracting, or value contracting, and opening up new ways for technology companies to engage with hospitals, with physicians --

DR. CROSSON: Please sum up. Please sum up. You've gone over your time.

MR. MAY: -- with creative contracting ideas, and that gets at removing safe harbors.

So thank you again, and we'll be reaching out to you as well with some more ideas.

DR. CROSSON: Thank you.

MS. McDONOUGH: Good afternoon. I'm Susan McDonough, a senior director at DataGen. DataGen helps do Medicare and policy analytics for 47 state hospital associations throughout the country, and I appreciate all the work and commitment that each of you have.

I wanted to just mention that participants, as you know, in the Medicare Shared Savings Plan, the Bundled Payment Care Collaborative, Pioneer ACO, the Comprehensive Joint Replacement Program, all have access to patient-level data that spans across time and care settings. And this has really enabled providers throughout the country to pinpoint deficiencies in care and to try to identify opportunities for improvement. And the level of data that they have includes 100 percent physician carrier file data, that's only available to providers that participate in one of these programs.

However, we find hospitals throughout the country clamoring for that level of data, from the 100 percent carrier file, so they can better understand and prepare themselves for the MIPS program that you discussed this afternoon, for the Oncology Care Model program that some of them are trying to ascertain should they participate in that program.

So I ask you today to go to Congress, or to recommend to Congress and to CMS that they provide access to that 100 percent carrier file to the industry, not simply just the 5 percent carrier file, which is

insufficient in order to do the total analytic work that is necessary to improve care in the industry.

Thank you.

DR. CROSSON: Thank you. Seeing no other individuals at the microphone, we are adjourned until 8:30 tomorrow morning.

[Whereupon, at 5:25 p.m., the meeting was recessed, to reconvene at 8:30 a.m. on Friday, April 7, 2017.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Friday, April 7, 2017
8:31 a.m.

COMMISSIONERS PRESENT:

FRANCIS J. CROSSON, MD, Chair
JON B. CHRISTIANSON, PhD, Vice Chair
AMY BRICKER, RPh
KATHY BUTO, MPA
ALICE COOMBS, MD
BRIAN DeBUSK, PhD
PAUL GINSBURG, PhD
WILLIS D. GRADISON, JR., MBA, DCS
WILLIAM J. HALL, MD, MACP
JACK HOADLEY, PhD
DAVID NERENZ, PhD
BRUCE PYENSON, FSA, MAAA
RITA REDBERG, MD, MSc
CRAIG SAMITT, MD, MBA
WARNER THOMAS, MBA
SUSAN THOMPSON, MS, RN
PAT WANG, JD

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AGENDA PAGE

P R O C E E D I N G S

[8:31 a.m.]

DR. CROSSON: Okay. Perhaps we can sit down and we can begin this morning. Welcome, everyone.

This morning, we're going to begin a return to our discussions with respect to Medicare Part D, and we're going to have a presentation on plan incentives, and I think we have got Shinobu and Rachel here. Who is going to start? Shinobu? Shinobu's going to start. You have the floor.

MS. SUZUKI: Good morning. The Commission has been concerned about the growth in catastrophic spending. Last June, the Commission made recommendations to address the issue through changes in incentives plans face. Today Rachel and I are going to talk about a couple of issues that came up out of that discussion.

One of them is related to biosimilars, which we discussed in October. It seemed that there was enough Commissioner interest, so we are coming back to it.

The other issue is related to rebates that plan sponsors receive and how that affects prices faced by different actors.

Another issue that we'll return to in the fall is exceptions and appeals in Part D.

In this presentation, we'll discuss changing distribution of Part D spending, factors behind the expansion in catastrophic spending, and concerns around the growing gap between gross and net prices.

We'll review the Commission's 2016 recommendations that could help address issues around plan incentives. We'll also discuss Part D policy with respect to biosimilars and the coverage gap discount.

You may remember this from our January presentation. Medicare defines a standard benefit; the amounts shown are for 2017.

Working our way up from the bottom, there's a deductible, and after that there is a 25 percent cost sharing.

At $3,700 in total spending, they are in what's known as the coverage gap, and that lasts until the person reaches the out-of-pocket threshold.

How long a beneficiary stays in this phase depends on whether that person uses brand or generic drug. This is because of the 50 percent manufacturer discount

that applies to brand-name drugs, but not to generics, and that discount counts as enrollees' out-of-pocket spending that's used to determine when a person reaches the out-of-pocket threshold.

As you'll see shortly, this discount makes a pretty big difference. Above the out-of-pocket threshold, the cost sharing goes down to 5 percent, the plan pays 15 percent, and Medicare picks up 80 percent in individual reinsurance, which is shown in white.

The combination of the 50 percent brand discount and the rising prices has resulted in double-digit growth in Medicare's payments for reinsurance. And because the discount continues even after the coverage gap is fully phased out, without a policy change this trend is likely to continue.

This chart shows that high-cost enrollees' share of spending grew from just under 40 percent in 2007 to 53 percent in 2014.

It's particularly notable among the non-LIS enrollees. Their share of spending more than doubled from 7 percent in 2007 to 18 percent in 2014.

Some of this is because more people are reaching

the catastrophic phase of the benefit. In 2007, there were 2.3 million people reaching the catastrophic phase. That number was 3.4 million in 2014.

But high-cost enrollees as a share of Part D enrollees has been stable -- 8.8 percent in 2007 and 8.6 percent in 2014. So one of the main reasons high-cost enrollees are accounting for larger share of Part D spending is higher prices.

Multiple factors are behind the expanded catastrophic spending. One is enrollment growth. Part D enrollment has grown pretty rapidly since 2010, particularly among the non-LIS enrollees. More people generally means more spending in the aggregate.

The problem is in Part D there's an interplay between enrollment growth, benefit structure, plan incentives, and market dynamics.

The brand manufacturer discount in the coverage gap pushes more people through the gap phase into the catastrophic phase. In a few minutes, Rachel will go over this in more detail.

Another factor is higher drug prices. It reflects both growth in prices for existing products and

new drugs with high launch prices. Going forward, the drug pipeline includes many specialty drugs and biologics that are likely to command high prices.

A related issue is the growth in direct and indirect remuneration, or DIR. It refers collectively to manufacturer rebates, pharmacy fees, and other payments that plan sponsors (or their pharmacy benefit managers) negotiate to reduce benefit costs.

Growth in DIR alone would be beneficial to the program and to beneficiaries, but when it's growth in both prices and DIR, it's not always beneficial to all parties, which I'll talk about in just a minute.

DIR is related to gross and net price -- terms you may have heard about a lot recently. Gross price is the amount paid at the point of sale, usually at the pharmacy counter. Net price is the gross price net of rebates and discounts, or DIR.

DIR, or the gap between the gross and net prices, has grown by 20 percent per year between 2010 and 2015, which is much faster than the 12 percent growth in overall spending.

Back to why we're concerned about the growing gap

between gross and net prices. It is because certain beneficiaries and Medicare payments are based on gross prices which are higher than net prices. These include higher beneficiary coinsurance and low-income cost-sharing subsidy that Medicare pays on behalf of LIS enrollees. More beneficiaries are reaching the out-of-pocket threshold than if the prices reflected rebates and discounts. And because more people are reaching the catastrophic phase, Medicare's payment for reinsurance is also higher.

Another concern is that the current risk adjustment may overcompensate plans for conditions treated with medications that tend to have high gross-to-net price differences.

For certain drugs, the large gross-to-net difference may provide financial benefit to both plan sponsors and manufacturers, and this arises because of the way the benefit is structured -- the coverage gap, the discount, and reinsurance provided by Medicare -- and the market dynamics, including higher prices.

The resulting financial incentives may affect plan formulary decisions. In such cases, plan incentives would not be aligned with beneficiaries and Medicare

because higher gross prices generally means higher costs for beneficiaries and Medicare's reinsurance.

As DIR grows in size, its importance also grows for both plans and Medicare. Plan sponsors report how much DIR they received to CMS, and then CMS retains some of it to offset part of the cost of Medicare's reinsurance.

CMS recently noted that plans get to keep most of the DIR, and we think that perhaps CMS' formula may be too generous to the plans. I'm going to walk you through how CMS currently determines how much to keep, and then I'll show you an alternative.

In 2015, gross Part D spending totaled about $137 billion. Cost sharing was about $54 billion, and benefit spending was about $84 billion, which was split almost equally between Medicare's payments for reinsurance and plan liability.

DIR, which consists mostly of manufacturer rebates, totaled about $25 billion. Current formula sets Medicare's share as its spending divided by total gross spending, or $137 billion. That comes out to about 30 percent. So Medicare keeps 30 percent of the DIR, or $7.6 billion. The remainder, $17.5 billion, is retained by

plans.

Because this is an administrative decision, not in law or regulation, CMS could use a different allocation method that would result in a more equitable distribution between plans and Medicare.

For example, CMS could set Medicare's share as its spending divided by total benefit spending, or $84 billion. Under that formula, Medicare keeps half, or $12.5 billion of the DIR. The remainder would be retained by plans.

DR. SCHMIDT: So Shinobu just described one approach that could reduce the rate of growth in Medicare's reinsurance spending. However, it would not fundamentally change incentives in Part D. Medicare would still pay 80 percent reinsurance above the benefit's out-of-pocket threshold and, in turn, there may be less incentive for plans to manage the spending of high-cost enrollees. We think that's a key reason for the trend you see on this slide -- the steady increase of reinsurance as a component of spending for Part D benefits over time.

You can see that back in 2006, Medicare's reinsurance -- shown in red -- and enrollee premiums -- in

blue -- each made up about one-quarter of the financing, while Medicare's capitated payments to plans made up the other half. By 2015, the positions of reinsurance and capitated payments had flipped. With capitated payments, plans bear risk because if the combination of the fixed-dollar payments from Medicare and enrollee premiums doesn't cover benefit spending, the plans lose money.

Reinsurance payments are open-ended and based on plans' costs. So Part D has gotten to a point where about half of the financing is cost-based, which does not seem in keeping with the original intent for the program.

Because of that trend and concerns about the financial sustainability of Part D, last year the Commission recommended significant changes to the program. A key recommendation was to phase in a reduction in Medicare's reinsurance from 80 percent of costs above the out-of-pocket threshold to 20 percent. At the same time, Medicare would increase its capitated payments so as to keep the overall subsidy the same. Medicare would continue to pay about three-quarters of the cost of basic benefits. This would put more insurance risk on plan sponsors so that they would have greater incentive to negotiate over prices

and rebates. In return for bearing more risk, plans would have more flexibility to use formulary tools.

Another recommendation was to discontinue counting the coverage gap discount towards the enrollees' out-of-pocket threshold. We'll pick up on this again in a minute, but the general idea was that counting the discount as the enrollees' spending was similar to the effect of using copay coupons. It lowers enrollee cost sharing, but also makes brand-name drugs look less expensive than they really are.

We recognized that this would lead some beneficiaries to have higher out-of-pocket spending, but the Commission also recommended adding a hard out-of-pocket cap rather than the current 5 percent coinsurance. The package also included changes to low-income subsidy cost sharing to encourage LIS enrollees to use generics and biosimilars when clinically appropriate.

An issue that was not part of our recommendation last year has to do with biosimilars. Part D law excludes biosimilars from the coverage gap discount and, in turn, that policy may discourage plans from putting biosimilars on their formularies.

This chart depicts a $30,000 reference biologic on the top bar and a biosimilar priced 15 percent lower on the bar beneath it. Look at the top bar first -- the reference biologic under current law. The different colors within the bar show you the phases of the benefit, and the key pieces here to focus on are the coverage gap and the phase above the out-of-pocket threshold on the far right. Remember, that's where Medicare pays 80 percent of the costs.

Notice that the coverage gap is shorter in the top bar. That's because the manufacturer provides a 50 percent discount, and that discount counts as though it were the enrollee's own spending. So under current law, the out-of-pocket threshold for this reference biologic begins at about $8,700 in gross spending.

In the bottom bar, you can see that the biosimilar has a lower price because the far right of the bar only goes to $25,500. But under current law, there is no coverage gap discount on the biosimilar, so the out-of-pocket threshold is farther to the right. This means that the plan is responsible for covering 75 percent of the costs much longer. So from a plan sponsor's perspective,

even if the biosimilar has a lower price, it might make sense for them to put the reference biologic on their formulary.

Now let's look at two more bars -- again, a reference biologic on the top and its biosimilar underneath it. Part of last year's recommendation was to change the law so that the coverage gap discount would not count as the enrollee's own spending. That's depicted in the top bar, so the out-of-pocket threshold happens at a higher level of spending than under current law. However, once the enrollee reached that threshold, there would be a hard cap on what he or she pays.

For the lower bar, the biosimilar, an alternative policy would be to change the law to apply the coverage gap discount. And to be consistent with last year's recommendation, the coverage gap discount would not count towards the out-of-pocket threshold for either type of product. With that approach, when the plan sponsor was deciding which product to put on its formulary, it would face higher costs if it chose the higher-priced product.

To summarize, there are a number of reasons we expect continued upward pressure on Medicare program

spending: growing enrollment, the coverage gap discount, a development pipeline that includes lots of specialty drugs and biologics, growth in drug prices and in DIR. Part D's unusual design and the way in which Medicare pays reinsurance may affect plan incentives and reduce the imperative for plans to manage enrollees with high costs. And, increasingly, those 9 percent of enrollees that reach the out-of-pocket threshold are driving overall Part D program spending.

The Commission's recommendations from last year would give greater incentive for plans to manage high-cost enrollees, but it may be difficult or take a while to make those changes. Short of that, CMS could administratively change the way in which it allocates DIR between plan sponsors and the program. We think this would be a short-term fix, though. There would still be a need to make more fundamental changes to incentives.

In addition, last year's recommendations did not address the issue of biosimilars and the coverage gap discount. Given that biologics make up more and more of overall spending, that may also be an important change to make, but it would require a change in law.

We'd like your feedback on what we've presented today. The goal is to incorporate this material within next March's report. If any Commissioners are interested in further pursuing the change to biosimilars that would require legislative action, let us know. And at this point, we're happy to take your questions.

DR. CROSSON: Thank you, Rachel and Shinobu.

We're open for clarifying questions. Can I see hands? Amy, Kathy.

MS. BRICKER: You referenced the term "gross versus net," and just as a point of clarification, gross does include the discount at point of sale that's negotiated with retail.

MS. SUZUKI: Yes.

MS. BRICKER: So I think it's a bit misleading because I would think any retail pharmacy that would have interest in this topic would, you know, be somewhat offended to believe that we think that that's a gross price. There's a significant discount that's applied at point of sale. So we might just want to make that clarification going forward.

You mentioned, too, that there would be some more

flexibility to use formulary tools. Specifically, what were you referring to?

DR. SCHMIDT: So there were a number of things that we referred to in our June 2016 report. One thing was to allow more flexibility for making formulary changes, both midyear and kind of at the start of a new formulary -- benefit year.

Another was we looked at the protected classes, and part of that was to follow a CMS recommendation that never became an actual rule to exclude two of those categories from protected status. We also called for allowing a little bit more flexibility in terms of using tools for specialty pharmacy, for example, allowing 15-day fills rather than 30-day if that's how the doc wrote the script and -- thank you, Shinobu -- the last one was asking physicians, if they're applying for an exception on behalf of a patient, to put a little more clarity behind the justification for that exception, so tried to standardize that approach, because right now we're hearing from plans that it's rather easily overturned.

MS. BRICKER: Okay. Thanks so much.

DR. CROSSON: Kathy. Microphone.

MS. BUTO: [off microphone] reference in the paper, but I think somewhere you refer to the midyear price changes and the fact that DIR is the tool that's used to lower or make it not a huge cost or any cost additional to the plan. Beneficiaries, however, pay the coinsurance based on the midyear price changes.

Is there something -- I'm trying to understand whether there's any flexibility to provide beneficiary protection, sort of having their coinsurance held at the same level before the midyear change, or whether that's something that would have to be done, you know, either through statute or regulation. Is it a big change, or is that really just a plan decision?

MS. SUZUKI: So we're talking about the drugs that have coinsurance rather than copay in the initial coverage phase.

MS. BUTO: Right.

MS. SUZUKI: But right now, there are rules around what the cost sharing is in different phases of the benefit. So if it's a coinsurance, plans have submitted the formulary, and they have to use that formulary to apply cost sharing.

MS. BUTO: Okay. And if there's a price increase midyear, they have to apply that to coinsurance.

DR. SCHMIDT: They do. I mean, I think maybe some future work could look into the decisions plans are making on coinsurance versus copays. There's a specialty tier for which, you know, plans are absolutely using coinsurance.

MS. BUTO: Yeah, yeah.

DR. SCHMIDT: But more and more we're seeing coinsurance in some of the other tiers as well. And it's possible you could use some of the rebate to turn some of that more into co-pay versus coinsurance. But that's partly a plan decision, but they also have to abide by some checks that CMS has for the value of that benefit.

MS. BUTO: Yeah. My thought is just that if the plan is protected from price increases, there ought to be some way of looking at ways to protect the beneficiary -- from some of that, anyway, if not all of it.

DR. CROSSON: Craig. Did you have your hand up?

DR. SAMITT: Yeah, I did. Thanks.

I'm curious about the intersection of the DIR recommendations with our prior June recommendations for a

transition of reinsurance from 80 to 20 percent, that whether we feel that they're complementary or additive or whether we would not do them both simultaneously.

So on Slide 8, how would this example change should the June 2016 recommendations be accepted?

MS. SUZUKI: So we were thinking this DIR reallocation as sort of a short-term fix.

As Rachel mentioned, the recommendation would take a change in law, and that may take a while to actually happen.

But in the short term, this is something that CMS can do administratively, and it would help with offsetting the cost of reinsurance.

DR. SCHMIDT: But we think you wouldn't need to do this reallocation if you had the 80/20 in place, the recommendation from last year. We think that that would really take care of that.

DR. SAMITT: That would solve the long-term problem, and the DIR recommendation is a short-term fix.

DR. CROSSON: Bruce.

MR. PYENSON: Yes. Shinobu and Rachel, excellent report, really terrific.

I have a very granular question and a bigger-picture question. The granular question is there is a phenomenon known as transitional scripts that get a patient one script was a formulary change at the year. That can be, I think, up to three scripts for people in long-term care.

Have you looked at that, or do you think that's a fruitful policy to look at as a -- whether that policy should continue?

DR. SCHMIDT: We have not looked at it in depth, and I'm sure I've heard you say before, in fact, Bruce, that you think that there's some issues perhaps, in particular, around long-term care.

MR. PYENSON: And I'm wondering if you could quantify. I think it's on the PDE. You can identify those scripts and quantify how much of an issue that is?

MS. SUZUKI: We can go back and look. I don't remember whether a specific claim is flagged as being a transitional supply versus just a claim that's filled, but we can go back and check.

DR. MILLER: I just want to understand the motivation here. Is this a freestanding thought, or is it

related to one of these two policies?

MR. PYENSON: It's freestanding. I suspect it's related to the 2016 recommendations on things like protected classes. I lumped it in with that kind of a --

DR. MILLER: I just wanted to follow the connection.

MR. PYENSON: So the bigger-picture question I have is looking at Table 5 in the material, and that's page 25. There's a terrific chart. It shows the increase in the percent of gross, as you've defined it, that is DIR and how that's dramatically increased in recent years. What do you think accounts for that change?

So, for example, towards the beginning of that period, there was a patent cliff, I think. If you could give your view from a macroeconomic picture or microeconomic picture, this industry.

DR. SCHMIDT: Right. So, as you are saying, around 2010, that is generally when people think of it as the largest part of the patent cliff, and at that point in time, brand manufacturers were facing much more competition, and in order to compete at all, they need to start introducing rebates. So you saw some rebates, which

is the vast majority of this DIR in this table, be a significant value.

But over time, you see faster growth at the end of the years, I would say. So now you are starting to see more specialty drugs that have come out into the market as some competition between some of those, so these are higher priced drugs, much higher, tens of thousands of dollars per year for a patient.

But to the degree that there is some competition between those products, then you are starting to see much larger rebates. You also see the price protection rebates starting to be used pretty widely, so the plan sponsors are demanding of the manufacturers: "Any increase in prices midyear above X amount, we want rebated back to us." So all of those factors, I think, have led to this dramatic increase in DIR.

MR. PYENSON: But just to follow up on that, of course, there is competition between brands before that period. Why did the patent cliff lead to this change, real fundamental change?

MS. SUZUKI: I don't know that we have an answer to say whether one factor led to this kind of pricing

dynamic, but what we are seeing is that with a lot of brand-name drugs, not just in Part D, the prices are growing fast.

But also for some of the drugs, like Rachel said, with competition, you are seeing that rebates are also growing on those products, and so you end up with a situation where you see a huge gap between gross and net, and DIR is growing.

I think it may be the competition in some classes. I think it may be that there were lots of changes made with ACA, and coverage gap discount was added. Lots of things may factor into pricing decision.

MR. PYENSON: Thank you.

DR. CROSSON: Okay. Pat.

MS. WANG: So I apologize for whispering. Can you hear me okay?

It is a very complicated benefit, and your answer to Greg's question was helpful to me, but I was wondering if you could talk also about the intersection of the RxHCC with all of these changes. I don't know whether last year in the context of the June recommendation, you talked about that, because obviously pushing more into a risk-based

premium puts a very high, high premium on getting risk adjustment correct. How do you even think about that given there are rebates flowing? I mean, does the fact that DIR kind of takes the Medicare share of that neutralize the phenomenon you were talking about with the inaccuracy and some of the HCCs overcompensating because of large rebates? How are you thinking about that?

MS. SUZUKI: So I think we are concerned with exactly what you said. I don't think it's the matter of CMS paying too much on average, but it's between the HCCs that some are overcompensated, which naturally means the others are maybe paid less than what it should be.

And I think what we are raising in this report is that they may want to consider factoring in the rebates that are associated with certain drugs. If it's very high, then a plan's net cost is much lower than what you see on the pharmacy transaction.

DR. MILLER: When you said factor in, what you mean is the CMS recalculating the weights, the relative weights within the HCC after adjustment for the DIR.

DR. SCHMIDT: Right. But we recognize that is not a trivial thing, because the rebate information, they

are starting to collect it on a drug-by-drug basis. But that is what they negotiate in the past, not necessarily what might be negotiated in the future.

MS. WANG: I think that's important because I think rebates change for a lot of different reasons, for example, trying to get a better price on your formulary, and it's the market at work. Has there been any research on the accuracy of the RxHCCs generally? Because I can tell you at least from the Medicaid experience, it totally doesn't work. They don't know how to risk adjust for drugs. So I think this is a very important topic.

DR. SCHMIDT: Early in Part D, there was some work that was finding that the compensation for low-income subsidy enrollees was too low, and in fact, we were seeing some market dynamics where some plan sponsors were trying -- it appeared to be they were avoiding LIS enrollees.

Subsequent to that, CMS redid its approach to the RxHCCs and has separate regression estimates for different categories, including LIS enrollees. We did speak with a number of actuaries for all the major plans, and of course, a couple of years of research before we came up with the recommendations. And at that point, they were telling us

that they thought for the most part that the compensation for LIS enrollees was fair. There were some issues with particular drugs, but it was much better than it had been.

And with respect to the recommendations from last year, we recognize that it was very important to recalibrate the RxHCCs if the recommendations were to take place, but we should also point out that the risk corridors are still there. So that is an added level of protection for the plan sponsors.

DR. CROSSON: Rita.

DR. REDBERG: Thanks for an excellent chapter and a really important topic.

I just am a little confused on why there is no -- for the reference biologic, the discount does not count towards the out-of-pocket threshold. It just seems inconsistent why the biologic would and the biosimilar would not.

DR. SCHMIDT: That's just the way the law was written. It was part of the ACA.

DR. REDBERG: Do you think it was an intentional thing or -- someone is nodding behind you -- or was it an oversight?

DR. SCHMIDT: And someone is nodding behind you too.

DR. REDBERG: Oh, I see. Intentional. Well, there you go.

[Laughter.]

DR. REDBERG: I will continue this later. Thank you.

DR. CROSSON: Warner.

MR. THOMAS: Have we quantified the annual and maybe five-year impact of what this change may generate? I might have missed it in the detail reading, but I didn't see the exact number of what we think this may generate for savings.

MS. SUZUKI: Which policy?

MR. THOMAS: Well, just having the biosimilars kind of count similar to --

DR. MILLER: Yeah. I think this is more of a setup conversation, and the question would be, is if we move forward with this, move into the fall, that type of thing, that's where all of that would come out, because I am not aware in any of our internal conversations that anybody has been throwing numbers around.

DR. SCHMIDT: And at this point in time, there are just a handful of biosimilars on the market. This is something to kind of prepare for the future. So putting together an estimate is a little bit tricky there. You have to kind of think about when there's going to be entry of these biosimilars.

DR. CROSSON: Okay. I'm sorry. Amy?

MS. BRICKER: You also mentioned the concept of removing the 50 percent discount from the benes out of pocket, and you equated it to coupons. Can you talk a little bit more about that?

I understand what you're saying. I just wonder how we would then -- rebates are higher, to your point. Yes, the gross list price is also inflating, but therefore, the 50 percent discount is inflating as well. And to remove that from the benes kind of benefit, can you talk more about that?

MS. SUZUKI: So in the recommendation, the way it would work, beneficiary would still face the same cost sharing as they would under current law, but what it would do is not no longer count that discount that plans are receiving as out-of-pocket spending to figure out when that

person reaches the catastrophic threshold.

So in 2020, if a beneficiary used a brand-name drug, 75 percent of the cost in the coverage gap would account it towards the catastrophic threshold. Whereas, if someone was using a generic drug, 25 percent, which his their out-of-pocket cost-sharing amount, that would count towards the threshold.

DR. SCHMIDT: This was a very controversial point as part of the recommendations because there were more people who would stay in the coverage gap long as a result of this policy, but we tried to balance that by having a hard cap in place. So for people who were actually reaching the highest levels, they would have some relief. And it was a tradeoff. It was a package full of tradeoffs, and no one was completely happy with it, truth be told.

But we felt it was important that there was this very distinct, different treatment of branded drugs versus generics, and we were trying to put them on more equal footing.

MS. BRICKER: Yeah. I'm following what you're saying, Shinobu. To the extent there is a generic alternative, I think you're right. You should encourage to

a greater extent, the utilization of those more cost-effective therapies and allow the plans the ability to put greater restrictions or more tighter management around lower-cost therapeutic-equivalent products. But I -- it's a Round 2, but thank you for the commentary.

DR. CROSSON: Warner.

MR. THOMAS: In the reading on page 30, Figure 5, I just want to make sure I'm interpreting this right. The below-threshold spending has grown to $86 billion. Is that right? And is that the Medicare program liability? It has got the cost sharing, the --

DR. SCHMIDT: It has got the cost sharing on the top, right. So the bottom part is what the benefit is covering.

Am I answering your question?

MR. THOMAS: Yes. What I'm trying to get at is what is the exact federal cost for the program. So is it the darker blue bar, which is the bottom piece, which is about, I guess, about $30 billion? And then how does that relate to the above threshold graph as well? Do you have to add those together? Are they included in each other?

MS. SUZUKI: So the federal cost is a little bit

hard to get from this chart because what we were calling "plan covered portion" is partly direct subsidy, which his federal cost, but partly premiums paid by beneficiaries. And we don't have the breakout for that in this chart.

MR. THOMAS: Is there a better part that just has the total federal spending on the program trended over time?

DR. SCHMIDT: We have that in the March report chapter.

MR. THOMAS: Okay.

DR. SCHMIDT: I'm happy to send that to you.

MR. THOMAS: Okay, great.

I am just trying to get a handle on kind of the total, the total amount of dollars, the trend on the total amount of dollars that we can understand, and then as we think about contemplating policy, what sort of magnitude is the change? Is it billion? Is it 10 billion? I mean, just try to understand the magnitude of the change, it sounds like it's relatively small, given that there's just not a tremendous amount of biosimilars.

DR. SCHMIDT: In the near term, yes, but I think over time, it could be much larger.

DR. MILLER: Actually, we can send in the table out of the -- because I think I know the table. That is the one where it shows the reinsurance 20 percent growth rate. Yeah.

So you could sort of be looking at this and saying, "Yeah, but the biosimilar thing is a relatively small thing," but as a phenomenon in the drug benefit throughout the entire range of drugs, the federal portion is growing very rapidly, and it's not a small-dollar issue.

I think part of what we're up to with the D recommendations in June and our conversation here, kind of building structures that are going to help the program doing forward when the biosimilars start to hit in a big way.

MS. BUTO: But, Mark, those federal dollars are being helped not just by biosimilars --

DR. MILLER: Absolutely.

MS. BUTO: -- but by not counting the 50 percent discount and a number of other things, so delaying the arrival of some of the beneficiaries or, I guess, stopping the arrival of some from getting even through the coverage gap. So there are a number of things going on in terms of

what federal dollars will be saved as well as the shift in federal liability above the threshold.

DR. MILLER: And Rachel referred to the controversy. It is saying to the beneficiary, "Well, this dollar won't be counted," and so you're going to be delayed at getting to the catastrophic cap, as she mentioned. If they get there, then they're fully protected, which is not the case in current law, but some of the tradeoff. And this is triggered by Amy's questions and other comments.

But by giving the discount, you are attaching the beneficiary to the more potentially expensive drug. You're raising the question: Well, is there an alternative? But in the instance where there is, you're attaching that beneficiary to the more expensive drug and saying why don't you just go ahead and stay there because the discount is there, and if there is an alternative, they are being driven off the decision to go find that. And that's why things get pretty hairy in this coverage gap.

DR. CROSSON: Okay. So I think we will move on to the discussion here. If we could put up Slide 12 again.

So what we have on the table here is a proposal to, in the next term, do more work to supplement the 2016

recommendations, as has been described, to change the DIR allocation and then to add the biosimilars to the policy that we have subsequently -- previously described, rather, for the coverage gap.

The question on the table is, Is there support for this direction? Would people see a way to enhance this, add to this, subtract? And the intention, if there is support, would be to proceed with this. We will discuss it in the fall, and as noted, it would become part of the March report.

So I think, Paul, you -- Paul is going to start off.

DR. GINSBURG: Sure.

Stepping back, this is really about -- starts with flexibility and benefit design. This Commission has wrestled for a long time with the problems where the legislation that created Parts A and B wrote the benefit design into law, and it is very difficult to change to bring up to date, as many other things have changed.

In Part D, it appeared to be that given the structure of plans and plans' ability that there would be more flexibility. But then the relationship between the

Medicare program and the plans was written in law precisely, and what we're seeing is two developments that have really made the original relationship problematic. One is the entry of new and very expensive drugs, meaning that more people get into the catastrophic range with the reinsurance, and also the growing gap between gross and net prices driven by both the marketplace and by policies, particularly the coverage cap discount being the policy driver.

I, for one, am very interested in moving forward, taking up the biosimilar issue, and working on fundamental change in this relationship between the Medicare program and the plans to, in a sense, reflect the current realities in the market and hopefully maybe even do it in a way so that when the market changes further in the future in a way that we may not be able to envision, it won't be such a restriction down the road as it is today. But that's a tall order.

Just a specific comment on biosimilars, I take the substantial investment by the major brand-name manufacturers in biosimilars as an indication that this is going to be very substantial, and it is really worth our

while not being dissuaded by the very small number approved now, but just anticipating that this is going to be a large phenomenon unless we inadvertently cut it off through bad Medicare policy.

DR. CROSSON: Thank you, Paul.

So we will have a discussion. Can I see hands? Okay. We have got a lot over here. Let's start with Craig and come up.

DR. SAMITT: So I concur with Paul's views on biosimilars. I think that the policy change that you've recommended for applying coverage gap discount to biosimilars makes complete sense.

I have some significant concerns about changing the DIR allocation, and part of it just really stems from not clearly understanding what the impact of that change will have on total drug prices and even on premiums for consumers. I think that plans seek to achieve the best total -- or the lowest total cost as conceivable for drug prices, whether it's direct discounts or whether it's rebates. And what I don't fully understand, especially given the drivers of increasing drug costs, is a simple redirection of the allocation, does that truly suppress the

drug costs or does it just reconfigure a broken system in a way that doesn't make sense?

The other thing that I just do not fully appreciate is it seems like a pretty fundamental change to especially the pharmaceutical supply chain infrastructure in terms of how this would work, and whether that reallocation of DIR, given that that isn't the way that the industry is applying rebates versus up-front discounts, whether we can actually fundamentally make that infrastructure shift and how that would work. So I think it's very much about uncertainty of the implications of DIR and whether it's operationally feasible.

DR. SCHMIDT: Just to help me understand, I'm not fully following how it would change things for the supply chain.

DR. SAMITT: Would the recommendation be at sort of applying the rebate effect at the point of sale, or would this be an after-the-fact reallocation between plan sponsors and CMS?

DR. SCHMIDT: I think we were thinking the latter, that things would be as they are, that rebate negotiations would take place as they are. They might be

affected by knowing that CMS is going to keep a larger share of it. But we were thinking that this is an after-the-fact thing. And I guess the end result we were contemplating is, yes, if there's less rebate revenue that the plan sponsors are holding onto, that might make them kind of submit a higher bid for what would ultimately be the fixed direct subsidy piece, so that they'd submit a higher bid anticipating less rebate revenue that they get to keep. But, in turn, since Medicare is keeping its subsidy the same, there would be higher capitated payments from Medicare.

DR. SAMITT: My first issue in terms of the net effect on premiums or whether plans would actually have the ability beyond the ability they have today to control the net cost, whether this fundamental change in DIR improves that circumstance.

MS. SUZUKI: So this is not necessarily to change the incentives plans currently face or the way they manage the benefit. But what it would do is simply reallocate the rebates so that all benefit phases are getting the same share offset from the rebates. And in terms of how that affects the premiums, if nothing -- assuming no behavioral

change, it is a simple shift in the rebates from -- some of the rebates from plan liability portion to reinsurance portion. And both pieces are feeding into the beneficiary premium, so theoretically, there would be no -- there could be no effect on bene premiums. But if plans do change their behavior, that could, again, change the beneficiary premiums.

DR. SAMITT: I think I'd probably want to understand more, and there may be others that have a perspective.

DR. MILLER: I have to process this, too, so I've had one more iteration than you. This is -- right? And they patiently try and take me through it. This is my civilian way of thinking about this. This in no way undercuts the need for the 80/20 recommendation. And to your comments, that's what we think changes the incentive structure for the plan. Okay? And, you know, people can disagree and have those arguments, but this doesn't change that. And you're correct -- the need for that. You're correct that this allocation thing doesn't necessarily change the overarching incentives. It's an accounting transaction at the end. I view it very much at the end of

the day that says, okay, now that these dollars have come in -- and I'm just using this term because you used it -- under the currently continued broken system, how do you allocate that between the plan and the government? But without in any way changing the notion that you really need to fix that 80/20 so you get a better incentive structure overall.

So it really is an -- I have always viewed it as just an accounting shift at the end of the day that now here's the block of dollars, how are you going to split it between the plan and the government?

DR. SAMITT: And I guess just to counter, the question is, while it's not just an accounting shift -- unless I misunderstand this -- it's also a shift of risk. And so while the rebate dollars are shifting to CMS, the risk is now borne on the plan to manage the rising drug costs. And the question is: Can they feasibly manage that risk with the shift in the DIR?

DR. HOADLEY: Isn't that more driven by the -- I mean, that's more driven by the 80/20 reallocation. This allocation we're talking about here is not so fundamental, partly because it's still going to be 74.5 percent federal

subsidy to the plan, we're just messing around with which of that 74.5 percent comes out of different pots, right?

DR. MILLER: Yeah, I would agree with that, and I'm keeping an eye on those two. I would agree with that and would say -- I would have said just directly in response to this comment, no, it's not fundamentally changing the risk. The 80/20 will, just to make sure that, you know, I'm walling that off. That's a separate thing. But this allocation deal, I wouldn't see that as fundamentally restructuring the risk. And so I'm agreeing with you, and I'm getting a nod out of Shinobu. And as usual, Rachel won't give me any response.

[Laughter.]

DR. CROSSON: Okay. Who is next coming up? It looks like Sue.

MS. THOMPSON: Thank you, Rachel and Shinobu, for your continued good work. And I do look forward and support the fact that we continue to work on Part D drugs, and I'm noticing the 2018 March report that we're preparing for.

It strikes me, though, that there's a piece of work that I really want to have available around the

assumption that drugs are good. I mean, there's an underlying assumption here that because they're available we should be using them, which I think in part is driving this increase in spend and this increase in utilization. And I know we've had some discussion about polypharmacy, so whether it be in the context portion of the chapter in March, I just think in order to more than just shine a light on the formulas and the 80/20 and where the risk moves, it feels a little bit like moving the deck chairs, when really getting to the root cause of what we're doing to our Medicare population by the direct-to-consumer markets that's going on, this point in time where these biosimilars are going to become very available, it just -- it strikes me that an important piece of work, as we make these recommendations -- and thank you for your good work and all the analytics that have gone into it -- has to do with the fact that the dollars we're spending on the drugs is but a small piece of the effect it has on our utilization of skilled and long-term care and the falls that are created and the confusion that happens as a result of 75-year-old people using five, six, sometimes 20 drugs. And who's accountable for that? And yet I just think

contextually that part of the story is really important as we move forward in our recommendations.

DR. CROSSON: Thank you. Pat.

MS. WANG: Hi there again. So I think that the product direction on biosimilars is good, and it is a tradeoff for the beneficiary. But to Paul's point about kind of getting in early and establishing a framework that does not stifle in any way or put a thumb on the scale, you know, biologic versus biosimilar, I think is important.

I share Craig's hesitation around the recommendation for DIR because rebates are not a static phenomenon. You know, they change based on plan approaches and PBM approaches to really trying to get the best price possible. And so this is kind of a point-in-time depiction. I just don't know enough about how that would change behavior on the part of the plans, how it affects the risk corridors, how it ripples through to the risk portion of the premium, you know, to think that maybe it's quite as straightforward as just CMS getting a larger share. So I would like to know more about it and just understand it better.

As far as the 80/20 recommendation which was made

last year, I really think whether we're talking about the 80/20 or any changes in DIR, I would like to see the Commission do more work around risk adjustment. It's very, very important to get that right. I mean, we can change incentives from 80/20 to 20/80, but, you know -- and I think all plans -- but I think regional plans, smaller plans really need to have correctly adjusted risk-adjusted premium in order to have, you know, a go at that and [inaudible] even though there were risk corridors. If risk adjustment is not correct, you may be underutilizing or utilizing those risk corridors in an arbitrary way. And the ideal, the goal I think would be appropriate use of the risk corridors because the risk-adjusted premium is pretty good to start with.

The other thing is just -- this is a separate thing that I can talk to you guys about separately, but on the issue of LIS, I think that there is a phenomenon in the way that the bid [inaudible] is set up in the bidding rules that Carlos would know more about. That makes it very difficult to offer zero premium products to LIS enrollees. That might be worth looking at as a recommended change. A tweak there would be helpful, I think, to encourage use of

generics and so forth.

DR. CROSSON: You know, I'm starting to like this whispering thing.

[Laughter.]

DR. CROSSON: I mean, I think we should take into consideration maybe this would be a policy for everybody. I'm not sure. At least in -- well, we could impose --

PARTICIPANT: [off microphone] equity.

DR. CROSSON: Yeah, right. We could impose whispering at a certain point in the discussion. I'm not sure. I'll work on it. Who's next? Rita.

DR. REDBERG: Thanks. Again, I will certainly just say I agree wholeheartedly with Sue's comments about, you know, before we look at prices, which are clearly important, we need to look at what is the value, and the value first means, you know, are our beneficiaries better off for the drugs that we're talking about? And I will just note that the same things we talked about yesterday with, you know, the pressure to get things on the market are certainly also operative for drugs, and a lot of drugs are now getting approved on surrogate markers, which are only useful if they actually correlate to clinical

outcomes, and that often has, you know, not been shown. So that is certainly an important point.

In terms of the recommendation, obviously, from my Round 1 question, I think it's really important to apply the coverage gap discount to biosimilars. I don't understand why it wouldn't apply to biosimilars.

In the pricing in DIR, I have to say I really don't understand the whole idea of having a price but then having a discount and then everyone gets the discount, but Medicare then ends up paying them because of what seems like to me gaming on this coverage gap and then Medicare, you know, pays more reinsurance because people are coming out of the coverage gap. It reminds me of, you know, the rug stores that always say, "Going Out of Business, 40 Percent Sale." I mean, every day for years it says that? And after a while, you think, okay, no one ever pays full price for these. You have to be really -- I mean, why don't we just have a price instead of having a gross price and a net price? I don't understand how we got into this system. It doesn't make sense to me. Am I missing something here?

[Laughter.]

DR. SCHMIDT: I don't know the full history of how we got to where we are, and I imagine Amy might like to jump in and --

MS. BRICKER: Sure. We could spend a whole -- maybe at our retreat on how we got here. But rebates are the tool that have been used well before Part D to just get formulary decisions, right? And so if -- albeit in the regulated space or in the commercial space, rebate was the tool to get additional discount to ensure formulary placement. To say we should just have a price I think on the surface sounds great, but in reality would never really pan out.

It's not often known at the point of sale what the rebate effect will be. So in the regulated space -- we've talked about this somewhat, maybe not in this forum, but just put the rebate at point of sale, right? None of this kind of after-the-fact nonsense. The price at the point of sale is the price, and rebate -- it's not known at point of sale what the rebate value is oftentimes because plans might negotiate 100 percent of rebate, not a flat dollar rebate. And so these percentages aren't known at point of sale. So then you have false claims issues, or

that's the concern of plans, and so there are lots of things that the government has restricted from a "why can't we just" kind of philosophy that doesn't allow plan sponsors to do some of the things that you might think, well, that makes more sense to the beneficiary or even to the plan sponsor themselves.

So I think we have to really unwind this quite a bit, and that's my concern with some of these things that are -- we're just putting our finger on little holes in the bucket and not actually taking a more holistic view of the issues and how we might be able to remedy. But, philosophically, how we got here was just literally the competition in the market and someone saying, "I'll give you another nickel if you prefer my drug over my competitor's." So that's how we got here.

DR. CROSSON: I'm trying to keep track of the conversation, and so far, Rachel and Shinobu, I've got two ineffable items for you to work on for next year. One is, How does legislation get written the way it does?

[Laughter.]

DR. CROSSON: And the other one is, How do markets evolve the way they do? Just take notes.

Next, David.

DR. NERENZ: Will that run over a hundred pages if it's done?

PARTICIPANT: I think it would be 200.

DR. CROSSON: Do you want to go?

MS. BRICKER: Okay. So just a couple things. Absolutely in support of the biosimilar recommendation. I would want to go a little further with what was recommended back in 2016. You can look at the effect -- and maybe it's my fault for not having thoroughly read or recalling all that was provided in the 2016 report. But on protected classes, the phenomenon that occurs if you take, you know, oncology meds of themselves, you know, anytime you create a system or a structure or regulation, the market will respond and attempt to benefit itself, of course, whoever that is. And so I fear by just putting, again, one recommendation around DIR and not looking at holistically kind of the impact of that, the unintended consequence that might occur, and just maybe Pat's or someone else's point about this being a point in time -- that was your point, Pat -- I agree with that.

And to the extent that the plan isn't going to

benefit in the same extent it does today by driving deeper rebates, they may take their foot off of the gas. I don't know. But I do think that the market will respond, and it's not going to necessarily continue in the same way.

I'm okay with, you know, continuing the conversation around shifting risk to the plan, but you've got to allow the plan to manage the benefit. And we have so many restrictions around, you know, what they can and cannot do, and we know there are plenty of studies that you've provided around the number of choices that beneficiaries have, and, you know, 700 plans or something that exist today, and many people have 20 or more choices. I think to just say there are plenty of options for folks and to be able to manage the benefit in a way that makes sense if you're going to shift the risk to the plan I think is absolutely crucial.

So I'm not as enthusiastic about the DIR option that was presented because, again, I think we need to look at it in total versus just one aspect of the benefit. But I understand why, to your point, you're not going to -- it's not going to require legislation, and maybe it's something we could do quickly. But I just think there's

more risk to the overall plan by just moving one piece of it around.

Thank you, though.

DR. CROSSON: Jack.

DR. HOADLEY: So on the specific issues of the things you raised on the slide here, I think on the coverage gap discount to biosimilar, I think that's absolutely something we should do, and I'm actually sorry we can't be putting it in this year's report because it just seems like a simple fix that it sounds like there's pretty much agreement on.

ON the DIR allocation, again, my instinct is that this is a good change. One question that occurs to me now as we've been talking about this, you talked about a fix along these lines the last time you presented on this issue, but this is a different approach than -- I'm trying to remember what was in that previous conversation.

DR. SCHMIDT: We didn't get to the point of proposing any alternative, just raised the issue that the current plan allocation may not be -- may be overly generous.

DR. HOADLEY: And I guess after some of the

discussion, I'd just like to think it through and hear through more of the details because to me it still seems like it's a fairly straightforward mechanical fix to sort of the way the allocation is working and some of the sort of odd disincentives that the current method has. So I think it would help when we bring this back to make sure we understand for everybody's benefit sort of whether -- how to think through whether there are broader implications or not. But I definitely would like to see us continue to talk about that.

What I think this DIR issue to me raised is just this broader -- and a couple people brought this up, especially in some of the Round 1 questions -- is the broader issue of how this relates to the out-of-pocket cost for the beneficiary in those cases where coinsurance is used. Not only is this an issue for any individual purchase of a drug -- so I'm getting a particular drug. Whether it's a bio -- biological or biosimilar on a specialty tier or whether it's just a brand on a tier with coinsurance in the sort of regular part of the benefit, I'm paying a coinsurance of 25 percent or whatever the amount is based on the retail price, without getting the advantage

of that rebate.

I get some benefit from that rebate, presumably, eventually in my premium calculation. It's saving cost for the plans. It's bringing the premium down. But there is an allocation issue of where the -- all beneficiaries in the system benefit from the premium, but the individuals who particularly end up using these more expensive and brand-name drugs that are in the coinsurance tiers don't get the benefit of that. So there is sort of a reallocation issues among beneficiaries that's implicated in this.

And then, similarly, because the overall design of Part D was actuarial equivalence to 25 percent coinsurance, again, that 25 percent is coming out based on the pre-rebate gross price or whatever term we think is right. The invoice price, I guess, would be another way to talk about it. So it has implications of how much people overall are spending in that initial coverage phase and eventually in the gap phase, putting aside the issues of the manufacturer discount.

So I really would like to see us think about how to provide some relief for the beneficiary in these

situations, and while like Rita, part of my instinct says sort of do it and just completely transparent prices, I do hear some of the arguments about we will get better discounts through the system.

I would like to hear more about the economics of that and whether there is good evidence of that. I know there has been some discussion of those points here and in some other settings, and so if there is a different way to provide the beneficiary who is using these brand drugs, some cost sharing relief, that is something we could look at, maybe. I have some ideas about that too.

The other thing that I am kind of struck by in this whole issue of the price increase protection that plans are increasingly negotiating on their thing is we kind of don't have that same price increase protection for a beneficiary, and an issue that I have talked a lot about in another setting is this notion that when a beneficiary shops for their plan during open season, they are seeing a set of prices.

But when they go to buy the drug -- so that's in November. When they go to buy the drug in February or even more so in June or September of the following year, they're

seeing different prices. So they feel like, "I shopped for this. This is what the plan told me it would cost," and of course, the premium is locked in. Your copays are locked in, if they're flat copays, but your coinsurance isn't, or the cost of the drugs that you're getting in a deductible.

While I think that's probably not fixable, I think what some of these issues might go to try to think about, is there a way to provide something more like price inflation protection for the beneficiary during the year? If we can't get all the way to that, how can some kind of policy options, particularly for those paying coinsurance or for prices faced during deductibles and other places could be addressed better?

The last point I'll make is just to remind us all, similar to yesterday's conversation about Part B drugs, is there's a lot of things affecting this that are outside of the narrow bounds of Medicare policy, and so the interchangeability issues for the biosimilars from the FDA, the state laws on substitution -- you know, we have gotten a lot of the generic -- the advantage of generics because pharmacists can make the substitution automatically without the doctor having to understand that there is a new

generic.

State laws have been changing to mean that can't necessarily happen for biosimilars, particularly those that don't have the interchangeability designation. While we can't make a recommendation to state legislatures to do something different, we can at least point out some of these kinds of factors. I think broader acceptance of what it means to be a biosimilar that is really substitutable in the eyes of many physicians, the naming conventions that FDA uses, the backlog of getting the biosimilars approved and on to the market. And as somebody mentioned, the direct-to-consumer advertising could become an even bigger issue and already is, yesterday, a lot of advertising on some of the biologicals.

Obviously, one issues is whether they're necessary drugs at all, to the point that Sue raised and Rita has raised, but some of those are ads, trying to make sure you're attached to the original biological. At a point when they're soon to be competition of biosimilars, will we see advertising from the biosimilars? I don't know.

So there is just really a laundry list, and I

could probably come up with another dozen of external factors that we need to keep in mind and maybe figure out whether there's any angle to work on any of those from inside our jurisdiction.

MS. BRICKER: Can I --

DR. CROSSON: Yeah.

MS. BRICKER: I would like for us to continue that particular, Jack, the discussion you had around inflation protection for the bene.

So the conversation has heated up as of late because of the increase in prevalence of percentage copays. Back when we were all paying 10 bucks or 20 bucks for a script, lots of things were happening behind the scenes, but the patient at the counter was none the wiser because their copay was flat.

With ACA and lots of things that have driven percentage copays, now you have the outrage of the mom at the counter with the EpiPen script for $600.

So it's philosophical. Do you move away from that percent copay to then not have the patient actually have line of sight into the actual price of the drug? I think pharma would love that because then they can

discontinue doing whatever behind the scenes, but the flip of that is if you continue with the percentage copay and you don't have these protections both for the plan and for the bene, then that also is quite unfortunate.

So I would love for us at some time to have more of -- if we could control for either scenario or what are the ramifications of going back to something that takes away the true experience of the drug increase at the point of sale, at the counter, what then happens to pricing in the country, and what levers could we pull so that we're holding pharmaceutical manufacturers accountable for the decisions that they are making with respect to price?

So it's a much, much broader conversation, but I think it would be a value to have that.

DR. HOADLEY: Yeah, I definitely agree. That's a good conversation.

One of the Medicare policy levers that's potentially implicated in this is that 25 percent base, so that's one of the levers that says -- apart from these factors that you're raising, a plan in making its design, when they're looking at expensive drugs, they are going to have to raise the flat copays a lot over time to maintain

that 25 percent.

So in that broader conversation, we should think about whether that's getting in the way of some kind of policy that might work better for everybody. I mean, this is definitely a broader conversation on this topic.

DR. CROSSON: Okay. Bruce and then Kathy and Brian.

MR. PYENSON: I've got a couple of points and suggestions.

First, in response to Craig on the incentive and the risk, I wanted to give an example and maybe get some response to it.

Suppose a patient comes in with a $100,000 script and you are not quite sure if the script is indicated, if it's the right one for the patient. Normally, if that were in a health insurance company, of course, prior authorization and that sort of thing. If you're getting a 50 percent rebate on the $100,000 script and you have to give 30 percent of that to the feds, but the feds are also picking up 50 percent of the cost, you don't have an incentive to even check whether it's an appropriate script or not. The incentive is to write the script. You make

more money. Because of the 50 percent rebate, you only give 30 percent of that.

So changing the rebate from the 30 percent federal share to approximately 50 percent would actually change some of the incentives in the plans, provided the manufacturers didn't also increase the rebate, and some rebates are north of 50 percent already.

So I agree it's not a fundamental shift, but I think in the short term, it would change some of the risk management incentives currently for plans.

But I agree that it's a short-term issue and probably has implications elsewhere for the member premium and things like that. So, ultimately, the shifting from 15/80 to 80/20 is the solution to that because that would fundamentally change the nature of risk unless -- except for products where there is more than 80 percent rebate or something like that, and there's probably a few of those but not many.

I think an important issue here to recognize what we're dealing with -- because the industry probably has one price that they apply to both Medicare, one gross price or WAC price or AWP that they apply across the industry to

both Medicare and commercial, what we have seen with the price inflation fueled by Part D has affected commercial plans. And likewise, fixing this will be important and helpful to commercial plans, I believe, so I think it's really an important task that we're taking for beyond Medicare. So I agree with moving ahead.

On the biosimilars and biologics, there's an enormous amount of confusion over terms across the industry. You can't find a -- there's no universal list of what specialty pharmacy or which biologics. There's insulin and there's vaccines, and there's huge confusion around that. I think MedPAC has been successful in introducing new concepts or clearer definitions for a number of things, Healthy Days at Home, the MedPAC regions. And I'd ask that as part of the biosimilar issue that we actually come up with -- see if we have a better way or a clear way of defining what that is and to use it.

In particular, there is a shorthand large molecular, small molecule. I think given the advances in protein synthesis and things like that, perhaps that's not the most useful definition. There is going to be -- there's other considerations there. So I think developing

-- seeing if we can develop something that's clear, maybe it's tied to regulatory, maybe it's tied to molecule size, maybe it's tied to something else.

Thank you.

DR. CROSSON: Okay. Thank you.

Kathy.

MS. BUTO: Let me just -- I think the work is terrific here and adds a lot to the -- at least suggests continued momentum in this area.

I started thinking about the biosimilars recommendation, and I agree with adding the coverage gap discount for biosimilars.

I began to think about whether that might cause a biosimilars manufacturer to raise prices for biosimilars that are aimed at the Medicare beneficiary population, and I guess that would depend on whether they are mostly delivered under Part D or Part B and how those two policies interact. So I think we just ought to keep that in mind. I don't think it's just a neutral policy, but -- particularly since many of these haven't even bene launched yet, we ought not to be aware that that could have impact. We already know the discount off of the original biologic

is going to be smaller than generic. So I think we just ought to be aware of that.

By the way, we don't apply a coverage gap discount to generics. Right? Is that correct? And is that because we think, at the moment, anyway, that those are a lot more affordable and that is not necessary? But I think we have seen, in some cases, generic prices have really jumped. So it is something we ought to keep on our radar screen as long as we are trying to be equitable here.

On the DIR allocation, I was listening carefully to Craig and Jack and others who have raised the issue of it's a good short-term approach until the 80/20 change is done through statute. I just don't know -- so our major benefit is the Federal Government gets more of the benefit of those DIR payments. I don't know if that's a lot of money. I assume it must be significant to go from 30 to 50 percent. Do we have an idea of what that --

MS. SUZUKI: So, in 2015, the total DIR was $25 billion, and the example we're showing, about $7.6 billion going to Medicare reinsurance. And under the policy, it would be not nearly double, but --

MS. BUTO: Go up to about 15 or so, yeah.

MS. SUZUKI: 12.6 billion.

DR. SCHMIDT: Remember that the capitated payments for Medicare would go up as well. So I think the net effect is more on kind of incentives to the plans for considering which drug to put on their formulary and that sort of thing.

MS. BUTO: Okay, okay. So it has two benefits.

Sort of my major issue in this set of recommendations is I'm not sure about DIR allocation and whether it's really going to have any impact on beneficiary premiums. We seem to think maybe a little bit.

What I'm struck by is that the beneficiary is really not particularly benefitting from these changes. There may be a slight increase in premiums. They don't get any benefit of DIR, and as I kind of mentioned -- and both Amy and Jack have elaborated on at greater length -- I think it would be good if we could think about if there is a beneficiary piece of this DIR that we can -- whether it's through some coinsurance relief or -- I don't know that we -- I don't know that I would support turning coinsurance back to copays, but is there some way to hold the beneficiary harmless to a price increase at least or

something like that?

So if you could think about that for the next go-round, so that it isn't all benefit to the Federal Government and -- really, it's the Federal Government in both cases, I think these recommendations would benefit.

The other thing is, of course, that the biosimilars recommendation would also create -- well, it wouldn't change at all the speed at which the beneficiary reaches the coverage gap, the threshold or the catastrophic threshold, as I understand, because now they are not getting a coverage gap for a discount for that, for biosimilars. So it is only brand-name drugs right now that there is a delayed access to catastrophic care.

What I am struggling with here is that these sound like the right direction to go, but if there's some consideration we could give to how the beneficiary might benefit from some of these changes, I think that would be a good thing.

DR. CROSSON: Brian.

DR. DeBUSK: Thank you for an excellent report.

I do support the proposed treatment of biosimilars, and I also appreciate the fact that in this

report and in other reports, we keep a mindful eye on their development and ensuring that they would get off the ground cleanly.

On the DIR, I do agree with Amy. I think it's sort of an unfortunate reality that we are going to have to deal with these direct and indirect rebates. I personally would be more interested in understanding the sources, how much of it is price protection, how much of it is an up-front rebate, and understanding -- because to me, it's almost like these DIRs are its own technology that evolve over time. They will develop a new type of DIR.

If we could at least keep an eye on and in a framework going forward to understand so that we can watch this technology evolve, again, so that we can see, to Kathy's point, is it affecting beneficiaries, because you are doing, say, a midway price increase that the plan is shielded from, but because due to coinsurance that the beneficiary isn't, I just understanding the DIR technology as it evolves, I think, would be very helpful to me. And you may have it. It may just not be in the report.

DR. SCHMIDT: Actually, no we don't.

DR. DeBUSK: Okay.

DR. SCHMIDT: Because it's considered so proprietary --

DR. DeBUSK: Okay.

DR. SCHMIDT: -- we don't have access to that.

DR. DeBUSK: I think being able to back into some of that -- I realize that's no small feat, but I think once we recognize the DIR is a -- again, I am going to keep using the word. It's a "technology" in and of itself. It's a price maneuvering technology, in my opinion. I would like to understand and follow that more.

The final thing, I'd like to agree. Susan and Rita made the point about poly-pharmacy. I do hope at some point, whether it's in this policy or in another -- I'd love to look at poly-pharmacy and then the other end of the bookend of medication adherence, because what would be great is to take fewer drugs, but take them the proper way. And I don't know if that's part of this work or if that's an entirely separate chapter, but it is nice to at least look at that in the context of how we are going to finance these drugs because it seems like they go hand in hand.

And, again, thank you.

DR. CROSSON: Okay. Let me see if I can

summarize here. I think I heard pretty much general support for applying the coverage gap discount to biosimilars, assuming, as Bruce said, we know what biosimilars are, but I think that's something we can handle.

With respect to changing the DIR allocation, I think we have mixed support and not a lot better than that, but I think there's a sense here that it's worthwhile continuing to look at that, particularly -- and this may be stuff that's easy or not so easy to do. If we can understand the context a little bit more about what we're really dealing with here, I think Brian's point, the dynamics of that, the interrelationship between making this change, a Craig brought up, and the 2016 recommendations, so maybe reprising those recommendations and the dynamics that we might anticipate would be helpful.

I think I also heard -- and I think this is not entirely tangential, but it is a little bit -- a thought about the position of the beneficiaries in this collection of changes, including this one, and whether or not there's some thought to thinking about a different allocation process, which would in some way include the beneficiaries

more directly than they currently are benefitted. I think that's a point that Kathy made.

And then the last piece, which I think is both important and not necessarily relevant to your thinking about what you might be doing in September or October, is this question about to what degree we can take and how we should do that in developing and consistently reiterating our holistic philosophy towards drug use and drug cost, and I heard a number of pieces of that from people.

Now, almost everything I've heard here has been something that we've done in part over the last number of years, at least that I've been here. But there may be some thought to not letting some of those pieces drop, and perhaps we can consider some way of bringing that all together and doing it in a more unified way, so that the important pieces of work that have been done before don't sort of get dropped and they're included in sort of an ongoing way of thinking about our position.

So those are just a couple of things, I think, to think about, but we'll be pleased to see what you come up with in September or October or some other time like that.

So thank you very much, Rachel and Shinobu, for

your usual clear, concise, and valuable work.

So we'll move on to the next presentation and discussion.

[Pause.]

DR. STENSLAND: Good morning. Today we're going to discuss consolidation in the health care industry. This is a follow-up on two earlier discussions you had in the fall.

As you may remember, in November Kate presented a paper on physician consolidation, and I presented a paper on other types of consolidation. Today we're going to combine those two papers into a possible June chapter.

We will start this presentation by showing how physicians and hospitals have been consolidating into larger organizations, and this consolidation we will show you can lead to higher Medicare and private insurer costs. Medicare costs increase when hospitals acquire physician practices due to Medicare paying facility fees. Private costs increase due to providers negotiating higher prices after consolidating into larger organizations. And then after we present data on the magnitude of the consolidations, we'll discuss two policy responses: a

site-neutral response, meaning leveling prices across settings; and we'll also discuss the importance of restraining Medicare prices rather than following commercial prices.

And then we'll really shift gears, and in the second half of this presentation, we'll discuss consolidation of provider functions with insurance risk, and this can happen in ACOs or in MA plans. ACOs allow providers to take on insurance risk. And in the case of MA plans, some MA plans own provider groups and in other cases MA plans are formed or purchased by provider groups.

We'll discuss findings in the literature on whether these provider/insurer consolidations improve cost or quality, and that will be a key discussion topic for today of whether we want to favor these integrated entities when setting payment policy.

So now we'll get into consolidation. Let's start by categorizing four types of integration or consolidation.

The first type of consolidation is horizontal hospital consolidation where hospitals join into systems.

The second is where physicians consolidate into larger groups.

The third is where hospitals purchase physician practices, and this is vertical consolidation.

The fourth is the merger of providers into an organization that accepts insurance risk. As I said, this can occur when provider groups take on insurance risk through ACOs. It can also happen when insurers purchase physician practices.

So let's start with the first of these, which is the horizontal hospital consolidation. As we discussed in your paper, hospitals have significant market power in many markets. In about a third of markets, a single system has more than 50 percent of all discharges. Many small metro areas only have one hospital system, and there is no expectation that the FTC will materially unwind consolidated hospital systems. Therefore, hospital market power is expected to be retained and possibly grow into the future. In other words, market power is now part of the health care environment that Medicare works in and is expected to work in in the future.

The literature cited in your mailing materials presents some strong evidence that market power leads to higher commercial hospital prices. There is much less

evidence that consolidation results in greater efficiencies or improved quality. In fact, some have argued that greater competition leads to greater quality.

In addition to looking at average hospital prices, we have looked at variation in hospital prices, and we have found that prices commercial insurers pay hospitals vary wildly from market to market and hospital to hospital. As we showed you in your mailing materials, a high-cost hospital may have a negotiated head CT rate that is five times the rate negotiated at a low-cost hospital for exactly the same service. This suggests that markets are not bringing prices down to a consistent level.

On average, we find hospitals' commercial prices are about 50 percent above cost and well above Medicare, with some of the highest rates obtained by hospitals with strong market power.

There has also been some horizontal consolidation of physician practices. For example, the share of physicians in practices with over 50 doctors increased from 16 percent in 2009 to 22 percent in 2014.

Practices are merging into larger groups that can jointly negotiate contracts. However, we find that

physical location of the practice often does not change when they join that bigger system of practices.

It is also interesting to note that about 20 percent of Medicare billings continue to be from solo practitioners. This suggests that the pace of physician consolidation has been slower than the pace of hospital consolidation.

In addition to horizontal integration, we have vertical integration where hospitals purchase physician practices.

After a hospital buys a practice, it often starts billing for the services as a hospital outpatient service. This means that the program and the beneficiary will receive two bills. Instead of just getting a physician bill, they get a physician bill and a second bill for the hospital facility fee. The result is Medicare program spending and beneficiary spending both go up.

For commercial insurers, we see less evidence that they are paying facility fees for E&M visits. However, two recent studies suggest that physician-hospital mergers lead to higher negotiated prices with commercial health plans.

One hope is that vertical integration could generate efficiencies. But the way the Medicare and commercial payment worlds are set up, there is an incentive to merge even when there are no efficiencies gained. In fact, even if some inefficiencies are created by converting physician practices to hospital outpatient departments, hospitals may still acquire practices in order to secure referrals and then partially fund the cost of those acquisitions with new Medicare facility fees and negotiating higher commercial prices for physician office visits.

So let's discuss an example of how Medicare facility fees affect program costs and beneficiary costs.

As I said, when a practice is bought by a hospital, that hospital often declares that physician office an outpatient department and starts to bill for facility fees for office visits and other services at the clinic. These fees increase Medicare costs.

For example, in 2015, Medicare paid an additional $1.5 billion for hospital-based evaluation and management services, and this reflects the hospital facility fees. Similarly, beneficiaries paid an additional $400 million in

cost sharing due to facility fees on office visits.

Now let's turn to the effect of horizontal and vertical consolidation on commercial prices for office visits.

This slide examines the association between horizontal consolidation of physician practices and the prices paid for E&M visits by three large private insurers. Market share in the first column refers to the group practice or health system's share of E&M visits in our data. The first three rows of this slide are for physician practices that are not owned by a hospital.

So let's start by looking at that first column of numbers you see -- first row you see for small independent practices. These are practices with less than 10 percent of the E&M claims in their market. These are the numbers in green. We see that for a small independent practice with a 10 percent share, they have an average price equal to 100 percent of the national Medicare price. In other words, if a physician practice does not have market power, commercial insurers will often pay them a rate close to Medicare rates. In contrast, as the market share increases, prices increase far above Medicare rates.

So if you go down to the third row in yellow, you'll see that practices with over 30 percent of claims have an average price equal to 141 percent of Medicare.

Now we're going to go down below to the next three rows. Now we're shifting from independent physician practices to hospital-owned practices. And you'll see when the hospital practice is owned, even for those with small market share, they tend to receive higher rates than the Medicare rates. And these findings of higher prices for larger practices and higher prices for practices that are hospital-owned are both consistent with the literature.

Now next we wanted to look within markets to see if the dominant practice within a metro area received higher prices than its competitors, and this is the column on the right. And if we look at the green number in that right-hand column, it shows that a small practice in a market tends to receive 93 percent of the average fee paid in that market as compared to the larger practices in that same market tend to receive 106 percent of the average price received by practices in that market for an E&M service. What this tells us is that there isn't a single commercial market price, even within a single city. Prices

will depend on market power.

In your mailing materials, we also provided some multivariate analyses. These other analyses are consistent with this descriptive story. Market power definitely has a statistically significant effect on the price.

Now, we just explained how Medicare has been able to restrain prices paid to physicians and hospitals to rates that are below commercial rates obtained by providers with market power. So a related question to ask is: How does this restraint of prices translate into lower costs for the Medicare program and beneficiaries relative to the costs of private insurance?

In this chart we look at growth in the cost of private insurance and fee-for-service Medicare over the past nine years. We find that the cost of employer-sponsored HMO and PPO insurance has risen by about 50 percent. Those are the orange and yellow lines on this slide.

In contrast, Medicare costs grew by about 23 percent. This is the green dotted line. Others have compared commercial and Medicare cost growth over a longer time frame with different data sets and have come up with

similar conclusions. Medicare costs have been growing slower than commercial costs since the late 1980s. In recent years, Medicare's cost advantage over commercial insurance has been getting larger as that price differential paid by the two is getting larger.

So we have seen the effect of horizontal and vertical integration on Medicare costs and on commercial insurer costs. How should Medicare policy respond?

MedPAC's first traditional response has been to not follow commercial prices upward. There was general support for that position in your discussions last fall. In fact, update recommendations in the past have been constrained in part to keep pressure on hospitals to constrain costs. However, in the long run, if private insurers do not limit price increases, the gap between Medicare and commercial prices will increase, and eventually this could create access concerns.

With respect to vertical consolidation, the Commission recommended site-neutral pricing for E&M visits as well as certain other services. Site neutral means a level playing field. Therefore, vertical integration that generate efficiencies should still happen with site-neutral

pricing, but integration that is driven purely to capture larger Medicare facility fees would not happen.

Now we shift gears to talk about the fourth type of consolidation, and this is the merger of providers with organizations taking on insurance risk.

There have been managed care plans in Medicare for 40 years, and for about 20 percent of MA plans, the managed care plan is aligned with or owns a physician practice. The single entity then has responsibility for insurance risk and for the provision of care.

As we discuss in your mailing materials, we see some providers acquiring insurers and some insurers acquiring providers. While some integrated systems have been longstanding successes, it is not clear that this model has a large enough advantage to always win in the marketplace. In some cases, providers have divested their insurance arms in recent years. In other cases, insurers have divested their physician practices.

Another option is the ACO. There is an increasing interest among providers in being rewarded for managing population health. Providers can take responsibility for the health of their patients, and in

models with two-sided risk, they also take full responsibility for the annual cost of care. That is the long-term expectation where ACOs are going.

Now we look to see how the integration of insurance risk and provision of care in MA plans and ACOs has affected patient outcomes and the costs.

The literature suggests that MA plans have had a mixed level of success relative to fee-for-service, and within that MA plan universe, provider-affiliated plans have a mixed level of success relative to other MA plans.

First, MA plans tend to do better than fee-for-service on process measures such as mammogram rates. But they are about equal to fee-for-service on patient satisfaction.

MA plans have also been shown to reduce service use below fee-for-service on average, but even with service use below fee-for-service, they tend to cost the taxpayer more due to administrative costs and the cost of supplemental benefits.

In 2017, Medicare pays MA plans about 4 percent more on a risk-adjusted basis than fee-for-service on average. The 4 percent reflects the MA bids, the cost of

extra benefits, and the coding differences between MA and fee-for-service.

Looking at different types of MA plans, it appears that integrated plans that are affiliated with their physicians have slightly better quality metrics on average, and we have seen this in two recent studies of higher quality in these integrated MA plans.

But one study found that they also charged higher premiums on average. A recent study suggests that while the number of integrated plans is growing, the market share held by integrated plans is shrinking. And it could be that even among integrated plans there are some that are better than others. And, eventually, the best integrated plans should rise to the top and gain market share.

With respect to ACOs, in general, there is evidence that ACOs have been improving their quality metrics; and from a cost standpoint they are about a breakeven point for the taxpayer.

I should say that ACOs and MA plans that I've talked about on average are about breakeven, but there are some markets where MA plans and ACOs do definitely save the taxpayer money, and these are often high-use markets. And

in these markets, you see MA plans bidding well below fee-for-service, and you also see ACOs generating some substantial savings. And I think Craig talked about our ACOs generating some reduction in the regional variation we see, and I think that is true, because when you look at the ACOs that are generating the biggest savings, they tend to be in the high-use markets, the predominant predictor of whether you're going to generate shared savings.

Now, in 2015 we examined regional variation in the relative costs of different models by looking at relative costs of MA plans, ACOs, and traditional fee-for-service, and we looked at 78 markets where all three of the models competed with each other. We found that traditional fee-for-service was the low-cost option in 28 of the markets, and ACOs were just a little bit lower cost in 31 of the markets. MA plans were the low-cost option in 19 of the markets, and MA plans tended to do the best in high-use markets such as Miami.

The point of this slide is to show that different delivery structures may have different levels of success in different markets.

Now we shift to the potential policy responses to

this type of consolidation.

With respect to insurer-provider consolidation, one approach is to level the playing field between fee-for-service and MA and let the models compete with each other. Fee-for-service can compete with integrated MA plans that have salaried physicians, and fee-for-service can compete with MA plans that contract with providers. Whichever model can convince beneficiaries that they have the most value, they will win market share. For example, if HMOs with employed providers are able to provide higher-quality care at a lower cost, they should win market share under a level playing field.

The second alternative is to favor one model. For example, in some markets CMS now favors MA plans by setting benchmarks above fee-for-service costs. We could also go a step further and favor specific types of MA plans. However, this has several risks.

First, we would need to accurately identify the characteristics that have led to success in the past, but that could lead to gaming. If we paid more for a specific corporate structure or organizational structure, MA plans may adopt that structure just to receive higher payments.

More importantly, it could also stifle innovation. Once payments are tied to a legal or organizational structure, it would act as a disincentive to innovate into more efficient models in the future.

In contrast, financial neutrality would create incentives for providers to continually innovate into the most efficient delivery model.

Now we'll shift to discussion. There are four types of organizations we have talked about today: traditional fee-for-service, ACOs within the fee-for-service model, MA plans that are integrated with providers, and MA plans that only contract with providers. And the question is: What should the Medicare program's policy or payment policy be with respect to these four types of organizations?

One option is financial neutrality. This means providers would only get higher rates if the patient has greater needs or the organization has better outcomes.

The other option is to favor one model over the other. This implies higher payments for certain legal or organizational structures.

I'll open it up for discussion.

DR. CHRISTIANSON: So, as usual, clarification questions for Jeff. David.

DR. NERENZ: Thanks. Very nice work as always. I appreciate it.

A clarification question. Can you put Slide 3 up, please, and this is also on 11 but 3 is good. The term "insurance risk," in these kind of discussions I'm comfortable with a distinction between insurance risk, on the one hand, and utilization risk on the other, and I'm looking at Bruce because there is a 2015 Society of Actuaries report that clearly makes that distinction.

In this context, I would argue, and I would have said before we started this, that ACOs, for example, are intentionally buffered from insurance risk, or protected to the point that they carry essentially none. It's the clinical risk adjustment feature that does that.

So in Round 1 I'm just clarifying, when you use the term "insurance risk," are you using it in that narrow, technical sense, or are you using it in a broader sense, essentially just meaning financial risk, in general?

DR. STENSLAND: I'm using it in the broader sense, because I don't think that we can really distinguish

between the insurance risk and the utilization risk, in terms of what they are able to accomplish.

DR. NERENZ: Okay. Well, in Round 2 I will assert we can --

DR. STENSLAND: Okay.

DR. NERENZ: -- but I just, for now, I just wanted --

DR. STENSLAND: Okay.

DR. NERENZ: -- no, I just wanted to know what the word means for now.

DR. STENSLAND: All right.

DR. CHRISTIANSON: Let's go up this --

DR. GINSBURG: Yeah, just sometimes I've heard the distinction between insurance risk and performance risk, performance risk meaning, you know, delivering more efficient services, and insurance risk, as David says, is presumably just differences in beneficiaries, perhaps you could say not accounted for by the risk adjustment system.

DR. CHRISTIANSON: Bill.

MR. GRADISON: There certainly were some who felt that ACOs were sort of a training ground for moving on to MA status. I have the impression if that is the case not

much has happened in that direction as yet, but I just wonder what is actually going on, if anything, in terms of that two-step possibility.

DR. STENSLAND: I don't have data but we certainly do see people that have ACOs that are interested in setting up MA plans and have gotten involved, and you see both things happening at the same time, expansion of MA enrollment and expansion of ACO enrollment.

DR. GINSBURG: Actually, if I could add, I've heard some anecdotes where just provider organizations really thinking through, is ACO or MA more attractive to me, and some of them going to MA.

DR. CHRISTIANSON: Warner, Craig, any -- Warner.

MR. THOMAS: How do you think about other types of consolidation kind of outside the provider world? So do you contemplate insurance consolidation, and, you know, that there is, you know, markets where the Blues have, you know, 60, 70, 80, 90 percent market share, the commercial market. I mean, have you thought about that? Do you think that plays a role here? You're just really focused, at this point, on the provider side of consolidation.

I think it also plays into GPOs and Pharma, and -

- I mean, just how do you think about consolidation overall in the industry, not just in the provider world?

DR. STENSLAND: The only thing we talk about in the paper is how some people have argued -- I think, the insurers might argue that when they have bigger market power they can offset the provider's market power, but I don't think we see any evidence in the literature that that is actually necessarily filtering down to lower premiums for the beneficiary.

In terms of the other things, I think the general concepts that we're talking about here of market power, of, say, being a sole hospital in a market is very similar to being a pharmaceutical company with the sole provider of a drug.

DR. CHRISTIANSON: And my recollection is that there's a paper by Glenn Melnick that addresses this topic and that, in fact, it does filter down to lower premiums.

MR. THOMAS: Yeah. I'm just wondering if you've looked specifically at states where you see a pretty dominant role of a payer, and if you have any data specific around that. I mean, there's -- I mean, look at the state of Alabama, for example. I think Blue Cross of Alabama has

about a 90 percent market share on the commercial.

DR. STENSLAND: We do. We just talked about that at one point. We do see lower prices in those markets where the provider has dominant shares. So you see lower commercial prices and then you also tend to see lower costs. So like Alabama you're going to see some of the best Medicare margins of any hospitals in the country, in part because Blue Cross has a dominant market share. They keep the commercial costs low because the commercial costs are low. They have to keep their costs low. Because their costs are low they have better Medicare margins.

MR. THOMAS: And just one last question. How do you think Medicare rates themselves play into kind of setting the rate structure in any given market? You know, I mean, obviously there's different -- taking utilization aside, just looking at the rate. Obviously there's a wide range of Medicare rates in the country, just based upon, you know, how the rates are configured. And how do you think that plays out, or doesn't play out in the commercial pricing as well?

DR. STENSLAND: So how do Medicare rates affect the commercial rates?

MR. THOMAS: Yeah, just on a -- you know, because what you're doing is a comparator. You're saying -- you're comparing everything to the Medicare rate, but my point is that the Medicare rate is significantly different in different geographic parts of the country, versus looking at it as a true dollar amount. You know, understanding that you have the wage index and there's different kinds of costs of living in different parts of the country, and I understand that's why the rate is configured that way. But also understanding that that probably plays into just how it drives the overall cost structure in all of those areas. Any thoughts around that?

DR. STENSLAND: Well, the Medicare rate doesn't vary nearly as much as the commercial rate. It's a much tighter band because it's really only based on the input cost differences. And the traditional provider argument is that if Medicare lowers their rates then we have to raise our rates, and that's why we raise our rates.

But I think the literature, in general, there's more -- especially recently, the literature sort of goes the other way around, that the commercial, and if anything, kind of follows Medicare, to a degree. So, for example, if

Medicare increases its rates for physician services, the commercial rates tend to go up, at least in the short run, because they may have -- we're paying X percent of Medicare in their contract.

DR. CROSSON: [Presiding.] Craig.

DR. SAMITT: So can we go all the way back to Slide 3? The thing that I'm struggling with is this slide, for me, is like which of these things is not like the other, and the fourth one, for me, is just a whole other different dimension than the first three. And you spent most of the deck talking about sort of what's happening with outcomes and pricing in horizontal and vertical consolidation, and I think that the general answer was it goes up.

But the fourth one, I didn't get that sense from you, and I just -- I wanted to understand why we put these two buckets together, because I started to get lost in the problem we're trying to solve. I guess the question in the fourth is have you seen that provider insurance consolidation is also driving up cost, or is the message more that we haven't seen the impact of the results that we would hope to see, because from my point of view that's a

whole other different issue than whether consolidation is driving up cost.

DR. STENSLAND: These are kind of like two batches, and I tried to say we're really shifting gears in the midpoint. And I think you're right. On the first three it's all pretty clear and the effects can be pretty big.

In the last part, I think that's not so much a choice of -- if you look at the general feeling out there in the market, it's going to be we're trying to lean against these first three types of consolidation because we really think it's going to increase costs. In the third one, the question is more, how much should we be leaning into this type of consolidation of the providers and the insurers. So it's very different and I think the whole questions are very different, and the outcomes that we talked about, I think, are very different.

When you talk about the magnitude of the effect on prices you can have through consolidation, it can be really big. When you look at the effect that ACOs and MA plans have had on Medicare costs, they're smaller difference, and even in the quality, which are generally

benefits of this consolidation, better quality for the MA plans, better quality for the ACOs, those, I think, are still also moderate in magnitude.

But I think that is more where we're thinking -- more of your discussion is going to be, because, to me, that's more of the difficult topic.

DR. SAMITT: So not to put words in your mouth but I think what we're asking, from a policy perspective is what policies can we put in place that dissuade the first three, and then which policies can we put in place that either encourage or further evaluate the fourth?

DR. GINSBURG: [Off microphone] -- yeah, at least to have -- allow things to happen in the fourth, because we don't have a strong opinion.

DR. DeBUSK: May I ask, on the first three, too, not dissuading seems almost overly ambitious. I would settle for us just not accidentally pouring fuel on the fire and forcing the consolidation, unintentionally.

DR. CROSSON: Okay. Brian. Is that your comment, Brian? Paul.

DR. GINSBURG: Two things. One is that it's really unfortunate that our field has labeled hospital

acquisition of physician practices as vertical consolidation, because it really isn't. And the thing I want to point out is that all of these transactions have very important elements of horizontal consolidation, that the -- you know, the acquired physician practice is going to be joined with physicians already employed by the hospital. It's going to affect -- you know, basically, a lot of physicians are competitors to the hospital. They may compete with hospital-employed physicians, or they might compete in their providing services in their offices, or ASCs, with the hospital outpatient departments. I think this is one of the reasons that hospital acquisition of physician practice is such a problematic phenomenon.

Oh, and the second point is that you had looked at commercial prices versus Medicare prices, and you did it for E&M services. I suspect if you did it for procedures you would get a different answer. It probably would be a larger difference. Kate?

MS. BLONIARZ: I just wanted to kind of pivot off that and answer something else Warner asked. One thing we do see with Medicare kind of influencing private rates is, you know, I don't know how much I would say that there's a

geographic effect, but the bigger one is the use of the Medicare RVUs for payment, you know, is very common throughout the private market, and in other work, you know, some other researchers have shown that, you know, the relative weights kind of persist in the private market but, you know, for a specific provider group or a specific type of service that's very consolidated, it may be multiples of those RVUs that kind of, you know, are the prices on the private side.

DR. GINSBURG: If I could add, I think it was initially after the Medicare fee schedule was implemented, the fact that commercial insurers used the Medicare relative value scale, of course, with their own conversion factor, to me was very gratifying. But recently -- but, you know, it diverges from that in two ways, that, you know, of course, as you've shown, that practices with a larger market share get higher rates, they tend to be single-specialty practices.

The other thing is in a discussion -- I haven't seen any data on this, but in a discussion I had with insurance executives recently, they did mention that sometimes, maybe all the time, they will actually negotiate

a lower rate as a percentage of Medicare for E&M services than they will for procedures. So this is something where the long-standing market forces are kind of pushing against the structure that Medicare has set up.

DR. CROSSON: Kathy.

MS. BUTO: So, you know, as I went through the paper and then as you did the presentation, Jeff, I found myself asking the question of what problem we were trying to solve, because I thought a lot of good issues or challenges were raised. The issue of provider consolidation, and you mentioned things like site-neutral policy and so on, to address that, the issue of the disparity between commercial and Medicare, and the possibility that access issues could arise in the future. But then when we get to the policy solutions, we are really talking more about the forms of Medicare payment to either fee-for-service or managed Medicare, or ACOs, which are kind of managed Medicare.

So I didn't connect the dots, really, among those, and so I wondered if you could, either one of you or both of you, tell us a little bit more about how that journey connects the dots between, or among, provider

consolidation, commercial versus Medicare, and then to the policy approaches that you are kind of asking us to look at.

DR. STENSLAND: Okay. So the easiest one probably goes back to Brian's comment of don't throw fuel on the fire, and this would be the site-neutral policy of if we tell an organization well, if you buy this physician practice, and now if they brought it on to the hospital campus, they would still get higher payments for those same visits that the doctors are doing now, and therefore we are, in essence, encouraging this, and as Brian would maybe say, putting fuel on the fire here.

MS. BUTO: But that's a policy solution that we've already addressed --

DR. STENSLAND: Right.

MS. BUTO: -- and it really doesn't -- it's not where you leave us at the end of the paper. You're sort of asking us, should a certain structure be favored over another? Should we use payment policy to do that? And I'm just trying to --

DR. STENSLAND: Yes.

MS. BUTO: -- understand how those connect.

DR. STENSLAND: So I think that's in the -- that's kind of on the first three types of organization, and then the other type is, okay, we see -- every year when we go through our margins or our rates we're tending to see this discrepancy growing between Medicare and fee-for-service, and there's the question of do we raise our rates or do we hold firm? And so far we've held firm, and we see that that has helped keep the overall cost of Medicare low. So that's kind of the other question, of what do we do in our fee-for-services rates?

Now there's also the question that something is going to have to happen with the growth rate of commercial prices, but that's kind of out of our bailiwick, so we don't have any sort of policy that we've stated there.

MS. BUTO: It seems to me there -- correct me if I'm wrong, but there we tend to look at it from an access perspective, and we evaluate that, right --

DR. STENSLAND: Right.

MS. BUTO: -- to see whether we're seeing any harm from that discrepancy.

What I'm just really trying to get at is are we -- is this short of premium support, trying to level the

playing field, or is it something else? Is it an interim step to look at ways --

DR. MILLER: Can I try this?

MS. BUTO: -- to improve -- yeah.

DR. MILLER: And maybe organizing the top three bullets with the fourth bullet turned out to be a mistake, which we'll just put that on Jeff.

[Laughter.]

DR. MILLER: But I think what Jeff -- and it's not, because I was very much, you know, involved in these discussions, so if this comes across as confused, I have the responsibility here.

What we were trying to say is that you could think of different forms of consolidation occurring in the market. Whatever the actual vocabulary ends up being on the risk or performance, I think, you know, that to the side. We're looking at consolidation, and we wanted to run through and kind of pull together, in one place, the evidence that's out there, because people still argue over those top three things, and whether their phenomenon have one effect or another. So we wanted to put that down, and we also wanted to put down -- and you're obviously picking

up on it -- where we've been in the past. And so you're correct in saying, "Why are you telling me about, you know, restraining rates or site-neutral, because I've already talked about that and I kind of know where we are?" And you're right. You're picking up on what's going on in the paper, no matter how much we accidentally confused you.

And then we come to -- what are you doing here, Jeff?

[Laughter.]

MS. BUTO: He's going to the end, because that's where I don't -- the disconnect occurs for me at the end, Slides 14 and 15.

DR. MILLER: So it's really kind of this -- you know, now, as a commission, we have this other phenomenon happening, where, you know, providers are taking risk, however we end up defining it, performance risk or otherwise, and as a commission, what policy posture do we want to begin to take there? It's not strictly a premium support thing. It's more whether we start to say we're going to tilt our payment to favor one kind of, you know, model or another, or whether we're going to try and maintain this. No, we're neutral. May the best man win,

type of phenomenon.

I think that is really what we want, from a policy perspective, to think about going forward. And we packaged it all together and perhaps confused people in the process of what we were trying to get them to focus on.

MS. BLONIARZ: Can I just answer your access point? I think one other thing, you know, yeah, the framework that the Commission generally uses on payment adequacy pivots off access on the physician side. That's what we measure most directly.

You know, you could see a situation where the Commission has to face, you know, relatively declining access for physician services because physicians make such -- you know, have so much higher revenue on the private side. And we will just have to face that, and I think we're trying to just kind of put that out there -- not that it's here, but you may want to think about it.

MS. BUTO: Right, and I think if you're going to do that, if we want us to look at that, then one of the payment policies we have to look at is the adequacy of the physician fee schedule. But that's not the way -- this is more like structures of care. Do you know what I mean?

So I'm just saying -- and we can get back to this in Round 2. I think more connectivity among these ideas would be a good thing.

DR. CROSSON: Okay. We're still on questions. Bruce.

MR. PYENSON: Actually, the confusing nature of this has led me to some other thoughts that I'd like to ask about, which is we're focused on payment rates, but there's a bunch of other policy kinds of issues that could be tied in with this that could be important for the markets and success, I think. And I'm wondering if you've explored some of those.

For example, if a hospital wants to participate in Medicare, its affiliated physicians must, or, you know, things that tend to force integration and remove some of the risk of nonparticipation is an example.

DR. STENSLAND: We have not gotten into that.

MR. THOMAS: Just as a follow-up, do you see that there's -- where physicians and hospitals are integrated, that physicians are not participating in Medicare? Because I think that probably is not a phenomenon.

MS. BLONIARZ: No, generally not. And there's

actually --

MR. THOMAS: Probably actually then being involved with a hospital keeps them in Medicare, frankly.

DR. COOMBS: That's right [off microphone].

MR. THOMAS: I think you'd see more physicians dropping out of Medicare if they were not involved with hospitals.

DR. HOADLEY: So in the paper, you had some findings on the facility fees and, you know, the notion that they were not so much paid in the commercial sector and, when they were, they were small. I just wanted to hear slightly more about that and, you know, the implication being that this is, I guess, reinforcement for the direction we've been going on the site-neutral policies.

DR. STENSLAND: Yes, so what we found -- and the same thing was found by Cory Capps in one his studies that looked at a different data set --was that it looks like while the commercial insurers generally are paying some multiple of Medicare and it looks like they are following the RVU schedule, so, you know, if your Level 4 visit is whatever multiple of a Level 2 visit, but when it comes to

are they going to follow Medicare and also then pay the hospital a facility fee for the E&M visit, they seem to not follow Medicare for that part of the game, and they say, "No, we're not going to do that."

And, anecdotally, over the past seven, eight years, we've heard hospitals -- or, I mean, insurers saying, "We are going to stop doing that." So in some places they used to do it, and then they said, "Okay, now we're not going to do it anymore." And I think, you know, part of it may have been some of the discussions we've had here and also certainly some of the stuff in the press where patients always did not appreciate getting two bills.

DR. HOADLEY: It seems like an important finding that is worth not getting lost in the midst of our sort of shifting over to these other topics. I wanted to make sure we highlighted that.

MS. THOMPSON: Just one quick question. Jeff, do we have any information in terms of from a standpoint of measuring effectiveness and care coordination, maybe specifically readmissions rates, in organizations where hospitals and physicians are integrated versus low integration rates?

DR. STENSLAND: We don't have anything that's really up-to-date. The one thing we did is at one point we showed a description of the integrated organizations and the nonintegrated organizations on hospitals and what was their 30-day episode cost, and you didn't see a whole lot of correlation there.

MS. THOMPSON: How old is that data?

DR. STENSLAND: Maybe three years or so.

DR. CROSSON: Yes, Alice, go ahead.

DR. COOMBS: Sue, so there's actually -- I just wanted to respond to your question. In Health Affairs in 2014, there's a comparative study that looks at small groups, onesie, twosie practitioners, compared to groups of nine to ten, by Castellino, and what they looked at was readmission rate, and the readmissions rate was 33 percent less with the small groups.

MS. THOMPSON: And that was '14?

DR. COOMBS: 2014, in Health Affairs.

DR. CROSSON: Okay. Thank you for the questions.

I'm going to -- have we got Slide 15? I'm going to turn to you in a second, David. First I'm going to tell you what to say. No, just kidding.

[Laughter.]

DR. CROSSON: I think people have said, okay, but we have a set of problems that have been posed. We've got a bunch of solutions, you know, previous recommendations that address some parts of that. But I think what's being asked here is a little bit more global question that's on the bottom of this slide, which is, you know, how should we be thinking about organizing our thoughts around payment policy? You know, we want to be completely neutral -- talking Medicare payment policy, we want to be completely neutral. We would like to develop ideas over time to change Medicare payment policy such that it favors certain legal or organizational structures. And then I would add, if this is acceptable, I would add a third bullet point to that. Do we want to favor changes in Medicare payment policies that are likely to lead to higher quality and lower cost and then we'd have the incidental effect of changing organizational structures? Because I think that's a third alternative, which is consonant with some of our other recommendations over time.

DR. NERENZ: All right. Thanks, Jay. I'll try to be quick and not to repetitive of things other people

have said.

Jay, just the way you led into this, I'll make my last point first. I would myself be a strong no on this last point here. I would not favor paying differentially on the basis of model. I don't see a conceptual argument for it. I don't see a data argument for it. It seems to run against some other things we said. I would just say no. But we'll see.

Just a few other points. This was an interesting chapter to me because of its complexity. Often we have issues in front of us, and I think this kind of plays off Kathy's comment. We say, "Here's a good thing. How do we get more of it?" Or we say, "Here's a bad thing. How do we get less of it?"

Now, here we've got a mix, and the goods and bads almost inevitably run together. But when we use terms like "integration," that has a good connotation. We tend to like that. Clinical integration is good, integrated care is good. Okay, that's all good.

Consolidation, at least this morning, is bad. You know, it drives up costs, it does bad things. But it's really hard to separate that. But I think that's an

interesting challenge to take up. Is there any way in the context of Medicare payment policy that you can actually get more good and get less bad? Given how tightly bound they are, I think that's tough.

Warner, Craig, Paul, and others pointed out how Medicare policy doesn't live in isolation here. A lot of these factors are driven by forces in the commercial insurance world, and those might be bigger and more powerful. I hear providers talking about getting together as a counter -- essentially a defensive posture against insurance consolidation. So a lot of these things may happen regardless of what we do.

And, as usual, I'm picky on the semantics. I already have been once today. In the chapter, not so much on the slides, you talked about pay for outcome as maybe one of the directions. Again, I'm not sure that's quite literally what you mean. I'm one of the folks that grew up in the Donabedian era, and "outcome" has a precise meaning. And as I saw it used in the chapter, I think that's -- again, you're using it in a broader sense. I was reading pay for value, pay for quality, not literally pay for outcome. But, actually, I think it would be fun to take up

literally that, but maybe this isn't the chapter to do it in. So, again, I just want to make that observation. I'm always a splitter and a literalist on words, and it doesn't always fit. But we ought to clarify that.

In the chapter, there are three policy options. They're framed a little differently than what we have on the slides, and without referring back and repeating them. I just thought we ought to add a fourth. I like them all. I thought they were all good.

The fourth one I would add was reduce administrative burden on small practices. We've talked about that in the context of MIPS. I think we could turn to meaningful use in EHR as another example. You know, those territories also have some mix of up-down benefit, but often I look at these and I say, "Well, there's the end of private practice" or "There's the end of small private practice." They can't do these things.

So it seems to me every time we have a discussion on one of these other points, we should be thinking about if it appears to us that this is something that big organizations can do more easily than small, are we then now unintentionally giving fuel to the fire, I think was

added.

Back to the insurance risk, I really think those can be separated. I really think that the separation is quite clear, actually in the ACO program, that the risk adjustment, particularly the way it's applied in a current-year basis, really protects ACOs almost entirely from insurance risk. What's left is performance risk or utilization risk.

Now, in my own taste, I think that's good and I think it's okay, which then is sort of my closing point. I think that there's a valid and good distinction between insurance entities and provider entities, and the kind of risk that insurance entities take on, and then a different kind of risk that provider entities should take on.

You know, insurance entities are governed by license and their governed by state insurance regulations, and they have the feature of financial reserve requirements. Okay. ACOs typically do not have that. Medical group practices do not have that. Hospitals may accidentally have it, but they're not in that same business.

And, you know, a couple times in the chapter

we've talked about sort of in a desirable sense taking on full capitation risk. I think that's a bad, bad idea. I think we learned 20 years ago that's a bad idea. So I just don't like -- I don't like the idea of provider groups taking on insurance risk in general, but certainly not full cap risk.

DR. STENSLAND: If you could explain a little bit more, you said these things are clearly distinguishable?

DR. NERENZ: Yes [off microphone].

DR. STENSLAND: In my mind, if you have an ACO and it's taking two-sided risk and you see that your utilization went down by 5 percent or up by 5 percent, how do we know that that utilization going down by 5 or up by 5 was due to good behavior on your part or -- you know, it went down by 5 because you had stellar management or it went down by 5 because you got lucky and your people just didn't get sick that year?

DR. NERENZ: It's the risk adjustment, particularly the way in the MSSP it's applied in the concurrent year. Now, others can correct me if I'm wrong, but I think the way it works is if you get a bunch of people either the incoming new people are healthy or the

people continuing -- well, it's easier to describe the other way. You know, if there's an outbreak of infectious disease or something, that is accounted for in the risk adjustment, and the financial target is adjusted on that basis. I think that really takes away the insurance risk. If your people are healthier, you have got a lower expenditure target because of that. If they're sicker, you've got a higher expenditure target. And then your risk is based on that adjusted target.

Am I misperceiving MSSP?

DR. GINSBURG: Yeah, I think there are a couple of things you're missing. First of all, you're assuming the risk adjustment mechanism is perfect.

DR. NERENZ: I wouldn't say -- well, I probably got close to saying there's no risk, but I think it's really small.

DR. GINSBURG: Yeah, but the other point I want to make is that there's a lot of other risk that's not classic insurance risk, which is just from pooling people. That's classic insurance risk. There are other risks that insurers take on, like the appearance of Sovaldi in the delivery system. You know, that meant a lot of insurers

paid out more in claims than they were projecting for that year.

MS. BUTO: New technology.

DR. GINSBURG: So a new technology. Having a bad flu season is another risk. So in a sense, it's a third category of --

DR. NERENZ: But just as a point, because this is a factual question. If there's a bad flu season, is that not adjusted for in the clinical risk adjustment in MSSP?

DR. GINSBURG: No.

DR. NERENZ: Then why -- well, okay. We may get off -- I'm sorry if I'm wrong, but I --

DR. MILLER: I think your point, David -- and you were getting close to saying it -- it's all taken care of.

I think what he was saying -- and you're sitting right here, so you can check it -- is because the benchmarks in, say, the MSSP world built off of history, that was -- you were saying in a sense you've captured the inherent risk in that population. I think that was your point, because it's not like an MSSP. There's a risk adjuster that gets applied to that. I took your comments as saying but it's the -- you know, you're building it off

of the history of my population; therefore, the risk is in there.

DR. NERENZ: Well, I clearly -- apparently I'm wrong on this, but I'll just say it and then you make sure that I know I'm wrong. When MSSP first came out, it seemed like one of its design features was that if a -- because of the retrospective view of it, you do not control enrollment, it's not -- but you had to protect the entities from an influx of sick people, and that in order to do that, the risk adjustment was not applied just based on history, but it was applied on the diagnostic mix in that year.

Now, if that's wrong, it's wrong. But that's what I thought was going on.

DR. GINSBURG: It is, but given the fact that there is churn in the attributed beneficiaries, you know, the ones that you had historically are going to be different from the ones that you retrospectively turned out to have in your ACO year means that you still are dependent on the risk adjustment mechanism to get that right.

DR. NERENZ: And all risk adjustment is imperfect. We certainly don't disagree. But I -- well,

okay.

DR. CROSSON: Okay. You know, I think, again, what we're trying to do here is we're looking for some direction, if I understand it properly, which is as a consequence of changes in the market, particularly those first three bullet points, how does that change our payment policy going forward at kind of a high level, not, you know, a specific one? We have a lot of specific ones we've gone, and they're listed. They're right as far as I'm concerned. But going forward, how should we be thinking about this? Should we be saying, you know, well, we're just going to continue, as the bullet point says, we're going to be, you know, neutral to this impact, we're going be just paying based on our perception of patient needs and outcomes.

On the other hand, we're going to potentially favor one model or the other or disfavor one structural model in terms of how we think about payment going forward. And then I said -- I'll say it again -- another option here, I think, is to say do we want to favor Medicare payment models going forward for the purpose of driving lower costs and higher quality, and so examples that have

been brought up already are going back and looking at the physician fee schedule? Is this the right way of paying in today's world, particularly, for example, with the evolution of single specialty groups, as Paul pointed out, which is driving a lot of the cost, or do we want to consider moving provider payment more towards some sort of global payment which takes into consideration both cost and quality factors? And how do people feel about the -- and, David, you've already said that the notion of paying for certain structures is not -- I would agree with you on that. I don't see any justification for that, but others might feel differently.

So unless I'm off base here -- and, Jeff and Kate, tell me if this is going to be helpful to you or not -- could we focus on that sort of question? And I realize it's difficult because we're kind of dealing in a conceptual level, and sometimes it's easy to deal on, you know, a very specific policy level. But let's try that, and if it doesn't work, we'll do something else. Let's start with Brian.

DR. DeBUSK: I do also agree that we should not pay for any particular corporate structure. But to answer

Jay's question directly, you know, what should we pay for? There's already about a 4 percent bias in MA, and ideally, someday we would work that bias out of the system. But, you know, I don't see that as a front-and-center priority.

The question would be: Would you want to put a similar bias into ACOs? I mean, is there a way that you could give, say, participants some latitude in deriving their benchmark, maybe partially from my history, partially from a national benchmark, partially from a region? And I realize that's all changing already. I mean, I think all those rules have been written.

My question is: If you were to come up with a method where they had a little bit of flexibility in choosing those component parts -- not absolute choice, obviously, you know, because then you could get tremendous adjustments. But if you gave them a little bit of latitude where you could say, well, I want 25 percent from the national benchmark, I want 50 percent from my own history. If you gave them a little bit of latitude, and let's say it did result in a 4 percent bias similar to what MA has, I don't think that's necessarily a bad outcome.

Putting your thumb on the scale a little bit --

and, again, I'm not advocating for someone saying, "I want to be 100 percent of my history because I'm a spending disaster," because I think then you're going to get a much bigger than 4 percent result. But I think if you bracket the components of how that benchmark is derived, I think you'd give them the opportunity to get that 4 percent bias, because I would like to see ACOs get a push start.

DR. MILLER: This is precisely the conversation that we want to have. Okay? As confusing as all this was, this is why we wanted to set up this second -- or this bottom conversation, because comments like that, in some cases, of our sessions have been "No, no. We should be neutral." We should be neutral, that type of thing, and then comments are, "No. We should put our thumb on the scale."

So the thing I would like either you or other people to talk about over time is if you do that -- and I am taking your comment, Brian, and you tell me if this is wrong. You're sort of saying, "I know this might not be the efficient place to be for now, but I'm going to put my thumb on the scale." When does the thumb come off, and how? And how does someone -- and since you're asking,

posing it, you know, you -- how does somebody say, "Well, I'm not going to let a financial disaster set their own benchmark, but I am going to let somebody else do that," that, I think, is the exact question that we're struggling with and we hear sometimes in this group and sometimes not.

DR. DeBUSK: And I think this is where we -- and by "we," I mean the royal "we." I mean you guys. Thanks. Thanks in advance. -- could actually model some brackets for us.

When we looked at those, I see a performance result several cycles ago. It was obvious there was a lot of selection bias in there. I mean, this was the group of the willing.

What would be nice is to have some general brackets where you could say, "Well, you know, don't let anyone do more than 40 percent of their history, but maybe let them choose 25 to 40." I know this is a big ask. Like I said, I don't mean to make minimal of that request earlier. But if you could help us just with a framework of, say, what are those three brackets -- regional, national, and historical -- maybe that's a good place to start just to see how broad those brackets could be,

because I think the broader they are, the more appeal they have, but the more financial exposure you have to selection risk as well.

DR. STENSLAND: I want to say I think this kind of gets exactly to the points we were trying to get at, and even in this example of the ACOs, I think it still does, in a way, fall into the legal or organizational structure because you could say, "What is my expected payment for Medicare if I do nothing other than have my lawyer put together an ACO and we just continue on as we have and we'll have some random variation in what's going to happen? Do I have an expected positive return on investment for my legal fees, even if I don't change my behavior at all?" That's the kind of question.

DR. CROSSON: Okay. Paul.

DR. GINSBURG: In response to your question, Jay, about moving into models that get away from fragmented fee-for-service, I think that's very separate from the issues that this presentation brought forward about the fact of consolidation and this issue about the increase in gap between what Medicare is paying and what commercial payers are paying.

I think that Medicare has or should have a strong interest in addressing some of these issues that have ramifications in the commercial market because it will ultimately risk putting pressure on its spending. So some of them are Medicare policies, like site-neutral payments. Some of them are not, which gets into Medicare or CMS advocating to the antitrust agencies and even the states to be more vigilant about these threats from consolidation.

I have some other comments. I don't know if we should give them now.

DR. CROSSON: Go ahead.

DR. GINSBURG: One thought on the financial neutrality, I think we've really seen in MA how Congress put their thumb on the scale in favor of MA. It generated substantial growth, but then, of course, it's been very, very difficult to take that back. I guess that growth has continued after some of it was taken back, but it shows.

And I think a really good comment from Jeff about it's so much more dangerous with ACOs because it's easier to stay qualified to be that kind of an organization.

The notion of higher quality receiving higher payments, this is something that the Medicare Stars

experience has made me very cautious about because I believe that Medicare is overpaying for quality based on star bonuses, and I think it's great that we have the stars. The beneficiaries in some cases pay attention to them, but in a sense, market share should be the reward for higher quality. And maybe there's some argument for higher payment, but the problem is that it's easy to become overly generous just because quality -- everyone agrees that quality is good, and why should we limit how much we pay more for higher quality?

I also agree that we shouldn't pay more for some structures or processes, but I do see as far as provider and insurer consolidation, my perspective at this point is neutral because we just don't know enough and suspect that the difference is the gains or losses from that might be subtle, and that we're nowhere near ready to actually encourage or discourage that.

DR. MILLER: And if I could just say one thing -- and I know Paul knows this -- the other part of the story on MA was would you put the thumb on the scale. I think that's what we're saying, and then it did grow the enrollment. And then the Congress had to come in and take

it back and still, in some ways, are working on that.

The other thing that was happening in the midst of all that is that we were creating really inefficient managed care markets. The fastest-growing product at that, you know, when finally action started to be taken was a private fee-for-service plan, which didn't manage anything, paid fee-for-service rates and took a 10 percent fee. And so that's what I think is the concern is, is if you set up a payment system and somebody legally sets up something that says, "Oh, yeah. It fits this structure, but it isn't doing at all what you think it might be doing" -- sorry, Paul. I know you know that we've had this.

DR. CROSSON: Right. And I just would make one other point, Paul. In the decision that was made around Medicare Stars to make it non-budget-neutral feeds into what you're saying. In other words, if it had been budget-neutral, first of all, I think the amount of payment -- industry would have pushed for a lower differential amount of payment, and secondly, it wouldn't have added to cost.

DR. GINSBURG: I agree with that.

DR. CROSSON: Kathy.

MS. BUTO: So let me start off by saying I hope

we never get in a situation where we're paying -- using payment policy to try to incent the development of some structure because I'm convinced we'll get it wrong. We don't know enough, and the structures are going to evolve, so why would we ever do that? I was appalled, actually, to think about using payment policy in that way.

I just want to go back to a couple things, one that Kate mentioned about the fee schedule, and in the report itself, as Dave said, on page 32, one of the principles we talk about is restraining Medicare prices rather than following commercial, which I think we would all agree with. But I think she raised another point, which we need to pick up, which is we need to worry about the adequacy or the availability of services and the adequacy of payment to assure access. So I would just make sure we covered that.

In terms of -- I'm still struggling with what is it we're trying to actually do here. In terms of ACOs, in my mind, anyway, MACRA at least attempts to put their thumb on the scale, if you will, by providing that 5 percent bonus for alternative payment models, so I wouldn't add another 4 percent to that. I don't think we even know if

that's going to work, and maybe that's how much you meant, Brian.

DR. DeBUSK: I would include MACRA as one of those pouring-fuel-on-the-fire sources.

MS. BUTO: Well, okay. So let's redesign MACRA, but I don't think we then add another set of layered incentives on top of that.

I'm just weary about using payment policy as the grand hand of government to try to tip the scales one way or the other. I think you got it right, Jay, that whatever we need to do to assure access, quality, good outcomes, that's what we ought to be focusing on, and the paper does touch on a lot of the things like site-neutral, where the Commission has really taken some leadership in that regard. And we ought to keep our eye on that ball.

Beyond that, I don't know what I'd do with MA payment policy or fee-for-service payment policy. I think we're doing a lot of it already. I don't know what else we are being asked to look at here beyond that, other than the structure issue, and I just think let's not do that. I would definitely be really opposed to the Federal Government getting into deciding through payment policy

what structures we want to incent.

If we don't like ACOs and the way that they're loosely configured, then let's focus on that and making comments on a better structure. That's more beneficial, rather than using payment to drive a certain result.

DR. CROSSON: Okay. Bruce and then Bill.

MR. PYENSON: I want to compliment Jeff and Kate on not using the term "cost shifting" anyplace in the report. I assume that that means that the issue has been solved forever, and that's really great news.

But I are with Paul on his comment on that it is of -- it should be of concern or investigation, the question what is going on, on the commercial side. That is critically important for Medicare potentially, but I don't know enough about it. For example, the comment that Warner made, the integration with hospitals and physicians is a way to, in effect, protect participation, I think those are things that we need to understand, because the chart on Slide 9 appears alarming. But I think we need to understand more what sort of breaking points. Let's get a picture ahead on what could happen and what, if anything, are the drivers of changing that.

I recall in the distant past, Medicare did tie in Medicare Advantage with commercial. I think on a policy basis, a long, long time ago, there was a requirement that you had to have a certain amount of commercial business before you could get into Medicare, the Medicare Advantage. So I raise that as a suggestion that maybe Medicare does have authority or policy to influence in some ways what commercial carriers do, and that might be a useful avenue that's not quite payment method but more policy performance based.

And I think, likewise, ACOs, the payment policy is not necessarily the most important issue with ACOs or ACO success. I don't think the financial reporting that we've gotten from ACOs really paints the picture of whether they're successful or not. For example, an ACO that shifts the leakage of its population from 50 percent to 20 percent may not actually show a financial gain, and it may not show savings for Medicare but could be a phenomenal success for the organization itself. And we'd never know, based on the kind of issues we have. So there's other ways, if we think ACOs are a good thing, other kinds of policies that we could think about that would, if you will, put the thumb on

the scale.

But I do agree really with what Kathy said. I would change the term from "organizational structure" to "bureaucratic structure," but I don't think we should alter payment based on those.

DR. CROSSON: Okay. I'm going to point out that we're 20 minutes over, so I'm going to plead for conciseness at this point.

Bill.

DR. HALL: I will try to be concise.

We are looking at a very good report concisely put together by Jeff and Kate that describes the apparent intended and unintended results of a lot of changes that we've instituted under the rubric of provider consolidation.

When I look at this, I say why are we doing that. Well, I guess it's because we think it's -- these aren't the results that we really wanted to see from all of this, and it's a little bit like the organizations, that all organizations are perfectly designed to get the results that they're getting.

And let's take that just for a second. One would

say from that we'd have to challenge why we're doing what we are doing. So I look at this, and I am going to quickly come down to the only world that I know reasonably well, and that's the clinical world that I live in.

In my community, virtually examples of this are everywhere, but the advantage I have is I kind of know the people. I know some of their faults and my own faults, and it flavors what I'm doing. So if I look at the consolidation I see in my own community, there's not one cause for that. In fact, the causes are diverse and sometimes going in opposite directions, but they're all getting the results they want to have.

Let me just give you a couple of examples. I think we have people who are sincerely interested and motivated along the lines of quality, and they're breathtaking in what we can do, and I think we can take that to -- in any part of the country. I don't know how they do it, but they are getting the results that they intend to.

I see a lot of changes in consolidation that are based on enlightened self-interest. Sometimes this is purely market share. Sometimes it has to do with

competition between groups, and I see this particularly in the ACO world or between individuals who are very powerful in the organization. But they are getting the results that they want. This is what they want to do in terms of using the mechanisms under the rubric of provider consolidation.

Everybody wants more revenue. Why are good ambulatory groups -- why are they anxious to get affiliated with hospitals? Well, so they can gain the hospital share in terms of enhancing their revenue. That's good for them, and they're getting the results that they want.

Academic health centers have a great desire to protect status quo Medicare for a couple of reasons. The obvious one is that they benefit from the system now that in a somewhat irrational way pays for medical education, both directly and indirectly. Why would they want to change that system to get results that would make it harder to take care of their academic mission?

So I think that we have to understand that part of it and then ask ourselves: Are there other things that we could do that would get through this, people getting the results that they deserve? And as has been mentioned by several people here, I think quality is really where the

action is. Unless we can motivate people for higher quality, we might just be kind of moving the deck chairs on the Titanic.

So I would make a real plea, and I will have nothing to do with this after the next hour is over.

[Laughter.]

DR. HALL: I think we always have to ask ourselves. We are getting the results that we have asked people, in many ways, to do, and it isn't kind of working out because a lot of these things can't be done all in one. I think everything we do ought to have a great emphasis on quality and let a lot of other things flow from that. Otherwise, I don't know what we're doing.

Thanks.

DR. CROSSON: Thank you. Alice.

DR. COOMBS: So I wanted to talk a little bit about Slide 3 and the consolidation. So we are faced with some prevailing issues from this chapter, and thank you very much. It was excellent. One is the consolidation being problematic in the sense that we know that the E&M coding and the facilities fee drives up cost, and then the other part is the disparity between the payment and

reimbursement on the commercial side versus Medicare, and what impact that has overall on Medicare long-term sustainability, in terms of competitive forces.

So this dwindling population of primary care doctors, I'm wondering, even with the recommendations, if we could actually hone in on the -- I guess it would be a physician in transition or a physician forum for us right before they become consolidated, because of the reasons why people are joining groups and what have you. If we could actually focus on, maybe in our interview for the fall, looking at physicians, reasons why they're consolidating, and to see what Medicare could best do to address some of their needs.

For instance, the majority of medical students graduating are not looking for a solo practice. They're looking for the minimal barriers to practicing medicine, and that, in and of itself, leads them to an employment type of profession, and right away they are centered in a medical center, which actually would change the paradigm going forward.

I don't think there's a lot we can do about those horizontal-horizontal kind of consolidation. I think the

last one, in terms of insurers and providers and provider-insurer relationship might be something that we could focus on and hone in on that piece, because the other -- the train has left the station on the other ones and there's not much we can do. And to be honest with you, if I was a solo practitioner, I would be tempted to get on with the bells and whistles and have everything laid out for me. That's just your harsh reality, and I think that we should focus on the ones that are in transition or thinking about -- small groups that are thinking about becoming consolidated.

DR. CROSSON: Jack.

DR. HOADLEY: So I will be brief but I wanted to reinforce two points that some other folks have been making. You know, one really started from Kate's comment about, you know, what we may look at down the road if consolidation means that commercial plans are raising physician payment rates, and we see an effect on Medicare access. I really want to see that we are prepared for that with what could our policy responses be beyond simply saying raise Medicare rates because it's the only thing we can do to not lose physicians to practice only on the

commercial side.

So we have a chance now to think about that and think about whether there are other things, and I don't have the answer, but I wanted us to really work on that.

And the other one is this sort of thumb-on-the-scale argument, and I think that the Medicare Advantage history, and a couple of folks have said this, is very sobering. You know, we started in the '70s with the notion that Medicare Advantage, or whatever it was called then, should come in at 95 percent of AAPCC, and you know, they would only come in the system if they could save money. And then, by the '90s, we were saying, well, let's figure out ways to pay more, to make sure they come into those areas that don't have them.

And we've been sort of dealing with the consequence of that for the last 20 years, and it feels like some of the options out there, that have come up, could get us back into that same game -- we'll pay more but then we'll be stuck with that, and it will be simply the private fee-for-service, I think is a perfect example of this -- we'll be struck with responses that aren't what we had in mind, just basically robbing the federal treasury.

DR. CROSSON: Okay. Coming down this way. I see Pat.

MS. WANG: I am very worried about the growing disparity between Medicare payments and commercial payments, and I think it's already happening that many organizations view Medicare as like the charity care payer -- I'm not kidding -- and I think it's dangerous. I don't know what to do about it. I think it impedes the negotiation or the setting of value-based payments in a managed care situation because those organizations with leverage will want 100, double-digit, X percent of the published Medicare rate, which, you know, means that if you're an MA plan that is capitated based on a percentage of the benchmark, that means you have to pay somebody else quite a bit less, it just -- that is not a fertile ground for anything that is value-based.

So I don't know what to do about the growing disparity, but I do think that one of the values that Commission has expressed is to try to put more pedal to the medal on the shift from volume to value. So I would -- you know, to that point, I think, you know, we should look at payment policy, not paying for structure. I agree with

that. That is intentional, and to be intentional to achieve that goal. And I had started a conversation with Jay and Mark that I can't actually complete right now.

But on the flip side of what Bill mentioned, part of intentional payment policy is to look for payment policy that actually creates disincentives for people to move to value suggests the way that special payments, GME, on compensated care, are tied to inpatient statistics, I mean, they require organizations that could have the capability to innovate tremendously to reduce admission and readmission rates, who have entire finance departments who are saying "I have to maintain my inpatient statistics in order to get my full share of IME, GME, and compensated care." So I'm not talking about the derivation of the amounts that people get, but I think that that is one area, perhaps, that we could look at along the theme of intentional payment policy includes changing the way that some payments get to organizations to remove the shackles from really moving forward off to value.

DR. CROSSON: Sue.

MS. THOMPSON: I will be brief, but I'm going to circle back to Brian's comments, in support of putting

thumb-on-the-scale for the ACO, because I think while we continue to hear we just haven't seen the results that we've hoped for, these ACOs are in their infancy, and the organizations that have taken on that work have invested, and continued to invest in the capability that is required to improve the status of the health of the population.

And I think this is a wonderful chapter to end this discussion, because we've talked about the need to not only improve status of this Medicare population but also look at the opportunities to build on the accountability within the accountable care organization, if we take on utilization of drugs, utilization of devices, and the whole low-value/no-value care, where I think there actually was a reference to ACOs have reduced the use of low-value care.

So I think it's a wonderful chapter and it's a wonderful concept to support the work of accountable providers in accountable structures, where you do have physicians, hospitals, and pieces of the full-care continuum on the same -- invest in -- huge investments in electronic health records. Let's not throw the baby out with the bath water here.

So I'm quite supportive of putting the thumb on

the scale here.

DR. CROSSON: Craig.

DR. SAMITT: I am as well. I am worried that our policy recommendations, especially the financial neutrality policy, will have unintended consequences. I think what we're trying to accomplish here is we're trying to drive delivery system reform and provider accountability, and I'm worried that our -- good, you know, to the point of good -- and that our policies aren't driving that. They're driving provider consolidation, with no better accountability -- bad.

And so my question is, what policies do we want to put in place that drive to value and drive accountability and not have the unintended consequences of driving to consolidation? And so I agree with maintaining the thumb on the scale, especially for MA, and while I know that we want to have competition between MA, ACO, and fee-for-service, I'm not so sure I agree with the notion of financial neutrality.

So what we're saying, essentially, to MA organizations is, you're going to attract a sicker population, you're going to take on risk in a substantive

way, you're going to deliver higher-quality results, and you're going to get the same as fee-for-service.

And so the perspective that I have is we keep reattaching MA to the fee-for-service chassis, when I think what we want to try to encourage is more -- now, granted, we can't paint all MA with a single brush, but we want to encourage the more innovative, true value-based MA organizations. And so I worry about the organizations like Care More and Health Care Partners and ChenMed, those that are actually out there, truly driving change, and that if we create these financial neutrality vehicles and policies that dissuade MA, and strengthen fee-for-service, that we're going backwards.

MS. BUTO: Jay, I think we need a longer discussion, not today, about what thumb on the scale means. I really don't get -- I'm having trouble with this, because the thumb's already on the scale. But -- so if we could do that next year, or retreat, or whatever, I think that would be helpful.

DR. CROSSON: Well, okay, so maybe what you're saying, Kathy, and I'm not sure about this, is it appears, on the face of it, that we really have some sharp

disagreements here on the Commission. Assuming that we're all saying the same thing when we're talking about favoring or putting thumbs on the scale, or all the rest of that, and depending upon what that means and further explication might be helpful, we might find that we are in more agreement, or we're not. So, I mean, I think that's valuable.

But it seems to me to go back to one of the first questions that was asked here, which was, like, what problem are we trying to solve? You know, I do think that, you know, that Jack and Pat -- I don't know if I've got it right -- helped me a little bit, because I think the problem we're trying to solve, or the problem we're trying to prevent is, over time, getting into a situation where the disparity between commercial rates and what Medicare pays, particularly to physicians, becomes so high that the little bit of creeping of access that we've seen in the last few years becomes a flood. Right? And then we've really got a problem, I think. You know, and one response would be to raise rates, but then, of course, we're kind of running counter to everything that we're trying to do here.

So is it possible that one way to organize this

for future work is to identify that, you know, as the problem we're trying to solve, and then align, you know, some of these other questions, and other solutions -- and again, I think, you know, some issues about how physicians are paid in general, the fee schedule, whether we're appropriately moving towards global payments through ACOs or other things, or are there other ways we could do that. Those are just my own ideas.

But the analytical principle would be which of these potential solutions, thumbs on the scale or not, or different payment things, we could project would make that potential problem better or worse, going forward? And to the extent that, you know, we can -- and it's easy for me to say because I don't have to do it -- but to the extent that we could think about some of these questions where we have disagreements, from that perspective, then we might find ourselves coming closer to agreement. That's the best I can do.

DR. MILLER: Yeah, and this is just a couple of sentences. I know we're way over time.

Taking Kathy's point -- and we fully anticipated this was not one conversation, so, yes, this is going to

come up again and you will see it again. But it would be kind of the notion like this. If you meant thumb on the scale meant you get paid more if you have lower costs and higher quality, then we may all be saying the same thing. But if you're saying, no, this ACO model gets, you know, a boost --

DR. CROSSON: Irrespective.

DR. MILLER: Yeah, right. I'm sorry. I should have said that -- then I think there is more division in the group. And so we will structure this along the lines that Jay said. This was not a one-shot conversation. You could see the level of complexity and however the organization occurred, we were trying to trigger this conversation.

MS. BUTO: But, Mark, it's really both the question as you phrased it and it's the question as Jay phrased it, which is, those are really two different things, the access and adequacy, and what are the problems with physicians, vis-à-vis commercial rates, and what kind of reward system does Medicare have to incent the right kind of care integration and quality? Those are related but not the same thing.

DR. MILLER: I didn't mean to dismiss that. I just was trying to go very directly at your particular --

DR. SAMITT: I would also argue, I wonder, when we continue the conversations, whether we split them, because we didn't even spend a lot of time talking about policy to dissuade or take the fuel off the fire for provider consolidation, because that still is a problem, and I don't know if we had policy discussions about what to do about that.

So it may make sense to separate them and have supplemental conversations about each.

DR. CROSSON: Okay. Very interesting discussion. Let me put it that way. That was an interesting evening.

Before we conclude here and go to the public session, I would ask Bill Gradison and Bill Hall to stand please. Together. Together. Come on. You can do this. And this is just simply to --

MR. GRADISON: Is this --

DR. CROSSON: No, no. This is just simply to thank you in public -- we've done this in private -- but to thank you in public for your six years of excellent contribution to this commission and its work for the

benefit of the Medicare program and its beneficiaries.

[Applause.]

DR. CROSSON: We will miss you both greatly and hope we will be able to see you again.

So we have time for a public comment period. If there are any members of our guests here to wish to make a comment, now is the time to come up to the microphone.

[Pause.]

DR. CROSSON: Seeing none, we are adjourned from our public meetings until next September. Safe travels, everybody. Have a wonderful summer.

[Whereupon, at 11:40 a.m., the meeting was adjourned.]