MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Thursday, January 12, 2017
9:47 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

[9:47 a.m.]

DR. CROSSON: Okay. Why don't we get started? This morning we're going to be starting out our work for the January meeting with essentially two status reports. The first one is going to be on the Medicare Advantage program, Scott and Carlos. And, Carlos, you have the look on your face like you're going to start. Go ahead.

MR. ZARABOZO: Good morning. Last month we provided the customary landscape or status report on the Medicare Advantage program. We are here to provide some additional information you requested. Today's material and the material discussed last month will be included in the March report.

Today we have a two-part presentation. In the first segment, we will have further discussion of the contract consolidation or cross-walking strategy that MA companies have been using to increase bonus payments, and the second segment of the presentation will be a review of the MA update findings and a discussion of the draft recommendation that you will be voting on which is intended to ensure greater accuracy in the determination of MA

benchmarks.

Here is a somewhat simplified example of how contract consolidation or cross-walking works. We illustrate the situation of an organization that begins with three contracts in three different states. Each contract has one plan and, therefore, one bid, except that in Maine, on the left-hand side of the graphic, the company has two different plans. Therefore, there are two separate bids for the contract in Maine. With the cross-walking option, the company is allowed to consolidate all three contracts under one contract. The surviving contract is the Maine contract, which we are referring to as Contract 1. Contract 1 now contains all four plans in the three different states of Maine, Alaska, and Hawaii. The company will submit four bids under the single contract because there will continue to be four different plans and, thus, four different bids.

Although this is an illustrative example, the configuration shown here is not unusual. Currently in the Medicare Advantage program, there is no requirement that the geography that comprises an MA contract must be made up of contiguous states. So the cross-walked Contract 1 that

includes three states is not an unusual phenomenon. For example, there is currently one contract that combines the states of Iowa and Hawaii, and in the mailing material we talk about a contract that now includes New England states combined with several states in the South.

This graphic shows the star ratings before and after the contract consolidation or cross-walking in the illustrative example. Star ratings are assigned at the contract level, not the plan or bid level. What were previously three contracts, each with separate star ratings, will now be cross-walked, or consolidated, into one contract. The organization has chosen to consolidate the contract under the contract that originally only covered the state of Maine, or Contract 1. By doing so, the plans in Alaska and Hawaii will now have a star rating of 5 stars, rather than the 3.5 star rating the contracts in the two states had prior to the cross-walking. For bonus payment purposes, all enrollees in all the company's plans will be in a bonus-level plan because the surviving contract had been a 5-star contract. Note that it is a contract that has only 10,000 enrollees that will determine what the star rating will be across all plans in the newly

consolidated contract.

In December, in discussing this issue, some members of the Commission suggested that instead of having all enrollees within plans paid on the basis of the star rating of the surviving contract, there should be some method for averaging the results across what had previously been three separate contracts. This would appear to be a logical approach for addressing the issue, particularly in the situation that is illustrated here -- where the plan with the smallest enrollment determines the star rating for 210,000 enrollees.

While using an averaging method for determining a star rating may seem to be a logical approach, it may not always achieve a desirable result. Contracts could still receive bonuses based on the performance of a different contract operated by the same company, and companies might have to make different decisions about when and how to consolidate. In the table on this slide, we assume that all the contracts in our illustrative example have the same enrollment levels so as to show how a weighted average would determine the level of bonus payments in different scenarios.

Example 1 in this table uses the star ratings in our illustrative example to show that, if all contracts had an equal number of enrollees, all enrollees in all the contracts -- that is, 30,000 enrollees -- would be in bonus level status because the star ratings in the example would average 4.

In the second example, if the Alaska and Hawaii contracts had had 3 stars rather than 3.5 stars, the average would drop to below 4, meaning that no plans of this organization would be in bonus status even though the contract in the state of Maine had had a 5-star rating.

If the policy was to use a weighted average to determine star ratings, then what a company could do when faced with the second scenario, when no bonuses are payable, is to consolidate only two contracts so that, in the example, the average star rating would be 4 for a contract combining Maine and Alaska, and the plans with 20,000 enrollees in Maine and Alaska would be in bonus status.

There are other more complicated methods of averaging, such as averaging across each of the 44 star measures, but it is also possible to set bonus payments at

the levels that would have existed in the absence of the cross-walking even under the current quality reporting rules.

As a longer-term solution, the issue that we are discussing would not arise if for quality reporting and bonus payment purposes, the reporting and payment was at the level of the market area. This is consistent with the Commission's concept of how quality should be evaluated, as detailed in the June 2015 report, and it is a longstanding recommendation of the Commission dating from a mandated report to the Congress included in the March 2010 report.

As I mentioned, there are now contracts that combine various non-contiguous states, as in the case of the contract combining Hawaii and Iowa. If reporting was at the market area level, results would be reported separately for Iowa and Hawaii market areas, and bonuses would be determined based on the performance in each market area (and eventually based on a comparison to fee-for-service quality in the area). Regardless of the contract configuration, the evaluation of quality would be at the market area level.

At a future Commission meeting, we will continue

the discussion of this issue and possible policy options. Now Scott will talk about the MA landscape and the draft recommendation.

DR. HARRISON: Let me briefly recap our MA enrollment and payment findings from last month.

The program continues to thrive. Enrollment in MA is about 18 million, accounting for 31 percent of all Medicare beneficiaries. The rebates that fund extra benefits have been growing over the past few years, and plans are available to 99 percent of beneficiaries.

At the same time, we have approached financial neutrality between fee-for-service Medicare and MA plans. The benchmarks without quality bonuses average about 102 percent of fee-for-service in 2017. The plan bids average 90 percent of fee-for-service, and payments average 100 percent of fee-for-service. So we have rough equity. But there are still some payment and equity issues.

As we discuss in the chapter, there is 4 percent in risk coding differences unaccounted for, meaning that the coding intensity difference results in Medicare paying 104 percent of fee-for-service for similar beneficiaries in 2017. And there are some inter-county benchmark inequities

that we have discussed. One equity issue in particular we discussed last month, and today we will vote on the draft recommendation from that discussion.

CMS sets the MA county benchmark based on the average risk-adjusted per capita Part A and Part B fee-for-service spending in the county. The calculation includes spending for all fee-for-service beneficiaries in Part A or Part B. All are included whether they have both Part A and Part B, or they have Part A only or B only. The main problem with this approach is that MA enrollees must have both Part A and Part B.

Our most recent data show that 12 percent of fee-for-service beneficiaries are enrolled in Part A only. And Part A-only beneficiaries spend less than half of what those with both A and B spend on Part A.

This results in an underestimate of fee-for-service spending comparable to MA spending and, thus, usually an understatement of MA benchmarks.

Also, the share of Part A only is increasing nationally, varies by county, and is correlated with MA penetration. The share of fee-for-service beneficiaries with A-only reaches 25 percent in some counties and is as

low as 3 percent in others.

As MA penetration continues to grow, we expect these calculation issues to grow. Higher MA penetration leaves fewer, and perhaps less representative, beneficiaries on which to calculate fee-for-service spending.

As for the draft recommendation, because by law beneficiaries must have both Part A and Part B to enroll in MA, it might be more equitable for CMS to calculate the county-level fee-for-service spending on which the MA benchmarks are based, using only fee-for-service beneficiaries who have both Part A and Part B. This way the calculations would be more reflective of MA enrollment.

So the draft recommendation reads: "The Secretary should calculate MA benchmarks using fee-for-service spending data only for beneficiaries enrolled in both Part A and Part B."

Compared with the current CMS process of calculating the county-level fee-for-service spending based on all fee-for-service beneficiaries, we believe that using the average fee-for-service spending of only beneficiaries with both Part A and Part B in the benchmark calculations

would increase spending between $750 million and $2 billion over one year and between $5 billion and $10 billion over five years.

Most benchmarks would increase, and the increase would vary by county. Thus, most plans would be paid more, depending on the counties they serve.

Beneficiary access to plans and enhanced benefits may increase based on plan reactions to the higher benchmarks.

Now I am going to turn it back over to Jay for discussion.

DR. CROSSON: Okay. So I think what I'd like to do is have clarifying questions -- we have two parts to the presentation and the work. Let's do clarifying questions on all of it, and then I think we'll go to the vote first on the recommendation, and we'll come back to the other.

DR. NERENZ: Thanks. Just a quick question on the epidemiology of this cross-walk problem, Slides 3 and 4. You said it's common or not uncommon. We have a couple of examples. Do we have numbers? And are there others that, in fact, go the other way where contracts are combined with the result being a lower star rating than

before?

MR. ZARABOZO: I don't think under this process that happens.

DR. NERENZ: I know of one. I know of one. But that's what I want to know. Is this a big pattern? Is it a little thing? What's --

MR. ZARABOZO: Well, we have been tracking this for the past several years, and we've quantified it in terms of the number of enrollees. Last year it was 900,000. This year it was like 700,000, I think was the number.

DR. NERENZ: Out of what overall total?

MR. ZARABOZO: Out of 18 million.

DR. CROSSON: I'm sorry. David, were you saying there were plans that are consolidated and result in a net reduction in the Medicare stars?

DR. NERENZ: Yes.

DR. CROSSON: One would imagine that the management of that organization would have a hard time, but, anyway, thanks.

DR. NERENZ: I mean, this will tip off Round 2. bit part of the question is, you know, the framing here is

that this is done only to maximize the star rating and the bonuses. But, presumably, there are other business reasons or other reasons for doing this action which then might produce the other result.

MR. ZARABOZO: Right, and CMS has been encouraging the consolidation of contracts.

DR. NERENZ: Okay [off microphone].

MR. ZARABOZO: But as a consequence, or because this is being -- this is happening, this particular strategy is a way to take advantage of that consolidation.

DR. NERENZ: No, it's very clear. I'm just trying to understand its scope and to some extent its underlying reasons given the whole scope of the MA --

MR. ZARABOZO: Yeah, I mean, the beginning reason was we would like to have fewer contracts, for administrative reasons mainly.

DR. NERENZ: Yeah, yeah.

MR. ZARABOZO: Both on your side as a company and on our side as the administrator of the MA.

MR. GRADISON: Are there examples of plans that have lower star ratings that have acquired a plan and then moved through this process? The examples you give, of

course, are with a common insurer. Yeah, just kind of curious. If you don't know, you might take a look at it. I'm just curious about it.

MR. ZARABOZO: The only thing I would say about that is there was a recent report from the stock analysts where there is a proposed purchase of one company -- one company buying another company. The buying company does not have any 4-star plans. The purchased company or intended-to-be-purchased company does. So the stock analysts said, well, they could use this strategy to, in fact, boost the star ratings across the new company.

MR. GRADISON: Not a surprise, and presumably you get a premium for it.

The other thing has to do with the apparent increase in the number of beneficiaries who are not electing Part B at all. I appreciate there are a lot of possible explanations for that, but one is the surcharge and the actual monthly cost under the current law for people in higher-income brackets. Do you have any data that would help to explain why the disproportion of people without Part B is declining?

DR. HARRISON: We have not been successful in

getting the data. We think it's out there somewhere, but we have not gotten it yet.

MR. GRADISON: Well, one suggestion -- and maybe you can answer this now -- would be to take a look at what somebody could do with that amount of money, taking into account the savings in the extra tax plus the regular Part B premium in buying a replacement policy in the private market and see if it -- would it pay, and you could still have coverage by simply going outside of Medicare to get the equivalent or a substantial equivalent. Again, for another day, but I think that might give you a little bit of a window into what might be going on here. Thank you.

DR. GINSBURG: Listening to the earlier discussion, it seems as though this CMS practice of moving to consolidate contracts for administrative savings seems to be problematic in that it directly undermines the entire star strategy, star quality rating strategy. Presumably, the strategy works when consumers looking at star ratings believe or know that the star ratings apply to the plans that they're considering in their county. And, you know, once you move beyond that -- so, you know, why even have star ratings? You completely eliminate the beneficiary

side of the process, and it becomes strictly an administrative thing of giving plans incentives to raise their quality.

MR. PYENSON: Thank you very much, Carlos, for your report. Just a request that as we go forward and consider this, that the kinds of other business issues be identified because there could be confusion with, for example, how plans change the geographic -- the counties in which they choose to operate. There's a whole series of issues around that that could sound similar but might be very different. So I'd ask that we get educated on that and identify that as either similarities or differences.

DR. MILLER: And this is clarifying questions, and so this informs -- this comment will inform the conversation going forward beyond that.

I don't know that you have to design a policy that says you can't consolidate. You can allow people to consolidate. It's just a question of how you want to treat the quality stuff. So they may be, David and Bruce, you know, consolidating for other reasons. The policy doesn't have to get in the way of that. Right, Carlos?

MR. ZARABOZO: Right.

DR. MILLER: Sorry.

MS. BUTO: My understanding is that both of these issues are secretarial level, in other words, don't require legislation to change. I'm wondering in particular about the A and B computation going into MA rates, whether there's been any lobbying or urging by the industry that this be done. And since it's administrative, it would not be scored, right? It was be an impact but not generate a score that had to be offset.

I guess I'm wondering why it hasn't been done, so that's my question.

DR. HARRISON: So it was done for Puerto Rico.

MS. BUTO: Okay.

DR. HARRISON: Puerto Rico was on the very high end of -- I think the majority of their people did not buy Part B, and so they had some big changes. And so it was accommodated for them. Other states have been in to lobby.

MS. BUTO: And CMS, even though there appears to be a strong argument in favor --

DR. HARRISON: The response --

MS. BUTO: -- doesn't want to spend the money, doesn't want to make the change for other reasons?

DR. HARRISON: I believe the response that one state got -- in fact, it was even in the advance notice -- was we're looking at this and we're not ready to do anything just yet.

MS. BUTO: And on the quality score issue, same thing? They've looked at it and they're aware of it, not ready to make a decision? Or is there any awareness -- since it's their policy to encourage consolidation.

MR. ZARABOZO: They are aware of it. When we first became aware of this, we asked is this what you intend to do, and the answer was, "We're aware of the consequence here, and yes, this is what we're doing."

DR. MILLER: And to your point on lobbying, my feeling about this experience in both of these has been rather than the industry approaching it, it's been more the affected areas on the A/B, who have made the argument, as opposed to the industry as a whole, though I could be wrong. But I don't feel like I hear that particularly broadly, and like you, I'm a little confused because it kind of only goes in one direction usually.

The other thing I would say about the consolidation, we also heard noises from within the

industry saying, "You know people are doing this, and it's not particularly fair." So there were some inside-the-industry comments on this.

DR. CROSSON: Jack.

DR. HOADLEY: So I do appreciate going through the greater detail on this consolidation issue, and on slide 6, you're going back to some of the earlier things. I think I recall that when we talked about these market areas and the premiums, the most recent premium support conversation, that there were about 1,200 market areas. Is that the same definition that you're sort of referring back to here?

MR. ZARABOZO: Yes.

DR. HOADLEY: I guess one of the questions is we might go forward with this, continuing to pursue this concept. Are there measurement issues when there are as many areas as that and, therefore, potentially a lot fewer enrollees? I know that's been one of the issues that's been raised at times by CMS, especially for those measures that might be CAP space or something like that, where you'd have to have your -- and whether there are other ways to sort of measure quality. It sort of goes to the -- you

could consolidate but not necessarily have one score through the whole thing and how much we've sort of worked through that or something to go --

MR. ZARABOZO: Well, we did talk about that in the mandated report that you may have very small numbers, similar to the hospital situation, small numbers and how do you evaluate quality. You could do multiyear or do other combinations, too, to address this issue.

DR. HOADLEY: Thank you.

DR. CROSSON: Brian.

DR. DeBUSK: First of all, to Paul and Bruce and Mark's earlier comment, I do think in recommendation 6-2, it's implied that we're decoupling the administration of the contract from the rating, the quality rating, but it might help to be a little more explicit in that.

But my question actually is very related to Jack's clarifying question. When you talk about the level of geographic units, are these MedPAC units that you'd be working on?

MR. ZARABOZO: Well, as the going-in proposition, we have the recommendation here as what the geographic unit should look like, and that was originally a payment

recommendation. So for the moment, that's what our recommendation is.

But, as Jack pointed out, I mean, there are issues that you would want to address, which may not be related to the payment, but on the quality side, you would say, well, maybe these areas do not work quite exactly the way we'd like them to work.

DR. DeBUSK: Well, I just wonder if there's benefit if the MedPAC units turn out to be useful and workable, number one, maybe coin the term officially, but second, as we do work in ACOs, it would be nice if whatever geographic units we use that we do them in parallel.

MR. ZARABOZO: Right. And that's the intent. When it comes down to comparing fee-for-service, ACOs, and MA, it would be the same geographic unit for comparison purposes.

DR. DeBUSK: Thank you.

DR. MILLER: That's what the June 15 report was kind of about, this notion of you define the market area. I am resisting the use of the terms, MedPAC, with all respect, Brian. But you define a geographic area, and then within that geographic area, you're measuring for fee-for-

service, ACO, and various managed care plans -- various ACOs and various managed care plans within that area. So, as a beneficiary or a policy person, you can look at quality within that market area.

DR. DeBUSK: It just seems like as we do this reading, the sooner we get the geographic area issue, unit of measure settled -- and there was some novelty in the way that you did that. The combination of CBSAs and HSAs, there's merit in the approach, and to me, it just seems like the sooner we get that coined and put into play, the more useful it will be because we won't have to revisit this concept of what is a geographic unit.

DR. MILLER: Your point is taken.

DR. CROSSON: Bill Hall.

DR. HALL: Back on slide 4, I'm trying to work out the math here. If there is consolidation or cross-walking between right now non-geographically related areas, what does this do to our ability to look at regional variation medical care.

Well, we're not mentioning states right now, but it just seems to me that that was something we spent a lot of time on, and it was a very productive way to take a look

at quality. But does this totally obscure it?

MR. ZARABOZO: Well, if you're looking at -- we have personal-level, for example, HEDIS data, so you can still attach. You can look at particular geographic areas. So, yeah, there is a basis for saying we are just going to look at these. It makes it more complicated for us.

DR. HALL: That's why you get the big bucks.

MR. ZARABOZO: Right.

DR. HALL: Okay. So basically --

MR. ZARABOZO: Except there is a little issue there because some of the measurement is done on a sampling basis.

DR. HALL: Right.

MR. ZARABOZO: So, previously, there would have been a sample of 411 for each contract. With this consolidation, there will be only 411 across the three market areas under the current rules because of reporting at the contract level.

If you're using encounter data as a basis of whatever comparison you're trying to do, then it's still you would know where the beneficiaries are located related to the encounter data.

DR. HALL: Thank you.

DR. CROSSON: Pat.

MS. WANG: Understanding that there's still more information to glean about the phenomenon of Part A only, folks of Part A only ant not Part B, do you have the sense or do you have an opinion as to whether or not that is a growing issue in the past few years, or has it always been that way?

DR. HARRISON: It's a growing issue.

MS. WANG: Okay.

DR. HARRISON: In the chapter, there's trends that show how much are in Part A only, and that's been growing semi quickly.

MS. WANG: Thank you. Thanks for that.

To Kathy's question also, though, the curiosity about why nothing has been done administratively about this, it is a curiosity. I mean, going forward for accuracy, I can see why it would be important to try to establish a different definition of what constitutes fee-for-service spending, but in prior meetings where you highlighted certain areas of the country where this is particularly pronounced, MA penetration was very high. The

bid benchmarks were actually above 100 percent because bid benchmarks in relationship to that calculated fee-for-service equivalent vary from below 100 percent to well over 100 percent, and it doesn't seem like it's damaging the attractiveness or enrollment in MA plans.

I mean, this is more of a comment, I guess, than a question, but I'm not sure the word "equity intercounty" is really the appropriate term. Accuracy, going forward, I can see if this phenomenon is seen to increase, but I'm not sure there's an equity problem right now because it doesn't seem to have damaged MA penetration or the attractiveness of plans.

And I also do wonder whether some of the bidding benchmarks were set higher maybe because of the perception that there's lower fee-for-service spending.

DR. HARRISON: So putting side the 95 to 115, which we haven't talked about this year, one of the things that causes this is higher penetration. As there's more MA penetration that people left in fee-for-service, they're more likely to be A only. So it gets worse as time goes on, and it's worse for those counties that have high penetration.

DR. MILLER: It is interesting, though, what she said, given the fact that it does then end up being coincident where the benchmarks are above fee-for-service. That may be why you haven't heard so much, and I think that was the first part of your comment, which I thought was kind of interesting.

DR. CROSSON: Jon.

DR. CHRISTIANSON: Two questions, I guess. One is following up on something Jay said.

I know there's like a zillion permutations the way these different contracts could be combined and the effect on the star ratings, but do you have any sense of how much sort of Medicare money is out there going forward that's at risk? Just looking at the bonus payment part of this whole thing, not at the consumer choice thing that Paul talked about, but just the bonus money, do you have any sense of money on the table yet that could be --

MR. ZARABOZO: Hard to say.

DR. CHRISTIANSON: Obviously real hard to say, yeah.

MR. ZARABOZO: Yeah. I mean, I could look at that, actually, to see what the possibilities might be, but

--

DR. CROSSON: If all plans became four stars --

DR. CHRISTIANSON: If they all figured -- I mean, so have all plans figured this out, and it's pretty much done with, or if there a lot of potential for plans to continue to pursue this strategy, how much money is at risk for Medicare if they did in terms of the bonus points? Just the general sense of that would be interesting. I don't know the nature of the dollars that we're worried about here.

The second question is more along the lines of -- some of my academic colleagues have suggested that we should be happy to pay Medicare Advantage plans more because they have higher quality, and the quality has been going up. Do you have any sense of how much of that increase in quality over time is due to the consolidation, strategic consolidation of plans, the sort of average quality for Medicare plans versus actual increments in quality?

MR. ZARABOZO: No. I don't have the answer to that, but, of course, the situation that was in the mailing material, where you have 20,000 employees, you get the star

rating of that with 180,000 remaining people. Presumably after two years in that particular case, they will drop to below four stars. So this is not a perpetual motion kind of --

DR. CHRISTIANSON: It gets back to my first point. If you look at globally the plans and you've got a lot of opportunity to continue to do this, we could continue to get impression of average improvement in quality among the MA plans. That might be at least partially explainable by this consolidation behavior.

MR. ZARABOZO: Right. And you could start new contracts also. So what we're looking at today may be different from what we'd be looking at two years from now.

DR. CHRISTIANSON: Absolutely.

MR. ZARABOZO: So yeah.

DR. CROSSON: Okay. So now if we could put up slide No. 9, the draft recommendation. We will entertain discussion on this recommendation leading up to a vote. Discussion on the recommendation. Amy.

MS. BRICKER: Philosophically, it makes sense that you would want to look at benes with both Part A and Part B. My visceral reaction is to the price tag, and so I

just worry about us proposing something that will cost upwards of $10 billion over five years. Do we feel truly that there is a deficit in plan access or that beneficiaries don't have ability to join MA or that we're at risk of other downstream impacts if this change isn't made? The price tag is just a little shocking.

DR. CROSSON: Do you want to make the --

DR. MILLER: Yeah. And this relates to Paul, a comment that Paul has made at different points in time.

So while it was somewhat confusing when we went through this in -- I can't even remember now what meeting it was. Maybe the last meeting. We were reminding you guys that there had been a set of coding recommendations that had been made, booked, and published in the June 2016 report, which resulted in net savings. If the Congress wanted to offset this, although I understand it's a secretarial action -- it's not necessarily a scorable event, but if anybody was worried about this cost, there is ample revenue in the coding recommendations that would offset this. And that was the point we were trying to make. It was a bit of a hard point and kind of hard to understand, but because they're separated by time and

space, there is some standing recommendations. With a straight face, you can say, "I have things that would leave the Treasury in balance," but you are absolutely right. This particular thing goes in one direction. This is a cost.

DR. CROSSON: So if the timing of the evolution of these recommendations had been different, we might be sitting here with a package on the table, some of which cost the Treasury money, some of which save the Treasury money, net-net Treasury savings. But because of the timing of the evolution, we voted for one and now we've got the other, and they're separated in time, as Mark said.

Paul.

DR. GINSBURG: I'm just thinking whether we could do something with language in this year's report to tie them better together saying that we're concerned about $10 billion over five years. This would be best if it could be combined with these prior recommendations we've made on coding --

DR. CROSSON: Absolutely.

DR. GINSBURG: -- and get the public to think about that, too, as a package.

DR. CROSSON: David.

DR. NERENZ: Just a quick follow-up to Amy's question. Not only the projected rise in payments here, but the distribution of those, it seemed to me when you talked about this last time -- and I think I'm picking this up again on page 28 in the figure -- that the geographic areas or the plans in those areas most likely to benefit from this are places with already high MA penetration. I think we used Portland as an example. So are we doing a rich, get richer kind of thing here? I'm inclined to support this just on logic and philosophy, but when we talked about this before, I think I raised that. Maybe others raised it as well as an impact concern. Have we talked about anything to deal with that in some way, or is that just how it goes?

DR. HARRISON: That is generally true because, again, places with high penetration are the ones that are likely to have this.

Now, I don't know that Pittsburgh is a 115 county, and some of the ones in Southern California are not, so --

DR. NERENZ: I think Portland was one I had in

mind.

DR. HARRISON: Yeah. Portland, we've always had trouble explaining why they were so low on fee-for-service, and maybe this is one reason. I don't know.

DR. MILLER: And everybody follows that, that there's an interaction here. The more you pull people out of the fee-for-service pool and put them into managed care, the more you're left with only-A or only-B people. So there is a certain circularity to the problem exists and then the result -- results because of the high penetration.

DR. CHRISTIANSON: Yeah. To David's comment, though, I think he's absolutely right that that's the way it goes. If you pursue this change, that is the result.

DR. CROSSON: Pat.

MS. WANG: So I think the concerns that have been expressed in the puzzlement over do we really need -- like is anybody hurting from the lack of this, I share that. I think as a matter of accuracy, going forward something has to be done because it's just a downward spiral. If your benchmark continues to increasingly be A-only beneficiaries, the fee-for-service kind of benchmark is going to be incorrect. That said, it does seem like it's

more of a methodological correction than a program correction.

In terms of the price tag, I agree with Amy. It's like really expensive to solve a problem that is methodological as opposed to being -- doesn't seem to be having a real impact on people that we can perceive.

To the extent that there is this idea of virtual package, referring back to proposals made earlier about sort of the pay for this methodological correction, I would ask that we also remind folks in that bundling, that bundle, that as part of the coding intensity recommendation, there was also a strong recommendation to stratify the level of the coding intensity adjustment to inter-equity among plans and to not apply it in an across-the-board manner.

DR. CROSSON: Kathy, Jack.

MS. BUTO: I support the recommendation.

One thing, if we decide we'd like more nuance we could think about is whether there's a threshold of penetration into MA that would cause us to say that the rate ought to be tied to more of a regional, broader geographic area, something like that, or at least allude to

a second generation of issues that revolve around fairness.

But I feel pretty strongly that the Commission ought to try for payment accuracy where we know that a clear inaccuracy exists because we're very eager to look for areas where accuracy would produce savings. I think we ought to be pretty symmetrical about that and be willing to spend money where it ought to be spent, but, again, I see this spiral issue, and I think we ought to look beyond the recommendation or at least talk about the fact that there might be implications beyond it.

DR. CROSSON: Jack.

DR. HOADLEY: I also support the recommendation for a lot of the same reasons that Kathy and others have just said in terms of getting things right.

I guess on the cost point, two things come to mind. One is I think the implication is that the additional cost will be fairly geographically skewed based on some of that graph that you looked at, you showed us to look at. And I don't remember whether the previous recommendations we're referring back to were more uniform in their geographic impact, so I don't know if that's something that -- I know when we talked about some of the

double bonus counties, there was a question of two things offsetting, but maybe not always in the same area. So I just sort of put that out there if there's anything we're able to say in making that linkage, that "virtual linkage," as somebody called it.

The other is whether there was any thought as to whether there is a sensible way to do this with budget neutrality. I mean, you presumably could reorganize the money rather than just spend it. I'm not necessarily saying we should go there, but whether anybody has thought through that as an option or whether it's even worth mentioning that this could also be done in some way if we thought there was a logic to that.

DR. CROSSON: I have Bruce, then Rita, and Pat and Craig.

MR. PYENSON: I support the recommendation but also finding a way to put this in the context of the earlier recommendations in the same language.

Part of sort of reading between the lines of call letters and other documents from CMS is that they do some approximate rounding of different influences in their calculus, and we just shouldn't -- and that's why it's

important to make this balanced with the other recommendations.

DR. CROSSON: Rita.

DR. REDBERG: I certainly see the reasoning for the recommendations, so support it for that reason, but I do share the concern expressed by Amy, Pat, and others about the cost, particularly because I always try to think about recommendations in light of our guiding principles of increasing access, increasing quality, and increasing value. And I'm not sure how this recommendation achieves those goals, so it does seem like a lot of money for something that it's not clear to me it's going to increase quality or value or access.

So if we paired it as much with coding, that would offset that and sort of better achieve our overall program goals.

DR. CROSSON: I think I've heard that as a general suggestion we'll take up.

Pat.

MS. WANG: If a lot of this issue is being driven by increasing enrollment in MA plans and a less and less representative fee-for-service cohort, I guess I have the

question and concern that even if you add the A/B-only beneficiaries, you are going to still have an unrepresentative remaining fee-for-service cohort, because perhaps there are unusual characteristics of those A/B beneficiaries that's an even smaller group of people. And I'm wondering whether once MA penetration reaches a certain level, whether there's a better methodology to set benchmarks and premiums. For plans, maybe they should be compared against their own historical spending. I wonder whether it would make sense for the Commission to explore that as well because there's an endpoint to this. So you add B, you add A/B for the time being, and then penetration gets to 55 percent, 60 percent, and there's 10 A/B beneficiaries left, and you're setting a fee-for-service benchmark based on those people. That's not good either.

So, at a certain point, have you guys thought about looking at -- once MA penetration reaches -- I'm just making this up -- 45 percent in a particular area, that it would be more accurate to set future benchmarks based on comparing MA against itself or some combination of MA against itself and against fee-for-service or something like that?

DR. MILLER: So, generally, when that -- and this problem is, I think, one that the program is going to face, depending on, you know, if it stays in its current configuration or if it goes to another.

So the way I would have started answering her question is several years back, on Congressional direction, or mandate -- I can't remember -- we did kind of go through bidding in the MA program, because one of the way you get away from, oh, well, I'm using this fee-for-service benchmark which is really an administrative benchmark set in law, that then people bid about -- or, sorry -- bid against, is you could think of competitively setting the benchmark through bids, and we did some discussion in MA back in the day, and then, as you know, we have repeatedly, at different points in time, talked about, well, what about the structure of a premium support type of model, which would then have MA fee-for-service.

But even in a circumstance like that, if you're building your bids off of MA and fee-for-service, you know, and you've moved to a competitively based benchmark instead of this administrative one, you still could have a problem where you draw all your people out of fee-for-service. You

continue to use fee-for-service as one of the bids but it could be a pretty crazy bid, but it would have a lot less influence on what the overall, you know, benchmark is in the area.

So my question answer to you, which wasn't quick, apparently, was, you know, we've sort of contemplated those issues in the context of the premium support types of discussion. Where do you really want to be in the big picture, as you go down that road? That would be my kind of best shot at it, unless I've left something out guys.

DR. CROSSON: Yeah. On this --

DR. CHRISTIANSON: Yeah, just to add to that, going way back, when plans were being paid on the APCC methodology, at the county level, this was a continual issue. It arose at the county level because when, in individual counties, when the MA enrollment grew to a certain amount there were very few people left in the fee-for-service sector. They tended to be less healthy, according to the research. And so this is a continual issue in terms of using the fee-for-service sector as the benchmark. It's been going on for quite a long time.

DR. MILLER: And then I guess the other thing you

could do is, when you found yourself in this situation, and think this might be a less -- well, I don't know -- you know, you start approximating things. You take past values when things were more stable and you project them forward. You take other areas and calculate fee-for-service on that basis. I mean, you start to approximate, extrapolate types of methodologies, but it will have all kinds of issues.

DR. CHRISTIANSON: Yeah, and Medicaid programs have faced exactly the same issue. How do you set the benchmark then?

DR. MILLER: Right.

DR. CROSSON: Craig and then Pat -- on this point, Pat?

MS. WANG: Yeah, just, would we ever consider, in the context of this recommendation, introducing at least language effective, you know, this is not the final answer, and particularly in the case of increasing shares of Part A-only beneficiaries being driving by increased Medicare Advantage communication, see chapters X, Y, and Z of prior MedPAC work or deliberations of different ways to calculate benchmarks, or that thought has to be given to a better way, going forward.

DR. CROSSON: Yeah. That can absolutely be done.

Craig and then Brian. Brian, are you on this point. Sorry.

DR. DeBUSK: Related to Pat's comment, I just -- and again, first impression, but I have issues with decoupling fee-for-service from the MA benchmark calculation for, really, a couple of reasons. Number one, you could find yourself where the MA plans are basically killing each other in a market where fee-for-service is poorly implemented and is high cost. But then the other question would be, let's say we decouple them and the MA plans started racing toward closer to commercial rates. Would we be prepared to accept an MA bid or benchmark that was 20, 30, 40 percent higher than fee-for-service in that geography?

So I think it's -- I appreciate where we're trying to go with it but I think there's some risks to not keeping those systems at least somewhat harmonized.

DR. CROSSON: Last comment. Craig.

DR. SAMITT: So I support the recommendation as well and I would concur with Kathy's comments that while there certainly is a budget implication to this that we

should be consistent about being consistent, that when we achieve savings because of consistency we also need to be willing to occasionally spend to achieve consistency, and I think that's important in this regard.

And, I mean, we've talked about this a little bit but in terms of the diminishing complement to fee-for-service over time, I think we addressed that through the discussions that we have had and that we will continue to have regarding premium support and competitive bidding.

The one other piece that I want to mention, that I don't want to lose as the discussion about geography, and I know we commented on a MedPAC geography, but I also just think that as we begin to harmonize comparators between MA and fee-for-service that we be sure that we keep these geographies consistent. So whether we're talking about comparative quality measurement or competitive bidding or benchmark setting, that, you know, if we call it a MedPAC geography that that should be the geographic unit that we would apply universally to all of these metrics, so that it is a true apples-to-apples comparison.

DR. CROSSON: Thank you, Craig. I want to agree strongly that consistently consistent is better than

consistently inconsistent. Thank you for that.

Yes, Paul.

DR. GINSBURG: I think one thing that came up briefly, and I'm not sure people picked up on it, about this Part A-only business really presumably affects the 95 to 115 percent calculations, and I don't think I'd want to do it on the spot now, but one implication might be to follow through and see if this rule should apply in that area as well.

DR. CROSSON: Okay. If we're ready for -- Scott, do you have a question?

DR. HARRISON: Yeah, I just wanted to check. So are you suggesting that you wouldn't do it in the 115 counties, or something like that?

DR. GINSBURG: The idea is that I would recalculate which counties are 115 and 95 on this basis.

DR. HARRISON: And see what happens. Okay.

DR. GINSBURG: Yeah.

DR. CROSSON: Okay. Okay. We have a recommendation before us. The secretary should calculate MA benchmarks using fee-for-service spending data only for beneficiaries enrolled in both Part A and Part B.

All Commissioners in favor please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: Recommendation passes.

We're running a little bit late. I would like, though, to open up the discussion to the, at least, preliminary proposal for how we deal with the crosswalk issue. So comments to be -- we'll come back to this again, but comments to staff on crosswalk. David. David, Jack.

DR. NERENZ: Yeah. I have a number of things that go beyond what we have time for this morning. I'm generally in favor of the idea of narrowing the geographic scope or the organizational scope of quality measurement so I'm consistent with the general direction we talked about.

The part I want to make, though, and maybe I can make it in more detail in some other setting, is that, you know, as I said when I was waving my little yellow sheets around a couple of months ago that we need an articulated

theory of quality here, specifically one that says, in the context of MA, what is the proper organizational or geographic locus of quality and why? And we can think of a whole organizational hierarchy, from the big company to the contract to the plan to the network within plan, and we're picking a spot but I'm not sure we've articulated the defensible rationale of why we're picking that spot. It sort of feels okay but I think we can do better than that.

And just as an example of the challenge question, I'd say if we're talking about an individual who is about to age into Medicare, has a PCP, has some kind of reasonable connection, say, to specialists and hospitals, and that is going to stay, the person can pick a number of plans. Is there any evidence that that choice of plan in that context, and its variable star ratings, makes any difference whatsoever in the future quality of care to be received by that person? I don't want to call the question. I just think we ought to have a theory that answers that question.

DR. CROSSON: So David, as we have said before, because you've brought this issue up, we will be taking this issue on broadly, later in this year.

I had Jack, Pat, and Jon.

DR. HOADLEY: So I do think this feels like something that both has a short-term potential fix that we could take some steps or recommend that CMS take steps to use, you know, potentially one of the alternative methods that you had on the chart, or the notion of assigning the bonus payments based on the pre-consolidation status of the beneficiaries that you also raised. You know, the latter wouldn't completely address what it looks like in the plan finder, which kind of goes to the broader points that Dave just was referring to, of, you know, are people really using these scores to help pick plans, and that's one of the two ways these consolidated scores create issues. They potentially create a misleading signal to the public that's shopping for plans, and they also potentially misallocate the bonus dollars, and it seems like we could do administrative -- recommend administrative fixes that would address both of those things.

But I was going to raise, and I'm glad you raised it in the presentation, that this really does go to that broader issue of what's the level at which contracts should be defined, at which quality could be measured, and even a

broader level, the way that David raised it, with some of the issues that I raised in my earlier question about size. And so I think this does penetrate the premium support discussion, the fee-for-service versus MA quality comparisons discussions that we've had, and obviously are going to continue to have.

DR. CROSSON: We have Pat, Jon, and Brian, and Bruce.

MS. WANG: I think that this phenomenon is going to happen more, contract consolidations for perfectly legitimate business reasons. There are major mergers that are proposed of national insurers, and I just -- so I think in answer to Jon's question, I think there will be more, and I think it's very important that you guys have, you know, flagged this as an issue to try to remove the star bonus from being a factor in consideration. To sort of neutralize that as a reason to consolidate or not to consolidate is very, very important.

You know, Jack's points about there's a lot of dimensions, is one is the bonus money, one is the marketing to beneficiaries and transparency and truth, truth in marketing. Another is, you know, just for the tally sheet

that is kept by the program about X number of beneficiaries are in four-star, five-star plans this year, it sort of -- it gets kind of murky. So without knowing all the answers, I just really encourage -- I think it's very important work to come up with a good solution.

DR. CROSSON: Thank you. Jon.

DR. CHRISTIANSON: Yeah. I guess second both of those comments, and, very briefly -- I mean, we support value-based purchasing when we know we don't have the value right. For the consumer's perspective, we have to do something about it, in my mind. And so when you're telling consumers here you've got a five-star plan you can choose, you're going to get high-quality care. But you really have a three-star plan. That's -- and we know that that's the kind of information we're giving consumers. We can't let that stand. We have to -- so I'm just saying I really support your work in this area. We need to correct this.

DR. CROSSON: Brian.

DR. DeBUSK: I think recommendation 6.2, as you've drafted it, I think is fantastic. I think it's a novel solution to the problem that's in front of us -- about, you know, again, the geographic units. But I also

think that it's going to have some long-term benefit, and I think several others have alluded to this, you know, not to take time from this meeting but I think the solution in 6.2 will have downstream benefits that we'll continue to enjoy, particularly when we get the geographic unit right and harmonized.

So there's -- I would congratulate you on what I think some really good short-term thinking, solving the immediate problem, but also some long-term thinking on where we want to go.

MR. ZARABOZO: Yeah. Just to clarify what you're talking about is 6.2 from the 2010 report, that is repeated in the mailing material.

DR. DeBUSK: On page 51 of the --

MR. ZARABOZO: Right. It is not a current recommendation that is being considered. It's already been recommended.

DR. CROSSON: Bruce.

MR. PYENSON: Thank you. Just to add to my previous comment that was out of order, as I think Mark pointed out to me --

[Laughter.]

MR. PYENSON: -- I just want to suggest the broader context of the rules that plans go -- have to abide by on both the contract level and the plan level, that might be influencing plan -- health plan behavior.

So, for example, the limits on the changes that are allowed in benefit design from one year to the next. And there's a whole series of detailed rules since the context for this could be, you know, optimizing is not just optimizing quality stars in ways that don't seem to make sense, but there's other dynamics going on. I don't want to drag down this discussion by making it too broad, but I think acknowledging some of those might be helpful.

DR. CROSSON: Okay. Thank you, Bruce. Thank you, Scott and Carlos. And very nice work. We'll be hearing more from you perhaps later this year.

So we'll move on now to the status report on Part D.

[Pause.]

DR. CROSSON: Okay. Rachel and Shinobu, just one second while we clear the changes in the audience.

Okay. Status report on Part D. Rachel, it looks like you're starting.

DR. SCHMIDT: Good morning. Shinobu and I are here to bring you a status report for Part D, Medicare's outpatient drug benefit. In Part D, private plans deliver drug benefits to enrollees, and in return, Medicare pays plan sponsors monthly capitated amounts and other more open-ended subsidies. Part D uses a competitive structure to provide incentives for plan sponsors to offer attractive drug benefits yet manage drug spending and keep enrollee premiums low.

In this presentation we'll describe the program and its general trends. We'll talk about the market structure of Part D plan sponsors and the strategies they use to manage drug spending. Then we'll describe what we're seeing in terms of drug pricing and trends in program spending. We'll wrap up by previewing our spring discussions about Part D.

In 2016, out of 57 million Medicare beneficiaries, 41 million, or 72 percent, were enrolled in Part D plans. Another 3 percent got drug benefits through former employers that were the primary insurer for their retirees in return for Medicare subsidies. This is called the "retiree drug subsidy." Twenty-five percent either had

other sources of drug coverage, no drug coverage, or coverage less generous than Part D.

Incurred program spending for Part D totaled $80 billion in 2015, mostly for payments to private plans but less than $2 billion also for the retiree drug subsidy. Part D makes up 12 percent of total Medicare outlays.

As has been true for a number of years, surveys continue to show high enrollee satisfaction. At the same time, we continue to hear about frustrations from nearly all stakeholders -- beneficiary advocates, plan sponsors, and even CMS -- about coverage determinations and appeals processes for the relatively small number of enrollees who are unable to leave the pharmacy with their prescription.

In 2017, Part D's defined standard benefit has a $400 deductible, and then the enrollee pays 25 percent of covered benefits, and the plan pays 75 percent. After the enrollee reaches $3,700 in total spending, there's a coverage gap in which enrollees get some plan coverage but pay more than 25 percent cost sharing. A really important point is that there's a 50 percent manufacturer discount on brand-name drugs in the coverage gap. The discount affects incentives because it only applies to brands, not generics,

and it makes brands look relatively less expensive to plans and beneficiaries. It also moves enrollees toward the out-of-pocket threshold more quickly because the discount is counted as the enrollee's out-of-pocket spending.

Although the coverage gap is phasing out by 2020, manufacturers will continue to provide the 50 percent discount in that range of spending. Once an enrollee reaches the out-of-pocket threshold, above it they pay 5 percent, the plan pays 15 percent, and Medicare picks up 80 percent through reinsurance. This is the defined standard benefit, but in practice nearly all Part D plans use different benefit designs -- typically with fixed-dollar co-pays. For 12 million beneficiaries who receive Part D's low-income subsidy, Medicare pays for nearly all of their premiums and cost sharing.

Here are a few highlights about the plans enrollees chose in 2016 and what's available for 2017.

In 2016, 60 percent of enrollees were in stand-alone prescription drug plans and 40 percent of Part D enrollees were in Medicare Advantage drug plans, compared with 70 percent in PDPs and 30 percent in MA-PDs during 2007. In 2016, 29 percent of all enrollees received the

low-income subsidy, compared with 39 percent in 2007. Thirty-four percent of LIS enrollees are in Medicare Advantage drug plans, which is much higher than at the start of Part D, but still most LIS enrollees are in stand-alone drug plans.

For 2017, plan sponsors are offering 16 percent fewer PDPs, but beneficiaries still have broad choice of plans. The total number of MA-PD offerings increased by 3 percent. There are 6 percent more PDPs with premiums below regional benchmarks, which means LIS enrollees do not have to pay a premium to enroll. That's three to ten qualifying PDPs in each region.

Here are some key trends we've observed since the start of Part D:

Enrollment grew from 24 million in 2007 to 41 million in 2016. That's about 6 percent per year. Enrollment among beneficiaries who do not receive the low-income subsidy has grown faster than those with it. Since 2010, some of that growth has been associated with employers that quit taking the retiree drug subsidy and instead set up employer group Part D plans for their retirees.

There's a lot of variation in Part D premiums, but the average premium has remained steady at $29 to $31 per month between 2009 and 2016. The drug portion of premiums for MA-PDs has grown somewhat faster than premiums for PDPs.

Remember that Medicare pays 80 percent of catastrophic benefit costs through reinsurance. So at the same time that average enrollee premiums have been flat, there's been much faster growth in Medicare's reinsurance payments to plans -- especially since 2010. This is the problem that the Commission has been pointing out for many years, and the recommendations that the Commission made for Part D last year were designed to address this issue.

Part D enrollment is concentrated in plans offered by a relatively small number of companies. The pie chart reflects 2016 enrollment in MA-PDs and PDPs combined. You can see the top nine companies account for nearly 80 percent of enrollment. Plan sponsors in the middle have expanded their market shares over time, often through mergers and acquisitions. Most of these companies are large health plans, but other companies have core business focusing on pharmacy benefit management and retail

pharmacy.

Your mailing materials go into some detail about the main strategies plan sponsors use to control benefit spending, including formulary design, rebates, pharmacy networks, and specialty pharmacies. In the interest of time, I'm only going to focus on two of these.

The first is rebates. Plan sponsors and PBMs negotiate with manufacturers for rebates in drug classes where there are competing therapies. Plans use rebates to offset overall benefit costs and lower premiums. The Medicare trustees have said that rebates as a percent of gross spending have about doubled since the start of the program. One reason may be that in recent years, plan sponsors have negotiated price protection rebates, and under these agreements, if a drug's price increases above some predetermined amount, the manufacturer rebates the additional price inflation to the plan sponsor. Price protection rebates are concerning because they keep plan sponsors more sanguine about manufacturers' mid-year price increases.

A second strategy is the use of specialty pharmacies. Specialty drugs, which typically have very

high prices, are accounting for greater shares of overall drug spending. This is increasingly a flash point because manufacturers use limited networks of specialty pharmacies to control distribution of and access to their drugs, while plans and PBMs have their own specialty pharmacies and face a different set of incentives. In Part D, plans cannot require enrollees to fill specialty prescriptions in a limited network. We think this is an important issue given that high-priced drugs are starting to drive program spending. We plan to get a better line of sight on this and come back to it.

We've talked about how average Part D premiums have remained flat at the same time that Medicare's reinsurance payments have grown. Now let's talk about the role of drug prices in all of this.

The blue line shows our overall price index for Part D. You can see that it's been flat or even declining, but over the past few years it's ticked upward, and let's talk about why. The yellow line at the bottom is an index for generic prices, which generally have declined since the start of Part D. At the top, the red line shows prices for brand-name drugs, which have grown pretty aggressively.

Now, these are list prices, so they don't take into account rebates. Nevertheless, they're relevant to us because it's list prices that determine what phase of the benefit an enrollee reaches and whether they've hit the out-of-pocket threshold. Remember that above that threshold, the beneficiary pays 5 percent coinsurance and Medicare covers 80 percent in reinsurance.

Looking again at the blue line, it was flat earlier in the program because a lot of blockbuster drugs lost patent protection and Part D enrollees switched to generics. But, recently, fewer drugs are going off patent and growth in brand prices has overwhelmed the moderating influence of generics. This means that brand price growth has become the cost driver, and increases in those prices make it more likely that an enrollee will reach Part D's out-of-pocket threshold.

In October, Bruce raised an important issue. Some of his Milliman colleagues have pointed out that there may be incentives for Part D plans to put higher-priced drugs with large rebates on their formularies rather than lower-priced drugs. This seems counterintuitive, but the reason why has to do with the structure of the Part D

benefit, reinsurance, and the way CMS shares rebate dollars, or direct and indirect remuneration, with plans.

This table has been updated since you received your mailing materials. It shows a hypothetical example of spending for a beneficiary who takes just one high-priced drug. From a plan's perspective, they want to consider their liability -- what the plan would be responsible for paying in net benefits if they were to select one drug over a competing therapy. Brand 1 is a drug with a list price of $60,000 per year, but the manufacturer offers a 25 percent rebate, so the net price is $45,000. Brand 2 has a lower list price of $30,000, also with a 25 percent rebate, so Brand 2's net price is $22,500. If the effectiveness of the drugs is the same, the beneficiary would pay less for Brand 2, and it seems at first it would make sense for the plan as well.

However, the plan doesn't cover all costs. It doesn't pay for enrollee cost sharing or any coverage gap discount provided by the manufacturer, and it receives reinsurance from Medicare as well as rebates and pharmacy fees. Medicare keeps a portion of the rebates to offset some of the cost of reinsurance, but the formula CMS uses

may be too generous to the plans. I can go into this in more detail on question, and we'll discuss this more in the spring.

In this example, when Medicare provides 80 percent reinsurance and keeps a relatively small portion of rebates, Medicare's net reinsurance would be $37,729 for Brand 1 and $15,729 for Brand 2. That means that the plan would actually reduce its benefit spending by $287 if it put the high-price, high-rebate drug on its formulary, compared to a net cost of $713 if it picked Brand 2.

Now, this dynamic changes completely when you follow the Commission's June 2016 recommendation to reduce Medicare's reinsurance from 80 percent to 20 percent of catastrophic spending. In that scenario, the plan would be more likely to select the lower price drug. The plan's liability would be $12,510 for Brand 2 compared with $28,000 for Brand 1.

MS. SUZUKI: Rising prices and plan incentives for certain high-price, high-rebate drugs that Rachel just described are reflected in the patterns of program spending, with Medicare's payments for reinsurance growing much faster than the rest. Payments for reinsurance have

also been the largest component of program spending since 2014.

Between 2007 and 2015, reinsurance grew by more than 300 percent cumulatively, compared with less than 6 percent for the direct subsidy, which is the monthly capitated payments to plans, and by about 55 percent for the low-income subsidy.

On an annual basis, payments for reinsurance have grown by 20 percent on average, compared with less than 1 percent for the direct subsidy and 5.6 percent for low-income subsidy. Overall, Medicare's program spending has grown by 7.1 percent per year.

We've been focused on the growth in spending for reinsurance for many years now. The number of enrollees who reach the out-of-pocket threshold where Medicare starts paying reinsurance -- what we refer to as "high-cost enrollees" -- has been growing since 2010. In 2014, the latest year for which we have data, 3.4 million enrollees, or nearly 9 percent, were high cost. Annual spending incurred by these high-cost enrollees averaged about $18,800 in 2014, up 11.4 percent increase from just below $17,000 in 2013.

While over 70 percent of those were beneficiaries with the low-income subsidy, the number of high-cost enrollees without the LIS increased faster than those with the LIS, in part reflecting Part D's enrollment growth as baby boomers began to retire. More important, however, is that prices have grown aggressively. And also important is the change in law that allows the 50 percent manufacturer discount on brand-name drugs in the coverage gap to count towards the out-of-pocket threshold.

High-cost enrollees accounted for 53 percent of all Part D spending in 2014, up from about 40 percent before 2011. In other words, there's been a shift in the distribution of drug spending, with high-cost enrollees driving overall Part D spending growth as you'll see on the next slide.

This chart breaks out the growth in spending per enrollee -- shown in gray bars -- into growth in price -- in blue -- and growth in quantity -- in white.

On the left, you can see that for high-cost enrollees, the growth in the average price per prescription has driven their spending growth much more so than the quantity of prescriptions they've filled. Between 2010 and

2014, the average price per prescription for high-cost enrollees rose by nearly 9 percent per year.

With the high-cost enrollees' share of overall spending now accounting for more than half of all spending, the average per capita spending across all Part D enrollees is increasingly affected by spending for high-cost enrollees.

On the set of bars to the right, you can see that between 2010 and 2014, per capita spending for all Part D enrollees grew by 3.7 percent annually. That reflects an increase of about 9 percent among the high-cost enrollees and a decrease of 2.3 percent for other enrollees. This shows that going forward, as more enrollees use higher-priced drugs, there will be even stronger upward pressure on Medicare program spending.

In short, many factors are converging to drive enrollees into the catastrophic phase of the benefit.

There has been a rapid growth in Part D enrollment, particularly among those without the low-income subsidy over the past few years.

We are seeing higher drug prices reflecting both high launch prices for new therapies and increases in

prices of existing brand-name drugs.

The brand manufacturer discounts move non-LIS enrollees more quickly into the catastrophic phase of the benefit.

And, finally, there may be cases in which plan sponsors find it more financially advantageous to encourage the use of higher-priced drugs because of how rebates and discounts affect their net prices.

The result is more high-cost enrollees and a rapid growth in Medicare's spending for reinsurance.

To summarize, Part D enrollees continue to say they are satisfied. They have many plan options to choose from, and their premiums and cost sharing have been stable.

However, the cost trends are increasingly of concern. Costs for reinsurance are growing much faster than premiums, and prices of single-source drugs continue to grow aggressively and are overwhelming the price-moderating effects of using generics.

Because of the way Medicare shares risk with plans, plans may have incentives to put high-price, high-rebate drugs on their formularies.

With the drug pipeline shifting towards higher-

cost biologics and specialty drugs, use of expensive therapies by Part D enrollees will likely continue to grow, putting even more upward pressure on program costs, particularly the reinsurance, which is the fastest growing and the largest component of program spending.

In April, we plan to come back to you with more detail on key policy areas that we touched on during this presentation.

The first item is related to Part D's exceptions and appeals process and how a move to an electronic prior authorization may improve the process by resolving many of the coverage issues in clinicians' offices.

The second item is how to slow the growth in the number of enrollees who reach the out-of-pocket threshold and the rising cost of reinsurance.

One way to better align plan incentives with that of Medicare's is to reduce Medicare's reinsurance from 80 percent to 20 percent and capitate more of the spending, as we recommended last June. That change would help address plan incentive and rebate allocation issues that Rachel described. The Commission also recommended that the brand discount in the coverage gap be excluded from enrollees'

true out-of-pocket spending. Making that change would lessen the financial advantage of using brand-name drugs over their generic counterparts.

Short of making changes to the law, we may want to explore a different formula for allocating DIRs to address the incentives plans may have in putting high-price, high-drugs on their formularies.

Finally, we will pick up from our October presentation on biosimilars to consider plan sponsors' incentives with respect to biosimilars and their reference products. We'll focus on the financial incentives resulting from brand discounts that apply to reference biologic products, but not to the biosimilars.

In the future, we plan to look into two other areas.

The first is related to specialty pharmacies and how its use might affect access and costs of specialty medicines in Part D. In particular, we plan to examine the different kinds of specialty pharmacies -- such as those that are operated by PBMs, those that are independent chains, or those that are closely aligned with pharmaceutical manufacturers -- to understand the

implications for the Part D program.

The other area is a broader focus on the role of pharmaceutical supply chain in setting drug prices.

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

DR. CROSSON: Thank you, Rachel and Shinobu. We've got time for clarifying questions.

Jack.

DR. HOADLEY: Thank you. There's a whole lot of really interesting material, much of which obviously didn't even have a chance to include in the presentation here today. One of my questions relates to a point that was in the chapter that you did mention, and that was the allocation of the Medicare Advantage rebate dollars, not the drug rebates, but the plan additional savings on the Part C side that are moved over to Part D. And you suggested that it was about $30 a month that's transferred over to Part D.

I was trying to ask you whether it's logical to think -- and you said that was split between -- roughly between basic and enhanced.

Right now, you're reporting about a $7 difference between Medicare Advantage basic plan premiums and PDP

basic plan premiums, and those numbers put together suggest that that difference is maybe fully explained or even more than explained by the rebate dollars. I'm not sure if that's a completely fair thing to draw from those numbers or whether that's -- you can also get back to me if that's ---

DR. SCHMIDT: Yeah. I think I will need to get back to you on that.

I mean, I would note that most enrollees in MA-PDs are in enhanced plans, so you probably need to look at the basic portion of those enhanced plans and the premium associated with that.

DR. HOADLEY: People do make that -- draw that comparison and even to look at the enhanced side, the appearance that MA premiums are lower, but it's distorted by this use of rebate dollars. So anything that could help to inform that question would be helpful.

My second question goes to this CMS formula for allocating the DIR. I assume that a particular formula that they had the discretion to implement a particular way they did. I actually had not looked into that and was a little surprised that they did it the way you describe. So

is it right that this is the discretion? They could administratively use other methods?

DR. SCHMIDT: Yes. We believe that's correct that it's a CMS determination, and I think one of the reasons they're doing it this way is it's administratively relatively easier to do.

DR. HOADLEY: Right. I mean, if you went down to sort of allocate based on actual claims level, money spent above and below the threshold, it would obviously be more complicated. So, I mean, I do see that.

DR. SCHMIDT: I think we will come back to this in the spring, but right now, they are kind of looking at -- it's a gross above spend as a percent of overall gross spend. As we talked about on that one slide with the table, there are portions of the benefit that are not plan liability, and so the issue is associated with that.

DR. HOADLEY: Right. So I look forward to that future.

My third question relates to slide 13 but also to the table in the chapter that this reflects. Here, you're talking about all the trends in average prices and gross spending. It seems to me, it would be useful to have a

parallel analysis for out-of-pocket spending and sort of how much -- would have been the trends in out-of-pocket spending for the high- and the low-cost beneficiaries broken by LIS and non-LIS, and it seems like that would -- we talked about changes last year in our recommendations in the out-of-pocket spending with an absolute cap, and it seems like this would continue to inform that notion of how out-of-pocket trends might be going on.

DR. CROSSON: Clarifying questions. Kathy.

MS. BUTO: Can you say a little bit more about the price protection rebates and whether the beneficiary cost sharing is based on the pre-rebate price or not? I'm just curious about that.

DR. SCHMIDT: But, in all cases, the beneficiary cost sharing is based on the gross or list price, the non-rebated price, no matter what the structure of the rebate.

MS. BUTO: Got it.

DR. CROSSON: Okay. Bruce.

MR. PYENSON: You noted in the report that the LIS has a higher drug use than non-LIS, and I think you identified several reasons for that health status as well as the full coverage. Do you have a sense for how those

two factors interplay?

MS. SUZUKI: I don't know that we can separate out how much of it is due to health status differences versus how much is due because they receive cost sharing subsidy, but we have looked at generic use difference for some of the commonly used drug classes. And we have seen differences there. So I think some of that is probably due to cost sharing being set by law and not a lot of difference between brand and generics.

DR. CROSSON: Okay. So we will move to the discussion part, and I think we have two things here. One is a general commentary, if you have any on the Part D program, but also particularly on slide 16, any support for suggestions for the staff in terms of this or future -- other future work for us to do on Part D.

We are going to start with Amy and then Jack.

MS. BRICKER: Thank you again for the chapter. It's a really good depiction of Part B and the landscape, so I appreciate all of the work.

I am going to struggle to stay in a bit of a box with respect to my comments, but I'll try to make this succinct and be as articulate as possible, so really around

three areas.

Manufacturers create businesses -- their business, and they structure their pricing and their go-to-market strategies based in part by the landscape that Medicare has created.

Plan sponsors don't have the ability with Medicare Part D specifically to use many of what's available in the commercial market to manage cost. So I would encourage the Commission to look more broadly and make recommendations that maybe are in the best interest of the plan and Medicare the benefit specifically.

Plans are not allowed to make midyear changes. When a new drug comes to market, in the commercial world, you would go to the current manufacturer along with the manufacturer coming to market, and you would play one against the other. As a plan sponsor, you're betting in February or March what's going to happen throughout the year, and the manufacturer knows that. If you're a Part D sponsor, you're going to put both drugs on formulary, likely, and your ability to negotiate rebate is minimal at best, so considering midyear changes, the fact that you can't make negative formulary changes midyear also an

issue. Our ability to exclude both from a protected class is an issue. Manufacturers know that there is nothing that a plan sponsor or someone that's trying to manage the benefit can do, and so, again, this is one of convenience for them. Then we wonder why prices go up, because they can, and there's not much that a plan sponsor can do.

With respect to access, there are 68-, 69.000 pharmacies in America, and we talk about McDonald's and Starbucks, and you all know where those are, and you don't wonder how to find one. And yet there are multiples of pharmacies beyond Starbucks and McDonald's, as an example, and yet Medicare has embraced an any-willing-provider provision. Come one, come all. And the ability, then, for plan sponsors to negotiate the best price from pharmacies makes that very difficult.

You mentioned specialty. Couldn't agree more. There is absolutely an opportunity here for plan sponsors to -- they can meet access while still having their own networks. This is a common -- really old tool of commercial plans. So, of course, there's a balance, and we can look at ensuring certain access standards were met, but we should have the ability in managing a pharmacy benefit

to narrow a network, just even for 90-day. What about requiring 90-day fills or maintenance supply medications? We know adherence goes up when that occurs. So, again, just allowing the plan sponsor to do more.

Lastly here with respect to LIS or LIS enrollees, the reason that you're seeing the spending increase is a number of things. It's very difficult. Even if you select preferred pharmacies, this lever doesn't work in the LIS population, and so, one, you don't get the best pricing from retail with respect to LIS because they know that they've given you rate to be preferred status, yet there's nothing that you can do as a plan sponsor to get those members to move to those preferred pharmacies. There's no lever.

Secondly, with respect to formulary, the lever, again, is minimal at best to drive those LIS members to that formulary. So you're out trying to negotiate rebate, yet you have one arm tied behind your back, so more that we can do there.

And people that are beneficiaries of Medicare, most had some sort of either private or Medicaid insurance coming into the Medicare benefit. They are used to these

sorts of things: What pharmacy can I use? What drugs do I have to use? Do I have to get 90 days? These things are normal. So I don't know that we have to feel nervous about putting additional parameters around a benefit. I know it's commonplace.

We've got to do more with respect to appeals. The appeals process in and of itself, it's almost -- it allows too much flexibility with respect to formulary, so very, very high approval of drugs when they're non-formulary or in some cases not covered. Ultimately, the plan is on the hook for those. Very, very few denials of appeal are granted, ultimately.

And lastly -- and then I'll get off my soapbox. Incentives for manufacturers to source and invest where sole-source products exist, we've got to, again, incent manufacturers to invest in this area, expedite the approval process through the FDA.

I am in favor of -- we could look at flipping the 80 and 20 but not in isolation. Plan sponsors actually would embrace taking on more risk. Again, if they had the ability to manage the benefit in a way that they do outside of the Medicare space, they could actually make money in

some cases, but in isolation, to just flip this one aspect of the benefit, I think it goes a step too far without thinking about what other things we could put in place to allow plan sponsors to manage cost.

Okay. I'm done. Thanks.

DR. CROSSON: Thank you. Thank you, Amy.

Jack.

DR. HOADLEY: So I want to both respond to some of Amy's comments and then also go back to the specific list on this slide.

I think to your very last comment, the recommendations we put forward last year, I think, represented a real attempt to have a balanced compromise between some of the goals of different perspectives, and so they did include some of the formulary flexibility kinds of things that you're talking about, and I think that's just important to remind the group that we've done that.

I think going forward with a number of the things that you've talked about, our challenge is finding that right balance, and for every one of the comments around where to give the plans greater flexibility to manage the benefit, which in turn can benefit beneficiaries if it

leads to lower premiums and lower overall prices on drugs, there's got to be a consideration of how we make sure we get the right approach to access for beneficiaries. And from a beneficiary perspective, you shop for a plan in November for drugs that you're going to be purchasing from January through the following December, and so that sort of intersects with some of the midyear flexibilities. You pick a particular plan because it has access to the drug that you need, and then if you find that a pharmacy availability or a drug on formulary has changed in midyear, that's a point of real concern for the beneficiaries.

Obviously, in some cases where there is a specific generic introduction and there's a potential to switch to the generics, that can work out, but I think what a lot of this requires is a greater amount of transparency on sort of what's being done. It is going to require -- and you guys raise this in terms of the exceptions and appeals -- the more electronic tools that allows us to do some -- and you talked about this too -- the ability to make sure that if a midyear change, for example, was done and a particular drug that was on formulary is no longer, that that exception ability is there for the beneficiary.

You're pointing out that once exceptions are filed, they often get approved, and the beneficiary wins. The issue often is the beneficiary doesn't know they have the right to ask for that exception, and so there's questions about how many people really do ask for those.

So those are the tradeoffs that I think we have to get into in terms of trying to reach what we all share as a goal, which his get the program's cost and drug cost and the cost to the individual down is doing it in a way that gives the plans a degree of flexibility to do the things they can do to negotiate prices, but make sure there's enough transparency, enough guarantee of access that a beneficiary who buys a plan and shops for a plan and picks a plan in November is getting what they think they picked for the rest of the year, unlike a system where you could constantly make changes in your choice.

To go back to your sort of menu of options into the future, I think it's a good list. Before I saw this list, I think I already had probably all of those items on as things I had considered to be priority, so I definitely agree that trying to understand -- I've already mentioned this notion of exceptions, appeals.

You know, it's so frustrating because it feels like for a decade or more, we have been talking about electronic prescribing, electronic prior authorization is going to make a lot of the problems we deal with work better, and we keep not quite getting there. And it seems like for reasons that I don't completely understand, whether it's translation of the doctor's office -- because this involves the plan, the beneficiary, the doctor, the pharmacy. All have got to be on board to make these things happen.

So if we could understand better sort of why we haven't made more progress than that and then if there are ways to encourage that progress, we could really make -- I think have some big impact on making that exceptions and appeals process work better.

I think this issue about the DIR and the rebate, I think that's a real issue that would be really helpful to address.

I think applying the gap discount to biosimilars, the specialty pharmacy that you raise that isn't on the slide, but you raised in your comments, I'm concerned

because I don't feel like I understand right now what this is going to look like from a beneficiary perspective. Is this still a brick-and-mortars place that they need to go to, and are those places located conveniently? Are these things that can be done without going to a brick-and-mortars location, either to initially set up and screen for the data? How is this going to work for a beneficiary, and how do we make sure that they're going to have adequate access, particularly for the lower income folks for whom transportation can be an issue?

I think, more generally, we've got to continue to look at the pharmacy networks. I think there's been lots of issues with the preferred pharmacies of people just understanding what's there -- I've made this point in past years -- and making sure that there's access to the more preferred list. People, when they pick their plans, still struggle to understand what they're getting and whether they're really locking themselves into particular pharmacies.

Issues that you didn't mention but came up in your chapter include this reconciliation and the sort of bidding incentives for when the reinsurance payments are

reconciled in the sense that in the end, the government ends up paying more than the 74.5 percent that the subsidies establish and whether there's any ways to fix that.

I brought up the out-of-pocket cost. I think we need to continue to focus on sort of what's the out-of-pocket cost burden, both to continue supporting the recommendation we adopted last year, but just look for trends and see whether the push to these more expensive drugs is -- what kind of effect it's having on out-of-pocket cost for beneficiaries, both at the back end, but also at the front end. And you did raise in the paper the issue of if you have an expensive drug and you're dealing with that initial 25 or 33 percent coinsurance, does it keep people from even starting to take a drug that they really need to be taking or could really make their lives better?

And then the last one is star ratings, and in some other discussions with stakeholders that I've been involved with, there's sort of a general feeling that the Part D star ratings may not really be capturing -- doing a very good job at capturing what's important about the Part

D program.

One that we've spent a little bit of time looking at in this multi-stakeholder group is, for example, the pricing accuracy and stability. The measure that's in there say that is the price on the claim match the price that's on the plan finder at that point in time, but what a lot of people look at when they're shopping for a plan back in November, they'll say, well, I saw a price in November. And when I went to fill my prescription in February or when I redo my prescription in June, I didn't see anything like that price that I thought I was promised, and there's a lot of reasons why that's the case. Prices change. But what are the tools that plan has, and could we in that particular case design a better star rating measure that sort of captures that?

If it's a price increase from the manufacturer that affects all the plans, then it's not going to have a relative effect on one plan versus another, but if some plans use things like these inflation protection rebates to sort of protect their part of the price, could they do the same thing on the beneficiary's part of the price?

So it seems like maybe there's an opportunity to

take a deeper dive into the star ratings and see whether some of the measures there could be improved to better reflect the experience the beneficiaries have with their Part D benefit.

DR. CROSSON: Thank you, Jack.

Further discussion? Bruce.

MR. PYENSON: Thank you. Just a further issue on the incentives associated with cost-sharing and LIS or non-LIS. One of the common features of commercial health plans is that people have access to copay cards from manufacturers, and in the development of Part D that was prohibited. But I think the rationale for prohibiting that was because CMS wanted the incentives for brands versus generics and other -- the cost-sharing incentives to work strongly.

I believe in the -- however, there are patient assistance programs that could affect a lot of spending, especially for higher-priced drugs in Part D, and I believe in the prescription drug event data, you can identify those amounts. So I think it might be an important, useful issue to understand the role of patient assistance programs in the use of high-priced -- the higher priced drugs. So I'm

wondering if that were something that you could look at in the future months.

Thank you.

DR. CROSSON: Thank you. Sue and then Amy.

MS. THOMPSON: Stepping back just a bit, I can't help but -- and I went through the chapter again a couple of times, so thank you for your good work and I look forward to our continued discussion.

But there's somehow an assumption here on the access side that all drugs are good, and there's a cost, not only to the Medicare program but to the individual beneficiary, for a lot of over-medication going on. And I'm wondering if we were to have some context around that, the price of over-medicating our geriatric population, what that does to the demand in post-acute, what that does to the demand in our hospital beds and ICU, if it might help us have a bit of a different philosophical context for the discussion around Part D.

And I think while we're very concerned about access and fairness and equity, and preserving the Medicare program, I think we really have an obligation, from the Medicare beneficiary standpoint, to look at what are we

doing with the number of our patients that are taking too many medications.

The second piece, and it caught my eye even in the executive summary, and it's the point that Jack raised about the more efficient approach, would be to resolve the issues at the point of prescribing. Yeah, simply said, absolutely true. But look to the practicing physician and the amount of work and the amount of complexity and the demands on their time. In today's current reimbursement environment, I would presume -- I don't have data to support this at this point in time -- that's why we run into why we keep kicking that can down the road.

So as I was reading even some of our work around the final chapter that we're going to do tomorrow, around primary care and specialists, and what we're doing to the work flow of physicians when we look to move that decision point, that conflict to that physician's pen or computer, where he's electronic, or he or she is electronically ordering, just to be very thoughtful about the unintended consequences of those recommendations.

So those are my comments, but thank you for this good work.

DR. CROSSON: Thank you. So, let's see. I have Amy, Warner, I had Paul, Alice, and Rita.

MS. BRICKER: Just one comment back on Bruce's point about coupons. What we know is that manufacturers don't give coupons out of generosity, but to counter plans' formularies, period. So when the coupon is given at point of sale, the formulary is kind of moot, the patient feels good, I pay $10, not $100, but yet the plan that's actually footing the bill go forward doesn't get any rebate on that.

So we've got to be careful about our recommendations around coupons. Patient assistance is different. That's different. That's based on need and, you know -- but manufacturers today put a lot of value in coupons when they're not on formulary to get people to do things that the formulary otherwise would direct them to do.

And that other point, just quickly, that Jack made on specialty, I think we also need to be careful about brick-and-mortar access with respect to specialty. I've said it before, but when you're diagnosed with cancer, you don't go see your family practitioner. You see an oncologist, likely, and most of these drugs are very

expensive so they're not in everybody's pharmacy. They typically, if they're able to dispense them, have to order them anyway so there is a delay in receiving them. And we've got to first look at the expertise of those pharmacies to actually dispense and counsel the prescriber and support the patient through that very complex and expensive therapy versus having access on every corner to a specific product.

DR. CROSSON: Thank you, Amy. Let's see. I've got Warner, Paul, Alice, Rita, Craig, and Pat, if that's correct. Not Pat. Okay. Sorry. I couldn't tell.

Warner.

MR. THOMAS: So my comments, I guess, first of all, all of Amy's comments around how we need to take the approach that's used in the commercial area and used in the Medicare area, I would concur with, and I know it creates some challenge in that, you know, things change during the year, but the other reality is that this is a dynamic market, new drugs come on, pricing changes significantly, and to not have the opportunity to adjust benefits, adjust formularies is just -- and, frankly, that's part of the cost escalation.

But stepping back from that, as I sit here, I just don't think we're dealing with this with enough urgency. It's probably the most important issue in the Medicare program today. It's probably the most important issue in health care in the entire industry, is drug pricing. And I'm worried that our comments are around the edges, and we're making some minor recommendations here and there, and we're not taking this on with a level of urgency. If we were the board overseeing an organization that was spending these dollars, and, to some extent we are -- we're at least advising -- I think we'd be dealing with this with a lot different urgency and more swiftly.

The idea that organizations can set their own pricing and change it as they see fit, when they see fit, and spend federal dollars however they want, to me it's just unconscionable. And to see the increases in drug pricing that we're seeing -- we're not talking 5, 10. We're talking 30, 50, 100 percent increases in drugs.

Now, we've all heard the anecdotes, you know, kind of in news and whatnot, but these are really happening. I mean, we buy drugs for my organization. They're happening to us and I'd like to think that we do a

pretty good job trying to get pricing.

So where there's competition, and you can basically look at a situation and switch to a different drugs, I think that works fine because you do have a choice, and I think the approach of -- taking the approach that they use in the commercial world allows you to kind of switch to different drugs.

Where you don't have that opportunity and you've got a sole source, or you've got drug shortages, I think the industry is -- I think the drug industry takes advantage of that situation and moves pricing disproportionately, and I think the Medicare program, the health care industry in general, employers, everyone that buys drugs pay for that.

So I would just encourage us to continue to look at -- and I know this is challenging -- but to continue to look at the idea of indexing inflators, so that we can control the increase in drug pricing, and also, especially in sole-source situations, setting the price. We're setting a cap on the price, so that we can control how these changes occur. Because today, that's not the situation. I mean, if you look at the literature we're

going to study tomorrow in Part B, you see the escalation in pricing. It happens across the entire industry.

So I would encourage us to be after more urgency, be more swift how we do it, and be more focused on, you know, capping the increases and also setting prices where they're sole-source or shortages.

DR. CROSSON: Thank you. Paul.

DR. GINSBURG: The first thing, the chapter and the presentation were really excellent and this is very helpful.

When I listened to Amy's comments, which were very meaningful to me, I started thinking of a context, and, you know, the context of it is that a lot of these issues that she raised were negotiated politically, back in 2003, when the Medicare Modernization Act, which led to Part D was enacted.

But the point I want to make is that the drug market is so different now than it was back then. You know, for the early years of Part D, people were very enthusiastic about how successful the program was because it really did foster generic substitution, and that really saved a lot of money. But that's over now. The issues are

different. We have a lot of new drugs, extremely expensive. Why are they so expensive? Because the demand side of the market has changed, and this is broader. It's not just a Part D issue.

So, in a sense, some of these compromises that were made in 2003, they really shouldn't hold anymore because the pressure, and what Warner was mentioning, you know, this intense short-term -- I mean, not short-term but very rapidly developing price pressure -- means a different solution to some of these issues that were debated, as far as the flexibility that our Part D sponsors should have in negotiating this very challenging market.

So I just wanted to offer that type of thinking, that I think it is time to revisit decisions that were made, that might have been wise political compromises, and question whether they really still should apply, whether the situation is so different that we just have to make different compromises now.

DR. CROSSON: Thank you. Alice.

DR. COOMBS: Thank you very much, Rachel and Shinobu. I just want to say that I appreciate, first of all, Jack and Amy's comments, but I want to speak from the

reference of a prescriber. Sue said something that really resonated with me and I've been thinking about this.

One of the things that would be really good is to have standards developed by vendors and the PMBs that allows the prescriber to actually have real-time information regarding the drugs, the prior authorization. That kind of thing actually improves the efficiency for the providers, and that's the next level, of how do you make a system more efficient where there's a lot of loose ends?

I mean, I've been in conversation with many physicians who say, "Oh, it's direct-to-consumer advertising." I mean, there's a whole lot of discussions out there, but I know one thing that actually moves the meter, when it came to opioid addiction in the state, is to have a multi-pronged approach. The prescription monitoring programs over here. This information that's flowing from a number of venues that allows the prescriber to actually make good information. And there's feedback. You know, you prescribe this. This is the reason why, and there's reporting.

But I think if the vendors adopted standards, it would be something that we could do to move the meter in

the environment for the prescribers, and I think that's huge, and I really agree with you, Sue.

DR. CROSSON: Thank you, Alice. Rita.

DR. REDBERG: I also want to thank Rachel and Shinobu for an excellent chapter, and a big problem and a lot of good suggestions. And like Sue, I always think first, when we're spending all this money, and the dollars are staggering, is it good for beneficiaries? And, you know, particularly because we're now moving to approving drugs more quickly, you know, approving drugs on surrogate marketers, you know, a study published in JAMA Internal Medicine 2015 found that most of the oncology drugs that were approved on surrogate markers had no correlation with survival yet, I mean, these are very expensive drugs coming on the market now.

With the reinsurance question is, you know, the OIG report that came out that echoed a lot of your findings, but highlighted the top ten drugs that are contributing to Medicare's huge increase in spending on catastrophic drugs. For example two of them, both from Gilead at over $30,000 a month, were Hep C drugs, and they came on the market based on a surrogate market, a Hep C

viral load, with a promise that they were going to reduce hepatocellular cancer and cirrhosis. I haven't seen data that they've actually done that. I've seen European data suggesting recurrences of hepatocellular cancer and failure, and I'm wondering if we have any data, because they've now -- the first one was approved by FDA in 2013, but I would be interested to see whether the promises of improved clinical outcomes are paying off for those drugs, because the prices and what we're spending are staggering for those drugs.

And again, same for the cancer drugs. And as we know with the 21st Century Cures Act and the move to approve drugs faster, I'm very concerned that approving these drugs on surrogate markers are not actually good for beneficiaries. They're all very toxic, all drugs have side effects, and we're spending billions of dollars on these.

So I think it's really, as Warner said, urgent to understand better what this money is going for, and a lot of the recommendations, I think, would help address it, but there are a lot of issues here that we really do need to address, for the good of the program and the beneficiaries.

DR. CROSSON: Okay. So I've got Craig, and then

I saw Kathy.

DR. REDBERG: Just one last comment. The other thing I wanted to -- also, in the top ten drugs in the OIG was Renvela, which is for dialysis patients, and it gets back to our discussion last month, because it's outside of the bundle and now it's become a huge spend to lower phosphorus, and I think we need to sort of look at -- again, it's a drug approved on a surrogate marker -- what's it doing and should it be in the bundle.

DR. CROSSON: Craig, Kathy, and Brian, and Jack.

DR. SAMITT: So to start, I want to reiterate support for the June 2016 report recommendations. We've certainly touched on that but it underscores the need for additional flexibility in tools and leverage that plan sponsors can use, similar to what's been used in the commercial space.

But I want to move on. I could not agree more with Amy's eloquent remarks and frustration, and then Sue and Rita tagging onto it. But as I was listening to Amy speak, for me it triggered an even broader issue. I know we tend to have discussions, to some degree, about each of the components of Medicare in silos, but it really brought

up, for me, a more universal problem of low-value services again, and it struck me that, you know, Medicare is nurturing a false paradigm that more care is better care, when there are a growing number of organizations that have proven that less care is better care.

And so I would love to -- I know we had a discussion in the last year on low-value services -- I'd love to bring that discussion back and discuss it more broadly. You know, our focus is, you know, we want to enhance the access and the quality and the efficiency and the service of offerings to Medicare beneficiaries. We're talking about things we order and do, whether it's drugs or procedures or tests, or even providers, that are not high value. And I would argue that we would not compromise our principles at all if we started to make some decisions about not being all things to all people.

I also just began to wonder, have we estimated the true cost to Medicare of low value, whether it's drug or test or network or what have you? I would imagine the number is staggering, that is, a potential savings without compromising any benefits. I'd be interested in knowing what that value is and having a deeper discussion that

spans the silos and segments that we talk about it within.

DR. CROSSON: Kathy.

MS. BUTO: So I support the outline of areas for further discussion in the spring.

One thing that hasn't come up, although I think Rita has touched on it, is the issue of evidence and Medicare's ability to require better evidence over time of appropriateness for the Medicare population. And it strikes me that, particularly in our discussion of sole-source drugs, that Medicare does have some leverage there, to look at whether, as condition of initial coverage, there would be more evidence requirements. What that would be, I can't say, but I just think we can't ignore the coverage side, because low-value care, or inappropriate utilization, or whatever it is, is driven by just the decision for Medicare to pay, and rarely is informed by any evidence of appropriate use within the Medicare population.

So at some point in the future I think it would be helpful for us to touch on that, get into it. It's a tough area. PCORI was explicitly prohibited from getting into this area. But it seems to me MedPAC, it's certainly within our purview to look at these appropriateness, not

just the price.

DR. CROSSON: Pat, do you want to make a point on this?

MS. WANG: No.

DR. CROSSON: Just get in line? All right.

MR. PYENSON: Just to pick up on Kathy's comment, a related question is on the protected classes. I don't recall if that was an issue in the June 2016 recommendation -- it was, and that was -- what was the recommendation?

DR. CROSSON: Do you want to narrow them?

DR. MILLER: Do you want to say it?

DR. SCHMIDT: You look poised to do so, so go ahead.

DR. MILLER: Go ahead [off microphone].

DR. SCHMIDT: So that was part of the June 2016 recommendation. It was one of the -- within the part of providing plans with more flexibility around their formulary. We proposed reducing at least by two the number of protected classes, the ones that had been recommended by CMS a few years earlier, in the 2014 proposed rule.

MR. PYENSON: Is there a basis for being more aggressive on that to change what's a blanket protected

class to something along the lines that Kathy suggested?

DR. SCHMIDT: I think that we had gone with those two because CMS and, in particular, their chief medical officer -- they had a panel that kind of reviewed some of the issues around the degree to which it was important for beneficiaries to have access to the full variety of drugs in that class or not, and -- because, you know, it was their medical opinion, we followed what they had decided.

MR. PYENSON: It's notable that the rules under ACA for the marketplace are much more flexible for the plans than for Part D plans. So there seems to be within HHS differences of opinion on that.

DR. GINSBURG: And maybe also the passage of time, that ACA rules were done in a different era than the Part D rules were done, and another reason to revisit the Part D rules.

DR. MILLER: And I think this is probably clear to everyone, but since it's been implicated, things like why don't you just identify another class of drugs to take off the protected list or, you know, why don't you have some coverage. And what I would say is that the Commission -- what at least I think is hard for the Commission to make

clinical determinations. I've gone into a set of drugs, and I've decided, you know, this because -- I think that's difficult for us. And other people may have a different point of view, but it doesn't mean that you can't speak to it.

So, for example, in Kathy's point -- and I'm making this up just on the basis of 30 seconds of her comment of whether you say, okay, this is the process and the way we want evidence to be assembled and considered before you make a coverage decision as opposed to making specific coverage decisions. And maybe there's some set of rules around the protected classes. We're just calling for CMS to review it and say we think these might be candidates, although we don't have a determination that this class should come up just to push the process along. But I do want to make the distinction between that and the Commission making what ends up being something close to a clinical call, which I think is much harder and much more -- well, harder.

MS. BUTO: Yeah, I just wanted to clarify. My understanding -- it may have changed, but when I was with CMS, the rule was Medicare would cover a drug that's not

prohibited by statute, so Part D, for the labeled use, and there would be flexibility around off-label. And at that time, it was really deferred to carriers, but as I understand it, that is deferred to Part D contractors or vendors.

So the question is: Given that flexibility, is there some room to look at -- beyond the FDA use, you know, how Medicare as a process ought to look, not so much that MedPAC should be making clinical decisions.

DR. MILLER: Yeah, and I figured that's what you meant. I just wanted to say it out loud.

DR. HOADLEY: So I'll be brief. Just following up on some of the comments, you know, the drug co-pay coupons were raised, and one of the issues there -- and, you know, I agree with Amy's comments generally on that -- is that often the drug co-pay coupons, which aren't allowed for the most part in Medicare, when they're used in the commercial sector, they don't even show up in the claims because they're part of the cash transaction, and so it's even further of an issue in terms of trying to understand their impact.

You know, I think the whole discussion about sort

of formulary flexibility and so forth, I mean, you have to go back to the fact that we're in a system that essentially separates the PDPs from the clinicians, and, you know, that's where a lot of the challenge is, whether you're trying to do it as good management, the PDP has no kind of contractual relationship with the prescriber. And so often the tool of implementing that formulary is you're going to show up at the drug store and you're going to discover thereby that your drug was not covered. And if it's a chance or if it was always there from the beginning of the year and you should have known it when you shopped, you know, whatever, and, you know, how we think about coming up with better ways to engage the plans who are the custodians of the payment here with the patient and the clinician over choice of drug, which goes directly to the formulary issues, over broader issues of adherence or broader issues of addressing overuse, you know, the system just isn't set up to do that. And, you know, that's the challenge when we're trying to make rules for Part D in a world that really doesn't kind of make sense to have that as a stand-alone benefit.

The other comment sort of picks up off of Warner

and Kathy to some extent. You know, if these overall trends that are sort of hitting drugs, a lot of which has to do with the sole source, and that's the one area where the plan has the least leverage. I mean, Amy can't go to a manufacturer and say, "I'm going to put you up against your opposition, your competing drug," if there's no competing drug, and so the ability to get a discount. And, you know, maybe this is a case where we're going to raise some of these issues in the Part B discussion, but, you know, should we be raising in the Part D discussion as well, either the issue of when should a drug be approved, which basically is just a passthrough now to the plans; if it's FDA approved and it's not excluded, you know, they do what they do. Or some kind of secretarial authority over prices focused on sole-source drugs, you know, with a negotiation method or whatever. You know, we could get into it, because that's the one area -- and maybe they don't come up very often. Maybe they only come up infrequently. But when they do, there's a good chance they're going to be the high-priced products.

DR. HALL: Thank you. This has been an incredible discussion, largely because you presented these

data in a very comprehensive way, but also understandably, and I appreciate that.

Just listening around the table, just seeing the way our topics have gone forward, we spent a lot of time on what might be called the administrative manipulation formularies. In the non-Medicare space, anyone who's involved with ACOs or any kind of managed care, these kinds of discussions go on all the time, and there's always a sense of hopelessness that we can't really do much about this, and we can't, importantly, link it to the actual prescriber. And that's a very, very important problem that we've touched on.

Then there's always the issue of, well, what are the things that we're -- how would we want to have this cooperation? And I think in the more primitive world of doctors, ten years ago, it was pretty simple that you prescribed generic medications instead of brand-name drugs, and it's pretty much accepted now.

But what I find is that, in working with my own system, that's often not the problem, but it's much more the problem when we get into cost of a single-source drug or a variety of generics that are coming on the market with

a very different price point.

We did some analyses of looking at different ways that diabetes could be managed in our institution -- not a rare disease, and not one, at least at the moment, where the really expensive drugs have not made a big impact. And we found out that, depending on the system and a few assumptions, the care of a diabetic could cost as much as 200 percent differently depending on what kind of variations in pricing had come along. And, in fact, in many cases, going with a brand-name drug was actually less expensive.

When pricing changes with generics, it's very difficult to get that information to the prescriber, and the consequence is -- we found at our institution, particularly in the ACO space, that a relatively simple educational program even helped the very best clinicians and specialists provide probably better care at much less cost.

So I think somewhere, as we talk about this situation and go forward, the points that were made here about there's true opportunity here to improve quality and also reduce price, pricing, by getting a better method of

communication between prescribers and system administrators is just absolutely huge. And we'd be remiss to not make sure that we talk about that when we make recommendations down the lines.

Thank you.

MS. WANG: I think Amy provided an incredibly good road map about how to ensure stronger market forces being able to operate in the Part D space, and I just hope that the 2016 recommendations, which did specifically have recommendation about formulary, are broad enough to also enumerate the other factors that she mentioned. I'm not sure that they are, so I would just put that on the table as something that we should -- I would endorse very strongly, being more explicit about that type of market flexibility to allow competition to prevail.

The broader topic, though, whether it's Part D, Part B, inpatient, drugs, you know, generics, specialty, that I think underlies the conversation and many people's comments is around value, and it is -- I know that this is really hard, but I don't want to take off the table -- and perhaps the Commission has discussed it in the past -- that this is one area where the notion of value-based payment is

not discussed. And I think it's a very difficult notion to introduce perhaps, but I would encourage us to think about whether there are ways -- every sector in health care today is being asked to demonstrate value and to have that reflected in payment methodologies, whether it is attempts through MACRA, ACOs, Medicare Advantage, you know, and so forth -- bundles. And the only sector that is really not being asked, to my knowledge, to demonstrate value in the form of payment methodology is the sector that we're describing today. I think it's difficult to get one's arms around, but I really think that that is a notion that needs to be introduced here. Perhaps it's a different discussion around generic price escalation where it doesn't really seem like -- I mean, the R&D arguments and so forth are a little different. I think Bill and others have described that, to specialty and sole-source kind of why is this level of payment justified for this drug. Where is the value? Where is the return? And there needs to be some sort of demonstrations actually reflected in a payment methodology. It's easier to say the broad concept, but I would urge us not to kind of eliminate that notion of value-based payment from this particular sector.

DR. DeBUSK: First of all, I always enjoy reading the Part D chapters. But every time I read one of these chapters, the one thing -- the impression that I'm left with is: How did we ever let this become this complex? I mean, this has taken on a little bit of a life of its own here. And, again, I don't shy away from complexity when there's utility there, but I would question if we have inadvertently created something that is overly complex. And I do applaud -- I think you guys do a wonderful job when you show some of the different conflicting incentives and some of the perverse incentives there. And I really appreciate that.

So my first -- it's really just a comment. Anytime you get a chance to keep following the money and unwinding some of this, I promise you I will read every page and every table and every footnote. You will have my undivided attention. So anything we can do to at least understand some of that is, again, greatly appreciated.

The corollary to that is, as you begin making -- bringing ideas to the Commission, if you could keep in mind some opportunities to simplify, and I think there are -- there are some existing recommendations, like the 50

percent manufacturer's drug rebate, eliminating that during the coverage gap. I mean, I think there are some good ideas already there, but anytime you get a chance to help us with the fork in the road, simplify the system, I would love to hear that idea and get a chance to consider it.

My second issue is more of -- it's a smaller point, but I was also -- in the reading, you know, they talked about how the MA-PDs offer more generous benefits than the PDPs. I think Jack had mentioned this, too. Obviously, some of that is the plans' rebate getting turned back around into the MA plan -- or into the PD plan. But if there was any way to quantify or get our hands around the synergy or the benefit of the MA plan and the drug plan being combined -- you know, and, again, Jack spoke to that. I think it's been talked about earlier. But if there was some way to quantify what that was.

I think back to that report. There was a mandated report we covered a few cycles ago where they were talking about physician services and their impact on Part D, and it sort of brought back some memories of maybe that's part of what we were trying to get to, is -- and, again, Jack, I think you mentioned this -- having the

prescriber on contract with the drug plan. What is that real synergy there? So I would love to hear more about that.

Thank you.

DR. CHRISTIANSON: Well, unlike Brian, I don't look forward to reading the Part D chapters. They generally give me a headache. It's so complicated. And I always appreciate the work that you two do and the expertise that you have.

As I was listening to the discussion, though, it's interesting how the Commissioners did not really spend a lot of time focusing on this last page, 16. A lot of the discussion was frustration with what barely can't be done, thinking about big changes that are needed in the system and so forth. And so I think the challenge for us as Commissioners, and clearly for Mark, is: How do we want this very valuable, scarce resource, the knowledge that Rachel and Shinobu have, to be directed going forward? And where's the biggest bang for -- you know, best use of their expertise here? We've raised a lot of very high level kinds of issues that we want tackled, basically, and the frustration is all there. So now I think as we go ahead as

Commission and continue to talk about this, our next challenge is to say, Where is the likely biggest value as we go forward? Is it sort of thinking about not including drugs which have limited effectiveness? Is it thinking about giving plan sponsors a lot more flexibility in what they do? And if that's the case, what exactly does that mean? Where is the most potential value?

So I think that's our challenge, and, you know, if Rachel and Shinobu said we're going to spend 80 percent of our time going forward over the next three months working on things on page 16, I'm not sure that that would be consistent with what I hear from the Commission in terms of where they think the big issues are and where the effort needs to be.

So, yes, I endorse these, but, you know, if this means we're not going to tackle some of these bigger issues for another three months or six months or something, then my endorsement is sort of less strong, I guess is what I'll say.

DR. CROSSON: Okay. All right, Amy?

MS. BRICKER: You seem exhausted with me. Just quick, for a specialty, gene therapy is on the horizon,

expected in the next year. There's a seven-figure price tag likely associated with it, so you might want to consider that. And I'd love to talk more about what Pat's recommendation was around, you know, putting the manufacturer on the hook for standing behind their product. If, in fact, they can charge $10,000, $50,000, $100,000, $1 million for therapy, in the Medicare system we're uniquely positioned to track that patient through the rest of their life. And if the outcomes are not seen, refunds come back to the Medicare benefit for that price. Just as an idea.

Thanks, Jay.

DR. DeBUSK: May I comment [off microphone]? First of all, I was saving that for the B discussion tomorrow, but I think that's a wonderful idea. My question would be: Could we now begin building the infrastructure through claims to begin collecting data? Because what I'd hate to see is for us to say, "Oh, wow, let's go do value-based purchasing or at-risk drugs," and then throw up our hands and have no data to support the program.

DR. CROSSON: Okay -- no.

[Laughter.]

DR. CROSSON: All right. Come on.

MR. PYENSON: Just on Jon's point. I would be concerned if we did not reinforce the reinsurance 80 to 20 recommendation and got distracted with other things, because I think that solves a lot of the issues. There's many issues here, but that in my mind is probably the biggest single issue and would address a lot of things.

DR. CROSSON: And that is, of course, a standing recommendation that we've made.

So this has been a good discussion. I actually was wondering, sort of at the beginning when we didn't hear much and I didn't see many hands, whether anybody was gong to say anything, but solved that problem.

No, really, first of all, I just want to reemphasize a couple things that Jon said. One is to thank Rachel and Shinobu not just for this paper, but for the body of work that they have been doing and the level of expertise they bring to us every time they come here.

Now, when you hear the Chairman make a prologue like that, it usually means that there's more work coming. You know, I think, again, similar to Jon, I heard two general themes here, both of which, I think, are worthy of being pursued. One has to do with this question -- and

it's been couched in different terms, "low value," "overprescribing," but essentially the issue of appropriateness of pharmaceutical use. It's a hard area to get to. You know, it's a hard area to get to even for clinicians dealing with other clinicians. But it's an important one because the last thing we want not only is the waste of drugs, but essentially the exposure of Medicare beneficiaries to the complications of pharmaceuticals. We have spent time on multiple prescribing problems before. So I think trying to figure out in the longer run how we could do that is one takeaway.

And the second one here, which is connected to some degree, is the question of whether or not, you know -- I don't know how to say this, but whether or not, you know, our agenda with respect to Part D has been as aggressive as it needs to be with respect to the changes that have gone on, not just in terms of the appropriateness of the Part D legislation, how it's implemented, but also the change in the marketplace, the cost of drugs, the willingness of Americans to continue to spend this amount of money on pharmaceuticals, which have changed over the time since the passage of Medicare Part D.

You know, interestingly enough, with respect to this aggressiveness posture, we're going to get a chance tomorrow morning to take a look at it from the perspective of Part B. But I do think -- then it just becomes a question of timing. So I think the issues you have on the slide are very good ones. I suspect that you already have these in mind for your work processes between now and March and April, and I would encourage you to do that.

Then it becomes a question for Mark and Jim and both of you to think about how to tee up and over what period of time the larger issues that we've brought today, because I'm pretty sure that you're going to hear them again.

So thank you very much, and we'll move on now to the public comment period. If there are any members of the public who wish to make a comment about the issues that we have discussed this morning, please come to the microphone so we can see who you are.

[No response.]

DR. CROSSON: We had a few head fakes going on, but I don't see anybody coming to the microphone, so we are adjourned until 1:15.

[Whereupon, at 12:13 p.m., the meeting was recessed, to reconvene at 1:15 p.m., this same day.]

AFTERNOON SESSION

[1:18 p.m.]

DR. CROSSON: Okay. I think we can reassemble now.

So for the benefit of our guests, we have a process here for the beginning of the afternoon where we're going to take our final votes on our recommendations for the 2018 updates in nine Medicare payment areas.

For those of you who were not at our December meeting or are not familiar with this process, in recent years, what we have done is to have a lengthy discussion in each of these areas with presentations from staff and discussion by the Commission members of all the aspects feeding into the final recommendation in each one of the payment areas, and if at the end of that discussion, we find as a Commission that we are in agreement with the recommendation, then when we come to the January meeting, we have what we call an expedited voting process.

And so you will see both in this session and in the one that follows, this session being focused on the areas of Medicare payment that are not related to post-acute care and the following one related to post-acute

care. That we will be having very quick presentations. We will not be having discussion, and we will be proceeding to the vote.

The only exception to this will be that in the second session, the one related to post-acute care, we are going to be having a presentation of some new material, an introductory chapter reflecting the Commission's perspective on post-acute care payment over the last number of years. So we will be having that presentation.

We will be then voting on the recommendations, and we'll return to the discussion of that new material at the end of that session.

Okay. So we're going to start off with hospital payment, inpatient and outpatient services. Jeff, go ahead.

DR. STENSLAND: Okay. Good afternoon. As Jay may have mentioned, there was a general consensus last month on the update recommendations for several sectors; therefore, we're going to move fairly quickly through the update recommendations, starting with the hospital sector.

But before I start, I want to remind you that in the hospital mailing materials we sent you, there were a

few changes from the December mailing. As several of you suggested, we added a text box where we now restate our past recommendation to equalize Medicare rates between the physician offices and the hospital outpatient department for several services. We also updated the margin data and made other small changes, as you all suggested.

To evaluate the adequacy of Medicare payments, we use a common framework across all sectors. When the data are available, we examine provider capacity, service volume, access to capital, quality of care, as well as providers' costs and payments for Medicare services. And this is the same framework that you'll see when the other individuals come up here to present on their sectors.

As you recall from last month, inpatient spending was up about 2 percent, and this primarily reflected price growth. Outpatient spending was up by about 7 percent from 2014 to 2015, and that reflected an increase in prices, an increase in outpatient volume, including physician office visits. But it also reflected a large increase in Part B spending for separately payable drugs, and Kim will talk about that topic tomorrow. On average, spending increased by about 3 percent per beneficiary.

To summarize our payment adequacy findings from last month, access to care is good, and there's still excess capacity in most markets, despite increasing volumes. Access to capital remains strong, with low interest rates.

Quality is improving. We see lower rates of readmissions and lower rates of mortality.

Medicare margins are low for the average provider, but relatively efficient providers were able to break even serving Medicare beneficiaries in 2015, and marginal profits are positive.

However, as we discussed last month, if current law holds, we would expect negative Medicare margins in 2017, even for those relatively efficient providers.

I should emphasize that we expect access to be preserved because hospitals will still have a financial incentive to see Medicare patients due to revenues exceeding marginal costs in 2017.

So the draft recommendation reads as follows: The Congress should update the inpatient and outpatient payments by the amounts specified in current law. This recommendation retains current law, meaning there is no

impact on program spending, beneficiaries, or providers relative to what current law impacts are.

The rationale behind this recommendation is that, first, most payment adequacy indicators are positive, but margins continue to be negative for the average provider.

The current law update, projected to be about 1.85 percent, will balance the need to have payments high enough to maintain access to care and low enough to maintain fiscal pressure on hospitals to control their costs.

Last month, we also talked about the need to obtain data on the growth of off-campus emergency departments. There was a general consensus on collecting this type of data. Recall the current system provides incentives for growth in off-campus EDs. There are higher rates paid to off-campus EDs than for urgent care centers, even for comparable services. There is also an exemption from the new site-neutral provision for office visits affiliated with an off-campus ED. So there is an incentive for these types of entities to grow.

However, currently, CMS cannot distinguish between on-campus and off-campus ED claims. This means CMS

cannot track the growth of off-campus EDs. The draft recommendation we discussed last month and you will vote on today would change that.

It reads: The Secretary should require hospitals to add a modifier on claims for all services provided at off-campus stand-alone emergency department facilities.

The rationale for this recommendation is that the data would allow CMS and Congress to be informed about the expansion of these facilities and the patients they serve.

The recommendation will not change Medicare program spending. It will also not increase providers' costs materially and only minimally increase administrative burden. Beneficiaries will not be directly affected.

That leads us to the two draft recommendations.

DR. CROSSON: The draft recommendations are displayed for you, as Jeff had read them. All Commissioners in favor of the recommendations, please signify by raising your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: The draft recommendation passes unanimously.

Kate will now take us through physician and other health professional services.

MS. BLONIARZ: So you have received an updated paper, which reflects a few changes since December, and I will go through them briefly.

We added detail on minority Medicare beneficiaries' access to care based on the conversation with Kathy. Alice, we added additional detail on the text surrounding the table showing per beneficiary spending growth and the fee schedule update to reflect some of your questions. And we added more detail about the ratio of Medicare payments to commercial PPO rates, based on the discussion with both Paul and Jack last month.

So to quickly go through the sector, Medicare pays for the services of physicians and other health professionals using a fee schedule, and total Medicare spending for the sector was $70 billion in 2015, or 15 percent of fee-for-service spending.

919,000 practitioners billed Medicare -- 582,000

physicians, 183,000 nurse practitioners and physician assistants, and 150,000 other practitioners, such as therapists.

And the current law update for 2018 is 0.5 percent.

This slide summarizes the payment adequacy indicators. Medicare beneficiaries' ability to access care is largely similar to those with private insurance. The supply of providers per beneficiary has remained constant, and volume of services per beneficiary was 1.6 percent from 2014 to 2015. Differences in provider compensation by specialty continue to implicate mispricing in the fee schedule.

Therefore, the draft recommendation reads: The Congress should increase payment rates for physician and other health professional services by the amount specified in current law for calendar year 2018.

This recommendation is current law, and so it has no effect on federal program spending and is unlikely to affect beneficiaries' ability to access care nor providers' willingness to furnish services to them.

So now I'll turn it over back to Jay.

DR. CROSSON: The draft recommendation is before you. All Commissioners in favor, please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: The draft recommendation passes unanimously.

Dan will now discuss ambulatory surgical center services.

DR. ZABINSKI: Okay. At the December meeting, you had a fair number of questions and comments regarding ambulatory surgical centers, and the draft chapter that you have that has been updated includes responses to those questions.

For Pat, Jack, and Jay, we've added more detail concerning CMS's decision to permit ASCs to suppress quality data from public reporting and added text about the Commission's concern about that policy.

For Bruce, you were concerned that risk scores may not be a useful measure of how much time and resources

it takes to perform surgeries, and we've added text that describes results from a paper that found that patients that have higher risk scores have longer surgery times in ambulatory settings.

For Rita, we added text that states a concern that a nontrivial share of ASC services may include unnecessary or low-value services.

And for David and Jay, there is now text that more strongly states the Commission's belief that the current set of ASC quality measures are not sufficient. In addition, we now say that new measures should be developed, and we describe two potential new measures.

Facts about ASCs in 2015 are that Medicare payments to ASCs were nearly $4.1 billion. The number of ASCs was 5,475, and 3.4 million beneficiaries were treated in ASCs.

And also, our data indicate that beneficiaries' access to ASC services has been good. In 2015, the volume per beneficiary increased by 1.8 percent. The number of fee-for-service beneficiaries serviced increased by 1.2 percent, and the number of ASCs increased by 1.4 percent.

In addition, Medicare payments per beneficiary

increased by 5.2 percent.

Also, growth in the number of ASCs suggest that access to capital is good. Moreover, companies that own and operate ASCs were able to borrow enough to acquire more ASCs, physician practices, and anesthesia practices.

However, our analysis is limited for two reasons. First, even though ASC quality data are available to the public, the quality measures need to be improved, and the data that are available are of limited value, because a nontrivial share of ASCs do not have quality data that are available to the public.

Second, we can't assess margins or other cost-based measures because ASCs don't submit cost data, even though the Commission has recommended on several occasions that these data be submitted.

So we have this draft recommendation for the Commission's consideration: The Congress should eliminate the update to the payment rates for ambulatory surgical centers for calendar year 2018, and the Congress should also require ASCs to submit cost data.

In terms of implications, ASCs are projected to

receive an update in 2018 of 2 percent, which reflects a CPI-U of 2.4 percent less a multifactor productivity of .4 percent.

Therefore, relative to the statutory update, this draft recommendation would produce small savings of less than $50 million in first year and less than $1 billion over five years, and because the number of ASCs has grown and volume of services has increased, we don't anticipate this draft recommendation diminishing beneficiaries' access to ASC care or providers' willingness or ability to furnish those services.

And, finally, ASCs would incur minimal administrative costs to submit cost data.

I will turn things over to Jay.

DR. CROSSON: Thank you. Just to reiterate the recommendation, the Congress should eliminate the update to the payment rates for ambulatory surgical centers for calendar year 2018. The Congress should also require ambulatory surgery centers to submit cost data.

All Commissioners in favor of the recommendation, please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

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

MS. RAY: During today's session, I will summarize the information on the adequacy of Medicare's payments for outpatient dialysis services that we discussed during the December 2016 meeting.

With respect to the questions you asked us during the December meeting, we have tried to address them in the draft chapter, as indicated in the cover memo.

Rita, we have added information about the early initiation of dialysis treatment.

Craig, we have a discussion about the trends in blood transfusions between 2011 and 2015.

Alice, we have added a discussion about spending for dialysis beneficiaries compared to beneficiaries with a kidney transplant.

And, David, we have added discussion about trends in ESRD-related admissions, comorbidities, and

complications.

First, I will review some key facts about the sector. Outpatient dialysis services are used to treat individuals with end-stage renal disease.

In 2015, there were about 388,000 beneficiaries treated on dialysis by about 6,500 providers. Medicare spending in this sector totaled $11.2 billion in 2015.

Moving to our findings on payment adequacy, access to care indicators are favorable. Between 2014 and 2015, growth in treatment stations, a measure of dialysis capacity, grew slightly faster than beneficiary growth.

For-profit and freestanding facilities account for an increasing capacity.

Quality is improving for some measures. For example, between 2011 and 2015, home dialysis modestly increased. We also see declines in the overall hospital admissions rate as well as admissions related to ESRD comorbidities and complications. We also see declines in mortality. We do, however, see an in emergency department use.

The dialysis industry appears to have good access to capital. For example, during the last several years,

the two largest dialysis chains either acquired or purchased majority stakes in other health care-related companies.

Moving to our analysis of Medicare payments and costs, the 2015 Medicare margin is .4 percent, and the rate of marginal profit is nearly 16.6 percent. The 2017 margin is projected at negative 1 percent.

The 2015 margin and the 2017 projection would be roughly the same if we did not include an accounting change that CMS made in 2016 and which we discussed during the December meeting.

So this leads us to our draft recommendation which reads: The Congress should increase the outpatient dialysis base payment rate by the update specified in current law for calendar year 2018.

The draft recommendation has no effect on federal program spending relative to the statutory update. Under current estimates of the market basket index and productivity adjustment, this would result in an update of .7 percent.

This recommendation is expected to have a minimal effect on reasonably efficient providers' willingness and

ability to care for Medicare beneficiaries.

Given the sector's large marginal profit, this recommendation is not expected to have an adverse impact on beneficiaries' ability to obtain dialysis care.

And now I will turn the session back to Jay.

DR. CROSSON: Thank you, Nancy.

The draft recommendation is before you. All Commissioners in favor of the recommendation, please raise your hands.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

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

Kim will now present the recommendation for hospice services.

MS. NEUMAN: So the updated mailing materials you received on hospice included responses to your questions from the December meeting. For example, Rita, we added more information on live discharges. Bruce, we added data

comparing hospice use by Medicare Advantage and fee-for-service beneficiaries. Amy and David, we added information on factors that contribute to lower hospital-based margins for hospices. And Jack and Craig, we added information about the likely magnitude of the effect of the new payment system on hospice revenues, by type of provider.

Now, to summarize, in 2015, more than 1,380,000 Medicare beneficiaries received hospice services, including about 49 percent of decedents. There were nearly 4,200 hospice providers and they received payments of about $15.99 billion in 2015.

Indicators of access to care are favorable. The supply of hospice providers continues to grow, increasing about 2.6 percent in 2015. For-profit providers account almost entirely for this growth.

Hospice use also increased in 2015. About 48.6 percent of Medicare decedents used hospice in 2015, up from 47.8 percent in 2014.

Average length of stay among decedents declined slightly in 2015, and that was due to a decrease in length of stay among patients with the longest stays.

Limited aggregated quality data have recently

become available for hospice, but at this point it's hard to draw conclusions from that information.

In terms of access to capital, the continued growth in the number of providers suggests that capital is accessible.

And so this brings us to margins. As you'll recall, our margin estimates assume that cap overpayments are fully returned to the government, and exclude non-reimbursement bereavement and volunteer costs. For 2014, we estimate and aggregate Medicare margin of 8.2 percent, and marginal profit of 11 percent. For 2017, we project an aggregate Medicare margin of 7.7 percent.

So this brings us to the draft recommendation. It reads, "The Congress should eliminate the update to the hospice payment rates for fiscal year 2018." The implications of this recommendation are a decrease in spending relative to the statutory update of between $250 million and $750 million over one year, and less than $1 billion over five years. In terms of beneficiary and providers, we do not expect the draft recommendation to have an adverse impact on beneficiaries, nor do we expect an effect on providers' willingness or ability to care for

beneficiaries.

And so I'll turn it back to Jay.

DR. CROSSON: Thank you, Kim. The draft recommendation is before you.

All Commissioners voting in favor please raise your hand.

[Show of hands.]

DR. CROSSON: Opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

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

Thank you, Kim.

We are now going to move on to the next session, which has to do with post-acute care. Carol Carter is here, and Carol is going to begin, as I mentioned earlier, with a discussion of some new material for the Commissioners. It's essentially a preamble. We'll form a preamble in our report in March on payment updates for post-acute care. We will then proceed to the voting on individual post-acute care recommendations, and then we'll come back, as a

Commission, to a further discussion based on Carol's new information.

DR. CARTER: Okay. At last month's meeting, Jay asked for an introduction to the PAC update chapters and for us to estimate what spending would have been if MedPAC's recommendations had been implemented.

This introduction to the PAC update chapters highlights the Commission's frustration with the inaction to date by both the Congress and CMS and is background for the update chapters for each sector. Immediately after the update presentations and voting, we'll turn our attention to future PAC payment policy, continuing our work on the recommended design for a payment system to span the four settings and some of the implementation issues.

For more than a decade, the Commission has worked extensively on changes to fee-for-service payments for post-acute care and outcomes-based quality measures. Our payment work has focused on updates to payments and revisions to the payment systems to correct shortcomings.

Our quality work has focused on developing risk-adjusted outcomes-based measures, and pushing for the collection of uniform patient assessment information across

the four settings, and value-based purchasing that ties payments to quality.

While there has been progress made by the Congress and CMS on the quality front, there has been much less progress on payment policy. As a result, payments for post-acute remain high relative to the costs of caring for beneficiaries, and the inequities in payments continue to encourage providers to treat certain types of patients over others and to advantage some providers over others.

Today I will focus on the information related to the update recommendations, but there is information in the paper on the Commission's work on quality initiatives.

The Commission has two goals in making the payment recommendations. The update recommendations aim to ensure that total payments are adequate so that beneficiary access is preserved while taxpayers and the long-run sustainability of the program are protected. The recommendations to revise the payment system aim to align payments to the costs of treating patients with different care needs. Aligning payments and costs for different types of stays increases the equity of the program's payments so that providers have little financial incentive

to treat some beneficiaries over others.

The Commission has had many discussions about the challenges to improve Medicare's payments. Medicare spending on post-acute care varies geographically more than any other service. This variation reflects the lack of evidence indicating which patients need post-acute care and which setting and how much care would achieve the best outcomes. Decisions about where to place patients often reflect a myriad of factors but not necessarily where the patient would receive the best care.

The home health and SNF payment systems encourage providers to furnish services unrelated to a patient's care needs. And across the four settings, Medicare has required providers to use different patient assessment tools that make it hard to compare patients admitted, the costs of their care, and the outcomes that patients achieve.

Medicare margins in post-acute care are high. For three of the four settings -- home health, SNF, and IRF -- they have been above 10 percent for most of the past 10 years. The margins for home health -- that's in yellow -- and SNFs -- those are in green -- have been especially high, averaging over 15 percent over the last decade, even

after rebasing and payment adjustments were made mandated by the Congress. IRF margins -- that's in the light blue -- have averaged almost 11 percent. The average margin for LTCHs has been lower, though still above 5 percent for most of the past 10 years and higher for stays that meet the criteria for LTCH payments.

In each setting, Medicare margins increased substantially soon after the prospective payment systems were implemented, indicating that the base rates were set too high, providers quickly adjusted to the new payment rules, or some combination.

Because the level of program payments has been high relative to the costs of treating treat beneficiaries, the Commission has recommended lowering or freezing Medicare's payment rates for PAC for many years. For home health, SNFs, and IRFs, the Commission recommended no updates each year since 2008 and since 2010 for LTCHs. In addition, the Commission recommended rebasing payments for SNFs for select years and in each year since 2009 for home health agencies. Yet during this period, without congressional action, SNF, IRF, and LTCH payments have been updated.

For home health agencies, although PPACA calls for annual rebasing of payments, the mandated reductions do not go nearly far enough in realigning payments to costs. Given the continued high level of payments, the Congress and CMS need to correct the substantial overpayments in PAC. To correct flaws in the payment systems, MedPAC has recommended revising the SNF payment system and the home health payment system.

The cost to the program of not implementing the Commission's update recommendations is substantial. For example, had the 2008 recommendations to eliminate the updates to payments for home health agencies and SNFs been implemented, we estimate that fee-for-service spending between 2009 and 2016 would be $11 billion lower today, all else being equal. Across the four PAC settings, if this year's update recommendations were implemented, we estimate that fee-for-service program spending would be reduced by $33 billion over 10 years, all else being equal.

Further, revising the home health and SNF payment systems based on the Commission's recommendations would have rebalanced spending towards medically complex care and narrowed the differences in financial performance across

providers, increasing payments for nonprofit and hospital-based providers and lowering payments to freestanding and for-profit providers. The industries as a whole would still be profitable. Further, the payment systems that focus on the care needs of patients rather than furnishing services would dampen the incentive for providers to selectively admit certain patients over others and would improve access for medically complex patients.

And with this as context, we'll begin our update recommendations for each setting. We did not get a lot of comments on the individual chapters, but each was revised to reflect those. Just like the others, we'll give three presentations for each setting and then turn the discussion back to Jay for your vote. We will start with SNF.

In 2015, there were 15,000 SNFs that furnished services for 2.4 million fee-for-service stays. Medicare spending was almost $30 billion.

All indicators point to payments being adequate.

Regarding access, supply was steady, and there was a small increase in admissions though the stays were shorter. In 2015, 88 percent of beneficiaries live in counties with at least three SNFs and less than 1 percent

live in a county without one.

Quality performance was mixed. The readmission and discharge to the community measures improved, but the functional status measures were essentially unchanged.

Capital is generally available and expected to remain so in 2017, but it may be tighter. The reluctance by some lenders does not reflect the adequacy of Medicare's payments. Medicare continues to be a payer of choice.

In 2015, the average margin for freestanding facilities was 12.6 percent. Efficient providers had average Medicare margins of over 19 percent, and the marginal profit was over 20 percent. We project the 2017 margin to be 10.6 percent.

Every year since 2008, MedPAC has recommended no payment increase and to revise the payment system. The broad circumstances of SNFs have not changed. Last month, you discussed the level and equity of Medicare's payments. Regarding the level, Medicare's payments have been 10 percent or more above providers' costs for more than 15 years, indicating that payments need to be more closely aligned with providers' costs. Regarding the equity of payments, the Commission recommends changes to the payment

system that would dampen the incentive to treat certain types of patients over others, would better target payments for drugs and medically complex patients, and these would narrow the financial performance of providers. The draft recommendation addresses both the level and equity of payments. It reads:

The Congress should eliminate the market basket update for 2018 and 2019 and direct the Secretary to revise the prospective payment system for skilled nursing facilities. In 2020, the Secretary should report to the Congress on the impacts of the reformed PPS and make any additional adjustments to payments needed to more closely align payments and costs.

This recommendation, therefore, freezes rates for 2 years while the PPS is revised, and in the third year, the Secretary would assess the need for further adjustment.

In terms of implications, the recommendation would lower spending relative to current law by between $750 million and $2 billion for fiscal year 2018 and by between $5 billion and $10 billion over 5 years.

For beneficiaries, we do not expect adverse impacts. Access for medically complex patients should

increase.

For providers, we expect providers to be willing and able to care for beneficiaries. The impact on individual providers will vary based on their mix of cases and current practice patterns. The recommendation would reduce the disparities in Medicare margins across providers.

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

DR. CROSSON: Thank you, Carol.

The draft recommendation is before you. All Commissioners voting in favor, please raise your hands?

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

DR. CROSSON: Seeing none, the draft recommendation is approved unanimously.

Evan, I believe you are going to take us through home health.

MR. CHRISTMAN: Okay. As Jay mentioned, we're

doing home health next, and just as a reminder, Medicare spent $18.2 billion on home health in 2015. There were over 12,300 agencies in the program, and beneficiaries received about 6.6 million episodes, with 3.5 million beneficiaries receiving services.

Overall, our indicators for home health are positive, if you look at the framework here. The beneficiaries have good access to care; 99 percent live in an area served by home health; 86 percent live in an area with five or more agencies. The number of agencies is near the all-time high hit in 2013, again, with over 12,300 agencies in 2015. The number of episodes increased slightly, and the share of beneficiaries using the service also increased.

The functional measures of quality such as walking and transferring continue to show improvement, and the rate of hospitalization declined in 2015.

Access to capital is adequate. We continue to see interest in the sector by outside investors, with some institutional post-acute firms buying home health agencies to expand their presence.

The margins for 2015 are 15.6 percent, the

marginal profit is 18.1 percent, and the estimated margin for 2017 is 13.7 percent.

I would note that we have revised our 2017 margins since December to completely capture all payment policies in effect. And I would note that these are average margins, and our review of the quality and financial performance for relatively efficient providers suggests that better-performing agencies can achieve better outcomes with higher profit margins than the average agency. The average margins since 2001 under PPS have equaled 16.5 percent for the home health industry.

Since our indicators are positive, the recommendation has several parts this year. The recommendation is to pursue a payment reduction of 5 percent in 2018 followed by a rebasing that would address the high margins of home health agencies. In addition, we have noted a problem with the incentives of the home health PPS: that it uses the number of therapy visits provided in an episode to set payment. Under this system, payment increases as the number of visits rises.

The Commission and others have noted that this incentive distorts decisions about care, and the higher

rate of volume growth for these episodes may reflect financial incentives and not patient needs.

As a result, our recommendation will include a clause calling for the end of therapy visits as a payment factor and would make the system fully prospective by basing payments solely on patient characteristics. Implementing this change would be budget neutral, and it would effectively move money from agencies that do more therapy on average to those that do less.

Our proposed recommendation with these components reads: The Congress should reduce home health payment rates by 5 percent in 2018 and implement a two-year rebasing of the payment system beginning in 2019. The Congress should direct the Secretary to revise the PPS to eliminate the use of the number of therapy visits as a factor in payment determinations concurrent with rebasing.

The impact of this change would be to lower spending by $750 million to $2 billion in 2018 relative to current law and more than $10 billion over five years.

The impact to beneficiaries should be limited. It should not affect provider willingness to serve beneficiaries. Eliminating therapy as a payment factor

would be budget neutral in aggregate but redistributive among providers. The policy would shift funds to agencies that provide relatively less therapy, such as nonprofit and hospital-based agencies, and shift dollars away from agencies that provide relatively more therapy, which are typically for-profit and freestanding agencies.

This completes my presentation, and I turn it over to you, Jay.

DR. CROSSON: Thank you, Evan.

The draft recommendation is before you. All Commissioners voting in favor, please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

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

Dana will present the recommendation on inpatient rehab facilities.

MS. KELLEY: Last month, the Commission discussed the findings from our update analysis of inpatient rehab

facilities. I'll review those findings and then present a draft recommendation.

This slide summarizes the findings from our update analysis. Overall, our indicators of payment adequacy are very positive.

Between 2014 and 2015, the supply of IRFs remained fairly steady. The number of IRF discharges per fee-for-service beneficiary grew by 1.7 percent in 2015, after remaining stable for several years. The average IRF occupancy rate was 65 percent, indicating that capacity was more than adequate to handle current demand for services.

To assess the quality of care in IRFs, we looked at risk-adjusted measures of patient improvement in motor function and cognition. We also looked at discharge to the community and to SNFs and readmission to the acute-care hospital. These measures have been stable or have improved since 2011.

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

Finally, the aggregate 2015 margin was 13.9 percent. Marginal profit in 2015 was 30.7 percent. Unlike most of the other providers we analyze, margins for IRFs increased in 2015, rising about one-and-a-half percentage points. We project they will continue to grow, albeit at a slower pace. Our projected Medicare margin for 2017 is 14.3 percent.

Since 2008, the Commission has recommended that the update to IRF payments be eliminated. However, in the absence of legislative action, CMS is required by statute to apply an adjusted market basket increase. So payments have continued to rise.

But growth in costs per case has been low in this industry. From 2009 to 2015, the cumulative increase in costs per case was 8.3 percent. That compares to a cumulative increase in payments per case of 14.2 percent over the same period. As payments have risen more than costs, margins have grown. The gap between cost and payment growth has been particularly wide for freestanding IRFs. In 2015, margins for freestanding IRFs reached an all-time high of 26.7 percent.

The high aggregate margin for IRFs in 2015 of

13.9 percent indicates that Medicare payments substantially exceed the costs of caring for beneficiaries.

That brings us to our draft recommendation. It reads: The Congress should reduce the Medicare payment rate for inpatient rehabilitation facilities by 5 percent.

Eliminating the update for 2017 will reduce spending relative to the expected statutory update. Spending would be reduced by between $250 million and $750 million in 2018 and between $1 billion and $5 billion over five years. We do not expect this recommendation to have an adverse effect on Medicare beneficiaries' access to care or their out-of-pocket spending.

Even with a 5 percent reduction in the payment rate, we project that the aggregate margin for IRFs will remain above 8 percent. The recommendation may increase the financial pressure on some low-margin providers, but this effect would be eased by our recommendation from last year that the high-cost outlier pool be expanded. You'll recall that expanding the high-cost outlier pool would reduce potential misalignments between IRF payments and costs, so it would redistribute payments within the IRF PPS. With an expanded high-cost outlier pool, the impact

of a 5 percent reduction in the base rate would be smaller for hospital-based IRFs, nonprofit IRFs, and IRFs with low margins.

That concludes my presentation, and I'll turn it back to Jay.

DR. CROSSON: Thank you, Dana. The draft recommendation is before you. All Commissioners in favor please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

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

Stephanie will now take us through long-term care hospitals.

MS. CAMERON: Now, moving to our review of last month's LTCH presentation, you'll recall that in 2015, Medicare paid about $5.3 billion dollars for about 131,000 discharges. The average Medicare payment in 2015 was over $41,000.

In our payment adequacy analysis, we first looked at access to LTCH services. Remember that many beneficiaries live in areas without LTCHs and receive similar services in other settings. While we found a 2 percent decrease in the number LTCH cases per capita, the occupancy rates across LTCHs do not indicate any issues with access.

Next, we considered changes in quality. We lack patient assessment data in this area, and until mid-December there weren't any available quality measures to analyze, so this year, as we have done historically, we rely on aggregate mortality and readmission rates. Since 2010, these measures have been stable or improving.

In considering access to capital, remember that Congress imposed a moratorium on building new, or expanding current LTCHs from 2008 through 2012 and again beginning on April 1, 2014, through September 30, 2017. We found that the moratorium has reduced opportunities for expansion and, thus, the need for capital.

As we discussed last month, the 2015 aggregate Medicare margin was 4.6 percent while the marginal profit was about 20 percent.

Because the implementation of the dual-payment policy began in fiscal year 2016, we calculated a pro forma margin that includes only cases that would have qualified to receive the full LTCH standard payment amount. Using the most recently available claims data, combined with revenue center specific cost-to-charge ratios for each LTCH, we calculated this margin to be 6.8 percent in 2015.

Looking ahead, we project that the LTCH margin for qualifying cases will be 5.4 percent in 2017. While we expect significant changes to admission patterns and per case cost associated with the implementation of the new patient-specific criteria, the extent of these changes is less certain. If we assume the relationship between costs and payments for the cases that qualify to receive the LTCH standard payment amount change to reflect LTCH's current overall cost structure, a conservative margin estimate for qualifying cases in 2017 would be about 3.2 percent.

The extent that LTCHs continue to provide care to beneficiaries who do not qualify to receive the full LTCH standard payment rate will ultimately determine the aggregate total Medicare margin in 2016 and beyond.

With that, the draft recommendation reads, the

Congress should eliminate the update to the payment rates under the long-term care hospital PPS for fiscal year 2018. Eliminating this update for 2018 will decrease federal program spending relative to the statutory payment update by between $50 and $250 million in 2018, and by less than $1 billion over five years.

We anticipate that LTCHs can continue to provide Medicare beneficiaries with access to safe and effective care and accommodate changes in cost with no update to the payment rates for qualifying cases in LTCHs in fiscal year 2018.

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

DR. CROSSON: Thank you, Stephanie. The draft recommendation is before you. All Commissioners voting in favor please raise your hand.

[Show of hands.]

DR. CROSSON: All opposed?

[No response.]

DR. CROSSON: Abstentions?

[No response.]

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

Now I'll ask Carol to return to the table, if you would.

[Pause.]

DR. CROSSON: I think you have a reserved seat for most of the afternoon, Carol.

So we are now going to return to a discussion of Carol's paper, the preamble paper, as well her presentation. And we'll start as we usually do with clarifying questions. Clarifying questions.

Seeing none, we will open the discussion to Carol's paper and presentation.

Jack.

DR. HOADLEY: So first of all, I mean, I think this proved to a really useful overview and I appreciate you spending your Christmas holiday putting this together.

DR. MILLER: Don't bring that up.

[Laughter.]

DR. CROSSON: Over time, over time, over time.

DR. HOADLEY: And I really do think it makes some pretty powerful points about, sort of, you know, the point that you're making, about the cumulative record, and we've been on the record on this for quite a few years and I

think putting it together like this does a nice job. I actually think some of the graphics that you put in the slides fit very nicely in the chapter, like the Slide 5 that has the sort of history of the updates.

And I also think there might be some value in a graphical representation of sort of the cumulating spending examples that you gave, or, if not, you know, for the chapter, certainly something that could go into testimony that might be coming on that.

So that was really my main comment. I really think it makes the case that we were all thinking about in the discussions last time, that this has been -- you know, we sort of look at these update discussions year by year, but this really kind of focuses on the longer-term picture and the fact that, you know, some very different things would have happened had our series of recommendations been enacted over the years. So thank you.

DR. CROSSON: Alice.

DR. COOMBS: So, Carol, I'll remember at the very beginning of this whole process, and I have to say that, you know, with the dyssynchrony that exists within this industry, you've been able to successfully come from that

modeling, looking at the disease processes, and looking at the CCI cases that we initially evaluated.

I think that this is a very good in that it can be used as a template for other areas, and I am very impressed with it and I just want to say that you've done a fine job with it.

DR. CROSSON: Yes. Bill and then Kathy.

MR. GRADISON: This may be around one question but I'll do it quickly.

With regard to rebasing, when that is accomplished, does it always require a statute or are there instances where the secretary can rebase and others where the Congress reserves that right to itself?

MS. CARTER: I think that it typically requires statute, because in the BBA, certainly for SNF, it specifies what the most -- the cost reports of the most recently completed year, that those cost reports be used for the base year. And I'm not sure about the other sectors, SNF -- okay, and where's Stephanie? Oh, I think she just left.

Anyway, I think, in general, you need statute.

MR. GRADISON: Thank you.

DR. CROSSON: Kathy.

MS. BUTO: I realize this is probably around one question, but as I was looking at the -- I agree with -- first of all, the paper's wonderful and really advances our thinking on this.

On page 24 of the mailing materials we talk about Congress should consider lowering the level of payments to more closely align with the cost of states. Were you thinking there of lowering the payment levels across all PAC providers by the same amount, or varying that by some judgment about the amount of, if you will, excess payments to that category of provider?

MS. CARTER: Kathy, I think you're talking about the PAC PPS, and we're not quite there yet.

MS. BUTO: Oh, whoops. We're not quite there yet.

MS. CARTER: But hold that question.

MS. BUTO: You're right.

DR. CROSSON: So you just --

MS. BUTO: That's exactly right.

DR. CROSSON: -- you just asked the first --

MS. BUTO: Now you can think about that question.

DR. CROSSON: So you got the first round one question on the next agenda item. Very nice.

[Laughter.]

DR. CROSSON: Brian.

DR. DeBUSK: First of all, I've really enjoyed your paper too. I thought you made a wonderful case, and, you know, as a call to arms for fixing this sector.

DR. REDBERG: Almost like Part D.

DR. DeBUSK: Almost like Part D. I love Part D.

You know, and I did want to point something out here, and I think this is fantastic that you made this observation, about -- because these overpayments get caught up into fee-for-service, they also get incorporated into MA benchmarks, they get incorporated into ACOs, you know, even BPCIs, for example.

And I just -- and maybe this is a clarifying question, but do we have a feel for just how more sophisticated or how much further advanced they are, and how they're managing PAC, then, say, fee-for-service? I have the sneaking suspicion that fee-for-service is far, far behind in this area.

MS. CARTER: So what I've read in the literature

is that participants in ACOs and in BPCI are much more careful about their PAC use, both in terms of selecting the sector and in shortening SNF stays.

DR. DeBUSK: Is there any work or could there be work done around looking at the outcomes? I mean, could we actually not only be overpaying and corrupting benchmarks but could we also be providing care that that -- is it not beneficial or potentially even harmful to patients?

MS. CARTER: I think that we could be looking at outcomes, and there has been a couple -- there have been a couple of recent articles comparing things like readmission rates. I haven't seen anything that's looking at the harm done to patients.

DR. CROSSON: Okay. Rita.

DR. REDBERG: Just to comment on that, and I was trying to find the reference, but certainly there has been, I'm pretty sure, published work showing that a lot of the savings from the BPCIs with the bundled joint comes from reduction in post-acute care without any harmful effect on outcomes. And then there was just that recent health affairs paper that showed less than 10 post-acute care was associated with better outcomes for enrollees in Medicare

advantage than those in fee-for-service. So it certainly suggests that -- I mean --

[Overlapping speakers.]

MS. CARTER: I think on the outcomes there's been some work comparing it, but in terms of harm --

DR. REDBERG: Harms, right. That's another step.

MS. CARTER: -- to patients I think there hasn't been work on that.

DR. REDBERG: Agree.

DR. MILLER: Yeah, in our walking around the kitchen kind of, you know, sense of the bundling is, the recent stuff is saying, to the extent that you're finding savings, it kind of comes from device negotiations and post-acute care. Lots of our conversations with the ACOs, when we were really focused intensively and talking to them a lot, a lot of them came in and said they were focused on post -- not all of them; some of them had other strategies -- but post-acute care. And my recollection there was, first and foremost on SNF, both whether they went to SNF and how long they stayed there. That's kind of my takeaway there.

MS. CARTER: And -- sorry.

DR. REDBERG: Go on.

MS. CARTER: And just less use of inpatient rehab, and then for some SNF patients, to be sent home with home health care, when that's possible.

DR. DeBUSK: So in other words, other than being overpaid and misaligned and potentially not beneficial, we have no problems in this segment.

[Laughter.]

DR. MILLER: Carol, do not take that question. You know better than that.

[Laughter.]

DR. REDBERG: Just to add, I did find the reference --

DR. CROSSON: She's writing it down, though.

DR. REDBERG: -- which I think you had but I can send it.

MS. CARTER: [Speaking off microphone.]

DR. REDBERG: No, it was actually -- I wanted to be sure it was published. But it was JAMA Internal Medicine last week, on the Medicare bundled payment model cut joint replacements by more than 20 percent, but that was in the mailing materials, at least the editorial that

went with it was. So thank you.

DR. CROSSON: Okay. Seeing no further discussants, Carol, thank you very much for the quick and excellent work you did in providing this. It did hit the spot, as a number of Commissioners have said.

And so, as a reward --

[Laughter.]

DR. CROSSON: -- you get to stay there, and we will go through the unified payment system for post-acute care, particularly from the perspective of when and how aggressively that change might occur.

DR. CARTER: Okay. Well, I want to start by thanking the PAC team because they've been really helpful in putting this work together, and I wanted to thank my colleague, Douglas Wissoker at the Urban Institute.

We just finished up our consideration of current law, and we're, therefore, meeting our statutory mandate to make recommendations about how current payment rates should change for the coming year.

Now we want to turn out attention to future payment policy, and here I am referring to the unified payment system to span the four PAC settings.

In this work, we apply the same guiding principles. We want to align payments to the cost of caring for beneficiaries and to have equitable payments across different types of patients.

In June, the Commission recommended key design features of a unified payment system to span the four settings. Today, I want to start by briefly summarizing that report so we're all sort of at the same starting point and then take up three implementation issues. We're planning on including this information in a chapter in this year's June report.

Under current policy, Medicare uses four separate payment systems to pay for PAC, even though the settings treat many of the same types of patients. As a result of the different payment systems, payments for similar cases can vary considerably.

Further, the SNF and home health PPSs favor treating some types of cases over others. In contrast, a PAC PPS would use a uniform payment system to pay for care in the four settings, base payments on patient characteristics, not the amount of service they received. This would dampen the incentive to treat certain types of

patients over others.

The Congress turned its attention to post-acute care in the IMPACT Act, passed in 2014. It required the Commission to prepare a first report in June 2016 that recommended key features of a PPS, and we estimated impacts. The Act also requires PAC providers to begin collecting uniform patient assessment information in October 2018. Then the Secretary must use two years' worth of these data in a report recommending a PPS design that's likely to be submitted sometime in 2022.

The following year, the MedPAC is required to include a report that proposes a prototype design in 2023. So, on this timetable, it is unlikely that a PAC PPS would be proposed before 2024 for implementation sometime later.

In its June 2016 report, the Commission concluded that a PAC PPS was feasible using currently available data, though the addition of functional assessment information would improve the accuracy of payments for some patient groups. The Commission noted that a PAC PPS could be implemented sooner than the timetable laid out in the IMPACT Act, beginning with a system that does not include the functional assessment data and then to refine the

design over time as these data become available.

Key design features include a common unit of service and a common risk adjustment method based on patient characteristics. Given the differences in coverage across the four settings, the design establishes one payment for non-therapy ancillary services, such as drugs, and one for routine and therapy services.

Payments to home health agencies would need to be adjusted to reflect this setting's much lower costs.

The design should include two outlier policies, one for unusually short stays and one for unusually high-cost stays. And other payment adjusters should be applied uniformly across all stays.

To evaluate the design and to estimate the impacts, we looked at the results for more than 30 different patient groups defined by clinical characteristics, medical complexity, demographics, cognition, and patient impairments. We found that a PAC PPS could increase the equity of payments because the relative profitability would be much more uniform across different types of stays. Average payments would increase for medical stays and medically complex stays and would

decrease for stays with services unrelated to a patient's characteristics.

Because payments would be based on the average cost of similar patients treated across the four settings, average payments would be lower for providers and settings with high costs. The redistribution between different types of stays would dampen the incentive to selectively admit certain types of patients over others.

And, finally, we found that the average payment was well above the average cost of stays.

The report covered other topics, including possible changes to setting-specific regulatory requirements to level the playing field between settings, companion policies to adopt at the same time such as a value-based purchasing policy, and the need to monitor provider responses to the new payment system so that unintended effects were detected.

So that's a summary of where we've been. Now I want to turn to new work.

In June, we said that it would be possible to implement a PAC PPS sooner than laid out in the IMPACT Act, and the Commission identified three implementation issues.

The first is whether to include a transition to PAC PPS rates. The second is the level of payments. Should a PAC PPS be implemented to be budget neutral to the current level of spending, or should the total level be lowered? And, finally, there are the periodic refinements that would be need to be made to the PPS, just like in any payment system.

We wanted to evaluate the need for a transition and the level of aggregate payments, and so we wanted to update our analysis of the 2013 PAC stays so we'd have a better estimate of the starting point for those discussions. For the 8.9 million stays that we included in the analysis, we updated the costs and payments to 2017. And we confirmed that the models accurately predict the average cost of stays for most of the more than 30 patient groups we looked at. The equity of payments across patient groups would increase compared with current policy, and the level of payments was still high, about 14 percent above the cost of care.

The first implementation is whether to include a transition when the PPS is implemented. A transition would phase in the PAC PPS over multiple years, blending new PAC

PPS rates with current setting-specific rates. For example, a three-year transition would begin in the first year with blended payments based one-third PAC PPS rates and two-thirds on setting-specific payments.

A transition would delay the redistribution of payments from rehabilitation-based care towards medically complex care, but it would give providers time to adjust their costs and their mix of patients. By blending with current policy, a transition would dampen the impact of a PAC PPS in the early years, and I illustrate this with two groups, one whose average payments would decrease -- and that's the orthopedic medical group -- and one whose average payments would increase, the severely ill group.

The details for the more than 30 patient groups are included in the paper. You can see that the impacts are proportional to the blending. In this example of a three-year transition, the blending tempers the impacts by one-third in the first year, so that instead of a 6 percent increase or decrease, it would be 2 percent.

To evaluate the need for a transition, we looked at the size of the average impacts across different patient groups. If the average impacts are small for most patient

groups, then maybe there's less need for a transition. If the impacts are large, there's more need for a transition or for a longer one.

We also looked at the distribution of impacts within each group. If there are large differences in the change in payments within a group across the stays, then maybe a longer transition makes sense.

We also looked at the relationship between changes in payments and providers' current relative profitability. If providers that would experience the largest decreases in payments are, in fact, the most profitable ones relative to their setting, we might conclude that there is less need for a transition or for a long one.

I should note that our analyses don't factor in provider responses to the policy changes, which we think are likely. If, for example, providers responded to the PAC PPS by lowering their costs, then the impacts would be less.

Here, we look at the average change in payments for several of the patient groups we've reported on, and a full list is in the paper. You can see that the change in

payments ranges from a 10 percent increase for patients with severe wounds on the far left to a 6 percent decrease for the average payment for orthopedic medical groups, such as hip fracture cases and other neurology medical groups. These are the non-stroke cases.

The changes in payments result in more equitable payments across the patient groups, with much more uniform payment-to-cost ratios across the patient groups compared with current policy. And for all of the groups based on patient characteristics, payments remain well above the cost of care, even for groups with decreases in their average payment.

We also looked beyond the averages and found a wide distribution in the changes in payments across stays. For example, even for groups with average payments that would increase, there are stays for which payments would decrease.

The variation in changes in payments lends support to having a transition.

We also looked at the relationship between changes in average payments for providers and their current profitability. We measured profitability as the ratio of

payments to costs and compared that to their setting average. So it's a measure of their relative profitability to other providers in their setting.

First, let's look at providers who are estimated to have large changes in their payments, and that's the first block in this table. In the first row, we see that of the providers that would experience large increases in their average payments -- and that would be more than a 25 percent increase -- the majority of providers have below-average profitability.

In the next row, we see that providers that would see large decreases in their average payments that is more than a 25 percent decrease, over two-thirds had above-average profitability.

Looking at the relative profitability of providers, we found that of the providers with the highest profitability , over two-thirds would experience decreases in their average payments. Conversely, of the providers with the lowest relative profitability, most would see increases in their average payments.

With the general shift of payments from high-profitability providers to low-profitability providers, we

might temper our assessment of the need for a transition or the need for a long one.

If a transition is included with the implementation, one decision is to think about whether providers should be allowed to bypass it and go straight to PAC PPS rates. Providers whose payments would increase would be most likely to elect this option. Allowing providers to bypass the transition will raise aggregate spending in the early years, but this cost could be mitigated if the aggregate level of payment was reduced as part of the transition.

So let's talk about that level. Our updated analyses estimate that payments exceed the cost of stays by 14 percent. This raises the question of whether the PPS should be implemented to be budget neutral to the current level of spending. If MedPAC's update recommendations for the PAC settings have not been adopted by the time the PAC PPS is implemented, it would make sense to lower the aggregate level of spending to align payments more closely to the cost of stays as part of the transition.

To illustrate the impact of lower payments on the alignment of costs and payments, we modeled two options

that would lower payments by 2 percent and 4 percent. Compared to the current payment-to-cost ratio of 1.14, the ratios would be 1.12 and 1.1, respectively. Even with a 4 percent reduction to aggregate level of payments, the average payment would remain well above the average of cost for all of the clinical and patient severity groups.

For groups whose payments are estimated to be below cost, such as stays with high therapy costs and stays treated in IRFs and LTCHs, therapy practices and the cost structures of high-cost settings explain these results. And given the objective of the PAC PPS, these results are expected.

The last implementation issue is the required maintenance of any prospective payment system. Under the new payment system, providers are likely to adjust to the new system, just as they have done to any other policy changes.

Consistent with other PPSs, the Secretary should periodically evaluate the need to refine the PAC payment system. These refinements include revising the case-mix groups and their relative weights. These changes help maintain the equity and accuracy of payments across the

different types of stays.

Revisions should also include rebasing if changes in cost of stays outpace the changes in payments. Re-basing would realign the level of payments to the cost of stays.

Both types of revisions are part of an ongoing maintenance of any payment system to keep payments equitable across different types of stays and to keep payments aligned with the cost of stays. The Secretary will need the authority to do both.

And with that, I am going to list the topics for your discussion and turn it back to Jay.

DR. CROSSON: Thanks, Carol.

We're going to do questions, and Kathy is going to go first, but I have one myself. And I apologize if this was in the paper and I've forgotten it. But on slide 15 -- so I think you said if the recommendations, including the ones that are so well summarized in the paper you presented before, are not enacted or enacted or implemented, then we would recommend a reduction. And you've got two examples here.

So, if they were, all of them somehow took place,

where would that fall between the 2 percent or 4 percent, or would it be greater or less or what?

DR. CARTER: I haven't done that math, but we certainly could.

I think the thing we should keep in mind -- and so now I'm not quite answering your question -- is I think we would want to make sure that the Secretary evaluates the current level of spending with costs when this comes to be implemented. I think thinking about a specific number might not be quite the right way to go because we don't really know what's going to happen between now and then.

We could do the math sort of back of the envelope, just to give you a sense.

DR. CROSSON: That's okay. I just wanted to see if you knew that.

DR. CARTER: I don't, but I know like in the IRF, which is 4 percent of payments, we've recommended a 5 percent reduction. For home health, which is a much bigger slice of payments -- I'm forgetting right now -- half. So, anyway, you can see the kind of math that we would do.

DR. CROSSON: That's okay. So you have a great future as a press secretary if you're ever looking for

another job. Thanks.

[Laughter.]

DR. MILLER: Wow.

DR. CROSSON: Let's go to Kathy.

MS. BUTO: So I'm going to refine my question a little bit, and this is kind of what I was thinking. If there were going to be a transition, you have designed it in such a way that we could have a portion of payment be the PPS rate and a portion be the site-specific. And what I was wondering was whether the site-specific could be taken down, assuming that what Jay is hoping for doesn't happen; in other words, the update recommendations are not taken.

What would happen if we were to recommend that the site-specific payments be taken down to the level that we think are more appropriate and that level be transitioned to the PPS? Okay. So you're starting at a more, I guess, reasonable level of payment for that site-specific provider is what I was thinking and then moving toward that transition. I don't know if you've thought about that or you looked at it.

DR. CARTER: We haven't. I mean, typically, a

transition is blending actual current payments with a new system. So that would be my sort of first order. I think the Secretary would be blending real payments with new payment system rates set by the PAC PPS.

I think for us, if we want to think about what's an appropriate level, we could do something like that, but that would be different than, I think, what the Secretary would be required to do.

MS. BUTO: It would be interesting still to know the answer to Jay's question of how does that compare to an across-the-board reduction. I mean, just in my mind, since we've already assumed -- I know what you're saying, but since we've already assumed and we believe that the overpayment to some providers, groups of providers is much greater than others, that it might be an opportunity to adjust for what we thought was a more appropriate level.

DR. CROSSON: Clarifying questions.

DR. MILLER: Can I get one clarification on that?

DR. CROSSON: Yes.

DR. MILLER: So the takeaway I'm trying to build in my head is that instead of saying you hit a year and you start transitioning the silo and the unified PPS rates and

weights on a one-third whatever basis, you're saying leading into that, you're saying to the Congress, "I need you to take the silo rates down to their proper levels to sync up with the date that I'm going to do the unified PPS," and then at that point, your rate might be your rate. It wouldn't necessarily be messing around with a blended rate. Is that what you were --

MS. BUTO: It could be. I don't know.

[Laughter.]

DR. MILLER: Okay.

MS. BUTO: It's sort of like walking around the kitchen, I think, is the way you described it.

DR. MILLER: Yeah. No. And we're going to have this conversation at the --

MS. BUTO: I just think it would be interesting to think about that if we really feel strongly.

And I thought the other chapter, the preamble, really laid this out nicely. There have been years of inequity here and correction factor. Whether it's -- and maybe it isn't 100 percent. Maybe it's just part of that correction because we don't want to make that transition too rocky, but why not look at that as well as just an

across-the-board reduction was what I was thinking.

DR. MILLER: Okay. Thanks. I'm sorry.

DR. CROSSON: Okay. So, Bruce, clarifying questions? Bruce. Bruce. Alice. Jon. Pat.

MR. PYENSON: Thank you very much, Carol. A terrific report.

Just a question on the modeling and how you did this. So suppose I'm a patient, post hip and knee. So right now, I'm going to SNF. In the future, I could go to a SNF or I could go to home, and the home care agency and the SNF would get paid the same for me. Is that --

DR. CARTER: So we would be basing payments on the patient characteristics. So, of course, there would be an adjustment for home health care because that cost structure is very different, but the payments would be adjusted for the patient characteristics, regardless of the setting.

This modeling assumes the way we've looked at impacts if the patient was treated in a SNF. We've assumed that the patient -- we didn't change where patients were being treated.

MR. PYENSON: So because under this unified

system, presumably the profitability of Bruce going to home health rather than Bruce going to SNF, the home health agency would make a lot more money probably as profit than the SNF because SNF would cost more?

DR. CARTER: The payments would be higher. I don't know that the profitability would be higher.

MR. PYENSON: So the payments wouldn't be the same if I went to home health or if I went to SNF?

DR. CARTER: No, no. Because the level of payments for home health, given there's no bricks and mortar, the home -- so you missed this last year, but there is an overall adjustment for all stays in home health agencies because the level of payments is fundamentally different than in an institutional setting.

MR. PYENSON: I'm confused, having missed last year. So when we're saying that given a payment is based solely on the patient characteristics, but then it's also adjusted for --

DR. CARTER: So the home health stays are adjusted for the setting. But what I mean by the other statement is that a patient's characteristics in terms of their age, their primary reason to treat, so in this case

it would be that they were a joint replacement, maybe they have certain impairments, they have a certain level of cognition, all of those factors would adjust the level of payment across the four settings in a uniform way. And then, in addition, there's a separate adjustment for home health payments to bring that level down.

MR. PYENSON: Okay.

DR. MILLER: In some ways, isn't it just unfortunate that he picked home health and a setting where his question would have stood if he had picked two institutional settings? So IRF and SNF -- and I want to wade into this carefully, make sure I haven't screwed this up. It was just unlucky, you know, you picked home health. That has a curious adjustment in this because of its cost structure. But if the same patient presented at an IRF or presented at a SNF, the starting proposition is they have the same base payment, and depending on the characteristics of that patient, they should roughly end up being paid the same.

DR. CARTER: That's right.

DR. MILLER: You selected home health, and there is a quirk in the model. Bad luck. But that was just why

I think you guys got crossed up.

DR. DeBUSK: A question. That's just a dichotomous variable that's an adjuster that only applies to home health in that we would build the model up, SNF, IRF, LTCH, identical, and then you just simply introduce that one dichotomous variable --

DR. CARTER: That's right.

DR. DeBUSK: -- to make the adjustment.

DR. CARTER: Yes.

DR. DeBUSK: So, Bruce, it really is that clean.

MR. PYENSON: So in the case of IRF and SNF, if the cost -- assuming the cost structures of IRF are different, that IRFs are more expensive than SNFs --

DR. CARTER: Yes, right.

MR. PYENSON: -- in general, then the profits that I generate for SNF would be higher than if I went to an IRF.

DR. CARTER: Well, here again, I'm trying to steer away from sort of implying a profitability at a case level. The payment system would make the same payment whether you were treated in an IRF or a SNF, and depending on the provider's cost structure, that may be more or less

profitable.

DR. MILLER: But to follow his example for just a second, all else equal, the way he set up the example, IRF is a more expensive cost structure than SNF, and, you know, again, all else equal, it's a true statement what he said. That would be true, you know, in your IRF-SNF example. It would also be true if two SNFs, one had a high-cost structure and one had a low structure. And I think she's trying to carefully pick her way through that.

So, yes, but the way you set it up, what you said is a true statement. The other parts of a lot of this conversation, which I guess he did miss a lot of -- I'm trying to think when we did this report.

DR. CARTER: Yeah, in June.

DR. MILLER: Did he miss it?

DR. CARTER: Right, yes.

MR. PYENSON: I thought I read everything for the last five years.

[Laughter.]

DR. MILLER: I only ask that because I don't want to go over something that you may have read. We also talked about the notion that, you know, this would put

pressure under certain providers, even within a sector, SNFs who are inefficient, or across sectors, IRFs are more expensive than SNFs, to change their cost structure. And as part of that conversation, we said we need to change the regulatory environment so they have the flexibility to do that. But your very narrow question as set up and hypothesized, I think he's right.

DR. CROSSON: Bruce, I have to say, if you read everything that MedPAC has written in the last five years and remember it, it would be terrifying.

[Laughter.]

MR. PYENSON: I'm not that scary.

DR. COOMBS: Carol, I had an idea, and then I thought again. You know, Bruce is talking about something that we've observed in our hospital, and that is that the orthopedic surgeons, because of the ACO that we're kind of incorporated in, they're sending a lot of their patients home. So their driver is a little bit different. They've got a large percentage of commercial as well as Medicare.

Could we, as part of like a two-quarter kind of thing where you want to promote the least -- I won't say the least costly alternative, but the most appropriate -- I

didn't say that.

DR. HOADLEY: Yeah, right.

DR. COOMBS: The most appropriate, efficient care setting, so in that case, would you want to do that to move the transition to early adopters? In other words, that whatever the result of this right here is in conjunction with this, would you want to stick that onto the one in terms of making the early adopters move quicker into the place where we'd like to see site-neutral PACs?

DR. CARTER: So if you allowed early adopters to bypass, you're going to have the low-cost providers -- providers who are going to benefit under this payment system will be the early adopters, and so maybe that accomplishes--

DR. COOMBS: I'm just wondering if you could enhance the transition by a combination of --

DR. CARTER: Of what?

DR. COOMBS: Of a reduction in terms of changing the cost ratio.

DR. CARTER: Oh, and so that would be part of what we'd like to hear your conversation about.

DR. MILLER: We're trying to --

DR. CARTER: This wouldn't be sort of --

DR. COOMBS: I'm going to suggest it then.

DR. MILLER: Yeah, because I think what -- I think, if I'm following this conversation, if you allow early adopters, you're going to get all the people who are efficient. And if you're worried about controlling the cost in that instance, you could say, okay, I'm going to take down the rate to make sure that you stay neutral. Still holding your thought in my head, Kathy.

DR. CROSSON: Okay --

DR. COOMBS: I guess we would probably want to be able to have some other numbers in between to see what's going to move and have the greatest impact as well, to kind of model that out, not just the 2 and 4 percent but maybe --

DR. CARTER: So you would like to see more examples?

DR. CARTER: Yes.

DR. CARTER: Okay.

DR. CHRISTIANSON: This is real quick. I think it's the same issue. You had this discussion of giving providers the option to bypass the transition. It's kind

of a brief discussion in the chapter. And, basically, the only argument I could see for it was that it was done in the past, transition to PPS. Everything else in that discussion seemed to be this is not good. Are there other arguments for that other than historical precedent, it was done when the PPS system was implemented? Because you talk about how it would increase Medicare costs and this and that.

DR. MILLER: The reason that -- but I want your point to stand. Largely, we were thinking of this as an option that has done -- that has happened in the past, so I think you're right. But the reason I also think about it is I know you're going to be shocked to learn that there's often resistance to these ideas. But if somebody thought, you know, within the industry, well, wait a minute, if I'm going to benefit from this and I want it to happen, and I want it to happen fast -- I want the option to happen fast, you get momentum and less ability to try to slow the change down.

DR. CHRISTIANSON: For a cost?

DR. MILLER: Say it again?

DR. CHRISTIANSON: For a cost.

DR. MILLER: For a cost, and then that, of course, brings us to the level --

DR. CROSSON: But the cost could be mitigated.

DR. COOMBS: But I just want to say that there's something very, very different about the way it's being proposed now and historical in that we didn't consider the resource utilization as a major component of the way we're doing it now. I think this is a far better plan for moving forward.

DR. CARTER: Well, it seems -- that was the point that I was going to make, which is the sooner you get providers thinking about the care needs of the patient -- this is a much more patient-centered way of paying providers, and so if you're trying to push providers thinking like that, then maybe you want to encourage early adopters.

DR. CHRISTIANSON: That could be in the chapter, and I don't think it is now.

MS. WANG: So unlike Bruce, I haven't finished the five-year review.

[Laughter.]

MS. WANG: He's much more fun than I am, you

know?

Can you just go back to what you were saying about the development about the PAC concept and the example of the SNF and the IRF? And I guess the end question is: Do you believe that the way that you kind of thought about designing the bundle of payment sufficiently recognizes patient characteristics, needs, service level, intensity, that it would capture legitimate differences in cost between settings?

In my state, we don't have LTCHs, but we have SNFs and we have IRFs. An IRF is a completely different animal in my market from a SNF. An IRF is a hospital. We don't send members to an IRF unless they have needs that really -- they are really, really sick and a SNF cannot take care of them.

So I think that -- I mean, it's a hospital. An IRF is a hospital as opposed to a SNF. So I don't think of these as sort of site-neutral, you know, like interchangeable settings, at least not from what I have seen. And so I guess the question is, if there's no specific adjustment for that kind of setting, do you feel like the adjustment for patient characteristics, severity,

and I guess service needs does take into account the legitimately higher costs that might in an IRF or an LTCh where LTCHs exist?

DR. CARTER: I think that the -- so depending on the markets, I think you do see souped-up SNFs that are taking a lot of the same kinds of rehab patients that some IRFs take. So I'm not sure -- maybe in the markets you're familiar with you're seeing large distinctions. I don't know that that can be blanket statement true.

These payments are trying -- the model -- the design is trying to recognize patient characteristics. It's not trying to capture differences in costs across settings, because we see similar patients treated in different settings with really different costs and really different payments. So that's the whole point of this design, is to say a similar patient is going to receive the same patient and it doesn't matter about the setting, with the little home health caveat.

So to the extent that we've successfully measured case mix differences, I would say that it's doing a reasonable job and certainly as good as the payment systems that are in place now. If you were Warner, I would raise

the question of, well, but you need to level the playing field, because as an IRF I have to -- there are certain requirements to participate in Medicare that make my costs higher. And so part of our report in June was talking about the need to waive some of those requirements and which ones those would be. And we have work that we're planning to do over the next year to do a deeper dive into that, because I think that that's a very important aspect to how do you level the playing field so that the cost structures across the settings -- some of those regulatory requirements raise the cost of settings, and so some of those things need to be waived in order for this to really be fair across the settings to providers.

DR. MILLER: The only thing I would add -- and I had a list here, and you were right on. The one other thing I would have added is we also built an outlier policy, so if somebody's patient goes south, there is an outlier policy to catch them.

And the other thing -- and Carol did make this point; I'm going to make it just a little bit differently. The modeling that she did with Doug and Bowen and whoever else was involved in this, you know, showed a relatively

strong predictive model. And to the extent that the IRF took -- even in this level playing field, the IRF took a more complicated patient, more dollars would follow that patient. Yeah, but your question was enough.

MS. WANG: Connected enough to resource utilization.

DR. MILLER: That's what we feel like we're observing.

MS. WANG: Okay. That's what your model -- may I ask a second question, which has to do with some of the conversation before? I just don't -- I want to make sure that I understand. So on page 13 of the paper, there was a very helpful table to illustrate the percent change in payments between the PAC PPS and current payments and the ratio of payments to costs under the PAC system. So this is prior to the votes that we just took on the update factors. If all of the update factor recommendations were to go through -- because some of them cut payments by as much as 5 percent, others kept them level -- these ratios would change, right?

DR. CARTER: Yes, they would.

MS. WANG: They would, okay. Because this is --

to me this was very helpful in evaluating, you know, the need and the appropriateness of a transition and how long a transition. Is your instinct that it would -- I mean, so for SNF, we just voted to reduce the payment factor update by -- or payments by 5 percentage points. Would I just subtract 5 from this list that, you know, payments between PAC PPS and current payments would go up 7 points, the ratio of payments to costs would be 1.22. Should I just subtract 5 percentage --

DR. CARTER: You can't quite do that because all of the payments do the blending across the settings to establish the average, and so it wouldn't be a simple taking down.

MS. WANG: I see. Okay.

DR. CARTER: Okay? So you can't, I don't think, do a simple --

MS. WANG: Okay. Is your gut feeling that these ratios would change significantly enough that it might raise questions in somebody's mind about the length or the appropriateness of --

DR. CARTER: I think there are reasons to do this design. If the number isn't 14 and instead it's 8, then

that might tell me that I don't need to lower the level. But the idea that you want a uniform payment system that narrows the profitability across the patient groups, that's not going to change. And those are, I think, the main reasons to proceed with something like that. What you're talking about is sort of the level. And I think one of the big benefits of this design is it is patient-centered kind of payment, and so the relative advantage of taking certain types of cases over others would be greatly diminished here.

DR. MILLER: And then I'll just remind you of a statement she made a few questions back, where she said, you know, obviously, if there were many changes in a silo-by-silo basis between now and the day that they implement it, you would definitely want the Secretary to revisit what that ratio is and ask the question: Is it 14 or is it 8? But we're saying assuming the current -- and, of course, the frustration that was expressed around the table in the last sessions was nobody's doing what we're asking. So you may very well be facing this situation.

DR. CROSSON: Okay. We're still on clarifying questions. Did you have another one, Kathy?

MS. BUTO: For Pat's benefit, and maybe Bruce's, one of the previous reports had a good analysis -- Carol did a good job of showing some of the overlap, I think, between patient characteristics --

DR. CARTER: Yeah, I could include that. Yeah, I think you'd be surprised.

MS. BUTO: It gives you a sense of what the overlay is and how much movement there really would --

DR. CARTER: Yeah, I can include that in one of the tables. That's a good point.

MR. THOMAS: Have you done any sort of analysis trying to estimate potential utilization changes? We talked about -- I think Brian brought up before that there's -- we know there's a difference in post-acute utilization in, say, MA versus fee-for-service Medicare. Have you done any sort of assessment of what that utilization change may look like if the fee-for-service Medicare continues to move closer to the MA utilization rates, you know, what that might look like for these various areas?

DR. CARTER: No, we haven't done that. So this is a pretty static view, not assuming -- this is sort of

what behavior patterns were like in '13, updated for changes in costs and payments. But it doesn't reflect, oh, but if PAC use looked more like MA PAC use, what would these numbers -- we haven't done that work.

MR. THOMAS: And has there been any work done on the length of stay differentials? Because it seems like probably some of the utilization here is linked to stay-driven as much as -- I mean, there's certainly a different reimbursement mechanism based on the different discipline, but I know some of these areas, I mean, there's, you know, provisions for 100-day length of stay and that sort of thing. And so my guess is that there's some pretty large length of stay differentials between the different disciplines. Is that correct or not?

DR. CARTER: I think there is, but now we're veering into the encounter data from MA and how good it is, because when we identify MA use, we use patient assessment information, but that doesn't have length of stay on it, and so we'd need the encounter day, and sort of how good is that data, in order to, I think, answer that question.

MR. THOMAS: Has there been any look at, say, high-performing -- because probably the length of stay

issues are more in the SNF world. I'm not sure. I guess you'd have to look at that. But has there been any look at length of stay on high-performing versus other types of facilities and looking at the differential in length of stay?

DR. CARTER: So let me take a quick peek at the SNF chapter because I think it leaves -- I don't know high-performing, but I think for the efficient provider, which, you know, means that the providers have high --

MR. THOMAS: Right. Okay. I mean, we don't have to --

DR. CARTER: Yeah.

MR. THOMAS: So if there is, it might be interesting to try to, you know, think about what that change in utilization might look like as you -- if the right incentive is there to change that.

DR. CARTER: Yeah.

MR. THOMAS: Because that would generate some savings to maybe pay for some of the payment differentials that you want to put in place.

DR. CARTER: Yeah. Well, we haven't tried to model provider behavior.

MR. PYENSON: A question on the transition issue. There's a three-year transition that's been modeled, and I'm wondering about the basis for a three-year transition, you know, three-year or two-year or no transition. And, in particular, when we think about post-acute care in a community, it's post-acute and presumably where a patient gets directed, where a patient gets referred to is appropriate.

So on a community basis, the referral process will -- there won't be a capacity issue if there were no transition at all. The services to care for the patient are there, currently, so a day later, reimbursement might change but there's not a resource issue. So I've just been struck why, in general, the business world works with cliff transitions all the time, and I'm wondering if the perception that we need a three-year transition so that providers can adapt is really appropriate in 2016.

So, put a question mark at the end of that, so it's a question.

DR. CROSSON: Nice question. I think we'll take that as a transition --

[Laughter.]

DR. CROSSON: -- to the next part of the discussion, which is going to be the discussion part of the discussion, and Warner may have forgotten but he volunteered to lead the discussion.

[Laughter.]

MR. THOMAS: I think it was one of two people. Actually, no. I guess the appointed one -- and I did volunteer, right. So --

DR. MILLER: We were going to have other people but then, it's all you.

MR. THOMAS: You were staring me down. I got -- at a weak moment I volunteered.

So it strikes me that, you know, the mental model I have here is, you know, currently most of the SNF and rehab facilities are separate, and LTCH, so many of them are in separate locations, they're -- so it's pretty fragmented. And I think the mental model, if we could create it, would be to have a post-acute facility that, based upon the level of care needed, you basically move from floor to floor, area to area, based upon the clinical needs. And I think what you'd see there is you would also see the facilities operate at a lower cost structure

because they'd be larger, versus having a 20-bed rehab, a 20-bed LTCH, and a 20-bed SNF, you'd have a 60-bed facility that would have three different disciplines, and it more than likely would operate at a lower cost structure.

So I think that would be the mental model I would challenge us to think about as we try to put together the payment mechanism, which then makes it important that we take the other regulatory limitations out of place to allow folks to move from LTCH to rehab or to SNF, or vice versa, you know, similar to an acute care facility where you have, you know, med-surg to ICU and back.

So I think that would be the mental model that I think we ought to think about, which then would probably allow you to have a lower cost structure and potentially, hopefully, lower length of stay, if you take out some of these minimums or maximum kind of length of stay.

So that would just be the mental model I would challenge us to think about. We're actually working to build one of these now that has all of these in one location. I know there are several being built around the country.

And the other thing we may want to think about is

allowing organizations to either be a part of a pilot or have CMMI do some demonstration projects to perfect this, versus trying to change all the reimbursement in kind of one movement. It would be nice to see if you could have, you know, 20 of these as a demonstration and try to see what happens and see if you can impact utilization as well as the cost structure.

So that would be something I think we ought to think about in our recommendations, is that structural model, and then we know we can't rebuild the whole rehab and LTCH and SNF facilities overnight, but if there's new ones that are constructed, or if there are opportunities to reconfigure facilities, you know in your analysis of the rehab -- and especially the rehab facilities -- larger facilities are usually more profitable because they operate at a lower cost structure. And I think it would be the same thing in putting all these disciplines in one location. So that would be something I would challenge us to think about in our recommendations.

DR. CROSSON: Okay. Good notion, Warren. Before we continue, could we throw up Slide 17?

Right. So I think, I'm going to say, my sense of

this is I haven't heard anything in the discussion relative to anybody suggesting the secretary should not have the authority to refine this process over time, but I do think we need to get a little bit more clarity as a Commission about what we think about the need for transition and its relationship to the timing of the change in level of payments. Is that -- Carol, is that kind of what you want?

MS. CARTER: Yes. That would be very helpful.

DR. CROSSON: Right. So let's focus on that. Start with Paul.

DR. GINSBURG: Yeah, well, I've been thinking as this discussion is going on about the trade-off between a more rapid transition and action on lowering the overall level of payments, and, in a sense, what it really poses to us a question of what is our priority? Are we more eager to get the rates down, or to move more quickly into this unified approach?

And I think it might have been Kathy that mentioned it, the notion of integrating a lower payment through the transition, with the new system part being reduced, and the old system part being old. That might actually be a way to combine them.

I should answer Bruce about why we need a transition, and a transition is not because of, necessarily, of the ability of the operators to cope with it. It's to get it through the political system, because, remember, members of Congress are going to be hearing by these providers, "This is the end of the world, what you're planning to do. At least give us more time to adjust." They may not need the time, but at least it delays a piece of it.

MR. PYENSON: I'm glad they didn't have a transition for ICD-10 when we were doing both ICD-9 and ICD-10, so I guess sometimes it works.

DR. CROSSON: Craig.

DR. SAMITT: So I actually like the combination of the need for transition as well as a reduction in payment concurrently, and I guess what I don't fully understand, given that we just voted on recommendations for yet another year, is how are we connecting those prior recommendations with this proposal? And the way that I think of it is a trajectory. You know, in many respects I would even argue that we should retract the payment adjustments that we just voted for and instead develop a

three-year transition plan to the new PAC PPS model, plus the reduction that would concurrently go with it, to get to a competitive level. And it feels like you kind of want to do those two things in lockstep, in a very thoughtful transition away.

So I don't even know whether that's feasible, but given that the annual recommendations are not getting traction, the question is, can we bake the necessary reduction into this PAC PPS proposal as well?

DR. CROSSON: You know, let me see what Mark says, too, but, I mean, I think you're right. There is a little belt-and-suspenders aspect to what we're doing here, and I think, to some degree, you know, it's a function of whether we -- how long we actually think it would take for the discussion and debate at the legislative level, you know, to accomplish this fundamental change in how post-acute care is paid for. And the underlying assumption, which may or may not be valid, is that it's going to take a little while, you know, to get through the political process, as Paul was pointing out, I think. And that maybe our shorter-term recommendations, one year, for the most part -- I think one, or at most, two years -- you know,

would have a better chance, particularly as we've now kind of aggregated the impact of not having done it, and going forward, the amount of money that maybe, that we have a better chance of hitting a single or a double in the shorter term.

Now, if something politically would have changed, and someone -- you know, it looked like Congress, for some reason, decided that they wanted to go ahead quickly with the transition, then I think, conceivably, they would do that, and they might adopt a more gradual rate reduction. But I don't think there's anything, you know, in what we've done with respect to the short-term recommendations that would obviate that in any way. That's my own sense.

Pat and Jack. Did I miss anybody? And Bill.

MS. WANG: On that point, maybe a simpler way to express that is simply to start at the end point and say, in implementing the PAC, the recommendation is that the overall ratio of payment to cost be no greater than 1-point-whatever it is, 0X. There are different ways to get there. One is if the payment update recommendations recommended by MedPAC are adopted, then it could get you that, and if they are not, another way is to do an across-

the-board reduction or to phase it in. But maybe instead of trying to think of all of the mechanics to really state the most important thing, which is we don't think that it should be a 14 percent margin overall, it should be something less than that, and the mechanics could be figured out.

As far as transition is concerned, I think that a transition is important. I think a three-year transition, just to remind, is not really three years. It's two years of blended payments and then by the third year you're in. So it's really a two-year transition. And given the level of change, you know, home health is sort of a different story. I don't understand what you're saying, Bruce, but even in home health, reconfiguring, I mean, home health agencies do things other than take care of Medicare patients. You know, there's a reconfiguration of responsibilities. But certainly anything that's facility-based, you know, if a SNF really thinks that it can take care of patients at the level of need of an IRF, then it's got a lot of work to do, and, you know, I think a three-year transition is -- it's not a long time for a change of that magnitude.

DR. CROSSON: Okay. So I had Jack, Bill, now Kathy. Jack, Bill, Kathy, and Paul.

DR. HOADLEY: So I was thinking in a very similar direction, and sort of starting from where Kathy started earlier, and even Jay, your initial comment. And I think what we could do is be explicit. If were today writing recommendations, you know, for a chapter like this, we could say things like if our March 2017 recommendations were implemented to do the various things they do, both the rate reductions or the rate freezing -- they're all reductions below current law -- as well as the rebasing, restructuring of the systems, as the various systems do, then the transition could be shorter, there's less need to build a reduction into implementing the new system. If they're not implemented, if the Congress does not do the various things we recommended, you know, then more transition, more reductions, et cetera. We can fill in as -- be as specific or as general as we want on those kinds of things.

But I think we can be very explicit about the fact that there's a linkage here, and that's, in a sense you know -- to what Craig said, if they were to act

quickly, we'll, you know, figure out how to do it all in one bundle, and if they don't and they ignore our recommendations this year, as they've done in the last couple of years, then we build things into the new system, transition, et cetera, level of payment to accommodate that.

You know, beyond that, I think, you know, it does make sense to have a transition. I think the issue to me is just how aggressive to be. You know, we could go 50 percent the first year and, you know, the next 25 percent the second year, and then to full. We could be more aggressive on a track like that. We could be -- and then the way we would blend that with the reductions could be the kinds of things you were talking about with Kathy. You know, it could be build the current rates in with some kind of a negative update, per our other recommendations, or that could be the basis to be -- put a bigger piece of the new rates in, with the reduction, how that's done. I mean, there's just a lot of different math you could do to put the pieces together different ways, to get to the end, and we can decide over the next couple of times we talk about this to get very explicit about the options, or we could

just say, a little more qualitatively, there are some variations available that would move these levers up and down.

But I think if we're very explicit in this conversation, in this chapter, to say how this links to what's done on other recommendations, we'd get at a lot of the points we're talking about.

DR. CROSSON: I saw -- let's see. I've got Bill Hall, then Kathy, and then Bill Gradison.

DR. HALL: Thank you. When we first started talking about this, I had some doubts about why we were doing this. It appears that there would be some financial savings to move in this direction, and I wasn't sure that was the right way to go. But as I've thought about this more, I think this is a really interesting opportunity to see if we can sort of change the form and function of post-acute care, coming out of the hospital.

The basic model of having an IRF and SNF, and then home care hasn't changed in 25 years. It's been around for a long time and there's some infrastructure built up there. At the same time, so many -- the paradigm of how you care for an older adult has changed

dramatically. We used to keep hip fracture patients in the hospital, and often cycle them through all three of these care modes, and the entire time of their rehabilitation could stretch out to three or four weeks, and almost invariably they'd end up being readmitted to the hospital because there really wasn't an emphasis on getting the patient home and then supporting them in the home environment.

So it's possible that one of the benefits of this whole program will be that hospitals are smarter than we are and will figure out how one can possibly give better care to people at lower cost, and I think there are many other examples of those kinds of opportunities.

So the hospital industry may, in fact, solve this problem for us if we allow them a certain amount of time. Figure out if you can get people home faster. I think that's always, I think, the emphasis, is not to incarcerate them longer. We all know that now this is a very, very dangerous thing to do.

So that, to me, would be the real advantage of this. Nobody argues with the fact that people get better faster in the hospital -- I mean, at home, if the proper

resources are there, but if all the resources are there in particularly an IRF, what they don't really need doesn't seem to make a lot of sense. So we're arguing over something, but maybe the expertise of the industry could solve this for us over a three-year period of time.

DR. CROSSON: Thank, Bill. I do seem to remember being incarcerated in the hospital when I was an intern.

[Laughter.]

DR. HALL: [Speaking off microphone.]

[Laughter.]

DR. CROSSON: Kathy.

MS. BUTO: I want to support Jack's, and I think Pat's formulation of how to think about framing this as we go forward, this notion of not trying to nail down every detail but trying to start where we've started, with some of the payment inequities with these specific provider types.

I wanted to -- I think we are going to need a transition, just going back to the list, because we haven't quite talked about it but we have a number of regulatory issues that are not insignificant -- three-day prior hospitalization, hospital requirements imposed on IRFs.

You can't go immediately to a PPS when some folks are required to meet, you know, very high-level standards, I think, and requirements for staffing and so on.

So I think, if nothing else, we've got to figure out how to step through that, so I think a transition is a good idea.

The one thing I hope we won't lose sight of is -- and remember at the last meeting, and Alice just ducked out, but Alice was very clear, when I raised the question of whether we really need LTCHs, that they perform an invaluable service vis-à-vis ventilator patients. Now, there aren't LTCHs in New York, so someone else is doing it.

But I think it would be good for us to sort of keep in the back of our minds, yes, there's an overlap of patients in each of these facility types, but there is some -- in some sense, a distinction, too, for some subset of patients, that we either agree is justified and ought to be recognized and paid for appropriately. I just don't want to lose sight of that, that we think everybody is kind of interchangeable, because the distinct -- I was very convinced by Alice's point last time that this is not true,

and there are some subsets of patients who really belong in one versus another setting.

MS. CARTER: And I wanted to remind you that one of the things that we talked about in the conforming regulatory requirement section was the idea of, in the short run, waiving certain requirements, but moving towards patient-defined conditions of participation. So if want to treat ventilator patients, this is the staffing, and these are the -- so much more patient-centered.

MS. BUTO: That's a really good point, and that's going to take a transition. I mean, we can't move immediately if that's the standard we're going to try to achieve.

DR. CHRISTIANSON: Does that speak also to --

DR. REDBERG: Can I just comment on --

DR. CHRISTIANSON: -- does that speak also to the --

DR. REDBERG: -- just comment on Kathy's --

DR. CHRISTIANSON: -- the viability of letting people opt into the new system immediately, or is that a separate issue? I mean, can you have all these regulation issues that have to be worked out, or do they not get

worked out for people that want to just say "I'll go to the new system"?

MS. BUTO: So I think what happens in that case, Jon, is -- correct me if I'm wrong, Carol or Mark -- is that those with the lower-level requirements are the ones who are more likely, as well as those who are going to do well under the new systems, more likely to want to opt in right away. The higher-level requirements folks are going to be arguing -- I think, legitimately so -- we're still carrying some of those additional costs that you're not compensating for in the PPS.

So I don't know if you've thought about that, but I'm assuming that's what would happen.

MS. CARTER: That is, I think, what would happen, yeah.

DR. CROSSON: Rita, first on Kathy, then I have Bill Gradison, and then Brian first, and then Paul.

DR. REDBERG: Thanks.

I just wanted to address Kathy's point on LTCHs and ventilator patients because, I mean, as you remember, there are lots of states that don't have LTCHs and take care of ventilator patients, and there's a lot of murky

issues. There's nothing great about being on a ventilator long term. So, in some ways, having that sort of ability to keep someone on a ventilator and an LTCH is not always so good. It's much better to have more incentive to extubate. Nobody wants to be on a ventilator. You can't talk. You can't live. You can't leave the ventilator.

And we've also talked about a lot of these patients perhaps should be in hospice. So it's not as easy as that.

MS. BUTO: I agree with that, and sort of that's where I was coming from.

DR. CROSSON: Okay. Bill Gradison. I have Brian and Paul.

MR. GRADISON: I've been trying to figure out how to work the word recidivism into this, but I can't figure out how to do that.

[Laughter.]

DR. REDBERG: You just did it.

MR. GRADISON: I guess I did.

I want to try to put this question of the transition in this perspective in which I see it. It was many years ago that the Congress set out this time table

which, under the best of circumstances, following their guidelines would not be fully implemented well into the next decade.

At the time they did that, it was probably the safest course of action, frankly, because just with the natural course of retirements, most of them wouldn't even be there anymore, seriously. And for that matter nor will any of us who are sitting around this table today. Not much is going to happen in the next six years if you really think about it. Well, a lot of planning and all, but in terms of actual implementation if you follow that schedule.

So, personally, I think that it is inconceivable that there won't be a transition. I think there are powerful reasons for it that have already been stated better than I certainly can, but I also wouldn't get in a sweat about what we have to say about it today. I just don't think it's very important what we say about it today. I think the strategic thing is how can we get this train to start to leave the station, however slowly it may move, because it hasn't been moving at all, and we can see that reflected in the failure of those who make the decisions up there to act upon our recommendations, which are hell of a

lot more modest than changing this whole system for some years.

DR. CROSSON: Bill, I just want to clarify. Were you suggesting that for many of us Commissioners, we might be actually experiencing this change as beneficiaries?

[Laughter.]

Brian.

DR. DeBUSK: Well, first of all, as we've talked about this, I mean, we do have, based on the report from last year, an elegant patient-centric model based on the patient's characteristics, not based on the venue. So we've got this really nice thing, and it's in four different venues. And I think in the reading, it refers to this. They have demonstrated the ability to adapt to changes in the PPS rapidly, anyway. I think you did that on pages 28 and 29.

And I think we all agree that we need a transition. I hear a lot of people say three years. Well, Bruce doesn't -- darn it, Bruce. That will have to be at dinner.

But here's the big question. We've got a good thing. We know we need to give it some time to phase in.

We know we're doing it in an industry that can rapidly adapt to change. Would we be willing to trade cost-neutral during the entire transition period in exchange for them adopting this model? What if we didn't take money out of the industry and we trade expediency of implementation for potential savings?

DR. MILLER: Well, I think that goes back to Paul's comment. What is our priority? You did say something along these lines, Paul.

The only thing I would put back in front of you is that you also said I want a front piece that just declares how frustrated I am that nobody has taken action up to this point, and so you would want -- I think you would want to be careful making that argument because delaying a transition can happen relatively easy, and if it's no reductions in payment until that happens, you could be really moving it out in time.

Now, I want to be really clear. It's up to you guys to answer Brian's question, but I want to tell you what I've heard is "I'm frustrated these rates aren't coming down." I heard a whole set of comments over here of like, "Why aren't we actually tying our rates and, in a

sense, almost driving the change?" So I want to say there's a contingent here or a set of comments here who should be responding to that in future conversation.

DR. CROSSON: Who wants to get after Brian? Kathy?

MS. BUTO: Well, I don't want to get after Brian.

DR. CROSSON: I'm sorry. I skipped Paul.

MS. BUTO: I'm sorry . Were you going to respond to --

DR. CROSSON: No. Paul was in line, and I forgot, so I'm sorry.

DR. GINSBURG: Well, actually, what I was going to say is that, first, despite what I said the last time I spoke, there are reasons besides politics in favor of a transition, particularly if we're asking service providers to change. It does take time to change.

When I was going to get up to -- I think Mark's point is really good about that you may think you're making a deal saying faster transition. We will avoid the cuts, but then you won't be able to enforce the deal because they -- so, in a sense, it's very dangerous to do that.

I'm not very enthusiastic about the notion of

giving some providers the opportunity to go without a transition because it seems as though these are the people who are, for the most part, getting a windfall from the new system. They may deserve the windfall, but it's a windfall to them, and it just doesn't seem like a good use of dollars to, in a sense, hand them more money because they're already getting a windfall. It's probably going to be difficult to predict how much this would cost if you're offering this windfall of very rapid transition.

DR. CROSSON: I saw Kathy and Craig. Is that right? Yeah.

MS. BUTO: Just my own preference would be that we proceed with the best policy, sort of combination of policy positions, because I know, Brian, that the Congress will make those tradeoffs, and I'd rather not make them for them and giving them even more room to make further tradeoffs.

We know that something will be done. Even if they were to adopt our recommendations, they're likely to come up with something that's more of a carrot approach than a stick.

DR. CROSSON: Craig.

DR. SAMITT: What struck me when I heard Brian's suggestion that we kind of try to negotiate the transition is all of the prior policy-related recommendations that we've made, and if we've needed to make negotiations regarding some of those recommendations, I don't know if we'd get anything done.

DR. DeBUSK: It did have the feel of a deal with the devil. I'll confess.

[Laughter.]

DR. SAMITT: So I 'd still advocate for, whether it was Pat or Jack or others, recommendations for being a bit more forceful as opposed to being a bit more passive.

DR. MILLER: And then so we're about done?

DR. CROSSON: We are.

DR. MILLER: Okay. Then I have just a couple of summation things.

DR. CROSSON: Yeah, go ahead.

DR. MILLER: So, at some level, I had some sympathy where Bruce started, which is why are we doing a transition at all and particularly if you're looking at a 14 percent. How much do you need? But in the end, I thought the points that sort of drive my thinking ended up

getting set. A real dominant one in my thinking is the regulatory regimes. We have imposed or the program has imposed regulatory regimes. There's probably some complexity in going through there.

I also thought Pat's comment was really good, which is three years is two years, and while I know there are differences of opinion on this, to the extent you said, "And if you want to opt in early" -- and this is fully hearing what people have said, and not everybody agrees -- you actually wouldn't be a third transition. You would get more than a third in your first year would be my guess. So that's kind of the way I feel there.

The other thing on this, the levels of payments and the synchronization for fee -- or the siloes, I'll call it, and then where we're going to, just a few things. First of all, Craig, thank you for making your comment on commissioner bingo. That was a huge winner there. I knew someone was going to say it, and you said it almost word for word, so --

DR. SAMITT: Is that a good thing or a bad thing?

DR. MILLER: No. That's a good thing for me, okay?

[Laughter.]

DR. MILLER: But there's a few things to think about. It is a complicated thought in a couple of ways, and I don't know if you guys meant this the way some of the comments went.

And I do think there is an out here where we can talk about linkage in a qualitative way, to use your word, between the siloes and the unified, and I think we can do a good job of sort of drawing a relationship between them.

I do think you have to be careful about some of the mechanical, like where you're saying working through the individual things, and here's at least two that I would be worried about. One is if you started making recommendations on the basis of a hypothetical world, you will be in a unified PPS, and that wasn't a certainty. Driving your updates on the basis of something that doesn't exist, I think, is harder to defend. That's the first thought. And the second thought is -- and, of course, I'm not sure if you were saying that exactly. So, if I'm off, I apologize.

But the other thought is this. Remember inside the siloes, part of our frustration is we want the PPS to

be reformed and focused on a patient because we think it will bring much more equitable payments, and so driving a set of reductions still in the absence of that rebalancing still has to be thoughtful because you don't want to put certain providers who take certain types of patients under water.

So, with those two caveats in mind, I do think we can write to this linkage, but those were the thoughts that were occurring to me, okay?

MS. BUTO: I don't understand your first point. Can you say a little bit more about that?

DR. MILLER: Which was the first point? Because in my mind, I passed out.

[Laughter.]

MS. BUTO: It had something to do with driving to a hypothetical and --

DR. MILLER: Yeah. I don't know if you guys were saying this.

MS. BUTO: Most of these PPS changes are hypothetical at the time they're thrown out there as legislative proposal.

DR. MILLER: Right. But if we were to say --

and, again, I'm not sure anybody said this, and so I may just withdraw the point. If our recommendation was saying we're assuming a unified PPS exists and then we're setting your update on this basis, that would have to be -- we would have to think that through.

So let me put it to you this way, Kathy. We make the recommendation in SNF and home health, where we take -- or in IRF, where we say we're taking a reduction because we also have some other ways to adjust the underlying payments. Do you see what I'm driving at?

Let me take home health. We said a 5 percent reduction in home health. That is coupled in the recommendation with -- and you need to be revising the PPS because it will strike a better balance underneath that rate between therapy and non-therapy types of services. So that we think even with this lower dollar, patients will still be served because they will be of equal attractiveness to the provider.

In making a recommendation, looking down the road to a unified PPS, we would have to really incorporate the presence and the impact of that unified PPS in making the update recommendation. Otherwise, we could potentially be

taking providers that look like this and lowering them as opposed to leveling them and then lowering them.

MS. BUTO: I think I get what you're saying, but I tend to think of it as more like rebasing before you actually start the transition, rebasing the total amount for that provider entity, but this is probably a lot more complexity than we need to get into.

DR. MILLER: And between you and me, this may be a dollar amount that we're talking about each other. You can take this much out safely and then think about it after the -- if you need more after the unified PPS. I think there is a place where we can meet.

DR. HOADLEY: And that was when I talked about that sort of qualitative thing, it was thinking about all of those pieces. So it was not just the reductions, but the recommendation, existing recommendations have for rebasings or new systems, and to the extent that those are done, we're already on a track that's vaguely in the same direction as the unified would take us or at least getting that tilting that you were talking about a little more lined up.

DR. MILLER: Right. If you adopt these set of

recommendations that we have proposed here, the amount that you would need to take out --

DR. HOADLEY: Exactly.

DR. MILLER: -- at the point of transition is less, and we might even be able to do some back-of-the-envelope --

DR. HOADLEY: Right. To the extent that we can get any numbers to put some meat around that, that's great, but even if we can't, we can talk about the principle of the moving parts intersect.

DR. MILLER: I just got to write this at some point.

DR. CROSSON: It's all good. We're all in the same place. Everybody write down where they think we are.

[Laughter.]

DR. CROSSON: No. I think it's been a very good discussion, and I think we've kind of come to a point here where Carol has sufficient information for her to come back to us with a definitive answer. Thank you, Carol.

By the way, I think you may have come close to setting a record for occupying that chair for the longest period of time, not certain. I don't keep that record, but

thank you for all your work, of course.

Okay.

[Pause.]

DR. CROSSON: Okay. I think we're settled pretty much behind you. So the last presentation and discussion for the day is going to be on balancing MIPS and A-APMs in MACRA. You get a lot of letters on the board at the same time.

Kate, it looks like you're going to start. Kate and David are going to take us through some ideas about how both Congress and CMS could, if they wish to, take some actions to improve MIPS and A-APMs. Thanks.

MS. BLONIARZ: Hi. So as Jay said, we're going to go through MACRA, describe implementation and some of the recent activities, and MACRA, as you know, changed the way that Medicare pays for clinician services starting as of last year.

So here's the outline we'll follow. The Commission has discussed MACRA on three prior occasions, and in last year's report to Congress, the Commission released principles for advanced alternative payment models, or A-APMs. And in the prior discussions, some of

the issues that have come up is the feasibility of MIPS, the relative attractiveness of MIPS versus A-APMs, and the appropriate amount of risk for practices to take on in A-APMs. And these are some of the issues motivating today's discussion.

So I'll summarize MACRA and the rulemaking that CMS has released to date, and then we'll move into policy discussions -- ways to restructure the MIPS program, and addressing the balance between the MIPS and A-APM path. David will discuss redesigning the A-APM incentive payment and how risk should be shared for certain types of practices, such as small clinician practices.

I also like to thank Sydney McClendon for her help.

This slide lays out the statutory requirements. MACRA sets out two paths for clinicians, starting in 2019. Clinicians with a certain level of participation in A-APMs will receive an incentive payment of 5 percent on their Medicare fee-for-service fee schedule revenue and higher updates in the future.

The statutory definition of A-APMs is that models must require participants to bear risk above a nominal

amount, use electronic health records, and the model must make payment on the basis of certain quality measures.

For clinicians that aren't in that category, a new program, the merit-based incentive payment system, would apply. MIPS is an individual-level payment adjustment that will use clinician-reported information on quality, use of EHR, and practice improvement activities, plus claims-calculated cost measures, to create a composite score that will apply to all the clinician's payments from Medicare.

The first year that MIPS and A-APMs will take effect is 2019, and CMS has set 2017, this year, as the reporting year for the 2019 payment year. This slide has a few highlights of the final rule, and I can address any other issues on question.

For the first year of MIPS, CMS is requiring only a minimal level of clinician reporting in order for them to be held harmless from negative MIPS adjustments. For each of the four MIPS categories, CMS reduced the requirements for clinician reporting from their proposed rule to the final.

Throughout the rule, CMS also states that their

intent is to increase the number of clinicians participating in A-APMs, and the rest of the slide goes through some of the ways that they intend to do that.

First, CMS established the definition of "risk above a nominal amount" for A-APMs, and there are two definitions. Models can qualify under either criteria. The first is that the A-APM entity must be at risk of losing or being required to repay at least 3 percent of the benchmark.

Second, the APM entity must be at risk for losing or being required to repay at least 8 percent of their own revenue, and David will talk about this policy in more detail later.

CMS made other policy changes, including allowing the mandatory episode payment models currently underway to potentially qualify as A-APMs. And on Tuesday, CMS released a fact sheet describing the new ACO model -- Track 1+ -- that incorporates a lower level of risk than the current ACO programs.

Over the next two slides, I'll describe some of the issues with MIPS program and describe a set of policies that you could consider for how the program could be

redesigned.

The quality component in MIPS will include almost entirely self-reported process measures that have very compressed performance. In addition to these quality measures, clinicians will also report and attest to clinical practice improvement activities and use of electronic health record technology, both of which are "check-the-box" activities that may not correspond to care improvement. The burden of reporting these measures may outweigh their value to the Medicare program.

Each clinician will have a composite MIPS score based on performance on measures that they choose, not from a uniform assessment of performance across all clinicians. In addition, because clinicians can choose which measures they report, it could be for a small number of patients, with corresponding noisy performance. And for most measures, clinicians will not know in advance how well they need to perform to score highly.

In sum, MIPS is unlikely to help patients identify high-value clinicians nor provide clinicians themselves with meaningful, actionable feedback.

A redesign of the MIPS program should build off a

clear-eyed assessment of the limit of the national Medicare program's ability to assess clinician performance and produce an individual payment adjustment for every clinician billing Medicare.

Here's a set of policies that you could discuss for ways to redesign MIPS.

First, CMS should move away entirely or largely from clinician-selected and reported measures. Instead, CMS could calculate measures of quality, resource use, and patient experience directly. This would address the burden on providers and the non-comparability across providers in the current program.

Second, clinician performance could be aggregated and assessed across a local market area or measured at the clinician group level, and this would address some of the concerns about the relatively small number of observations for some clinicians.

And, third, Medicare could focus its efforts on clinicians who have practice patterns that reliably indicate poor performance or inappropriate use of services.

In total, the idea of this approach is to address concerns about burden, comparability, and reliability in

the current MIPS program.

Switching topics to the balance between the two paths, the Commission has stated an interest in moving clinicians from MIPS to A-APMs, and one way to do this is by making MIPS less attractive.

Under current law, there is the possibility for very high positive MIPS payment adjustments, which could persuade some clinicians to stay in MIPS.

Part of the reason for these high payment adjustments is that the law created an exceptional performance bonus of $500 million per year for clinicians at or above a certain threshold. But if MIPS overall is unlikely to identify high-value clinicians, then this additional funding is unlikely to be well spent. The MIPS exceptional performance bonus could be repealed altogether or used for another purpose, and Ariel will talk about using it for primary care tomorrow.

Another option is to set the MIPS adjustments so that the maximum upside is relatively small. In other words, clinicians could do okay in MIPS, but not great.

Finally, a redesign of MIPS like we just discussed would simplify the choice facing clinicians. For

example, if performance can be calculated solely by CMS from claims and other information, not requiring any clinician reporting, clinicians could be in both programs, proportionately. In other words, clinicians would have the share of their revenue in MIPS adjusted by the MIPS amount, and the share of their revenue in A-APMs, eligible for the A-APM incentive payment. Or another option is to exempt clinicians from MIPS altogether if they have any A-APM participation.

I'll turn it over to David now to discuss A-APM policies.

MR. GLASS: These are the principles you established that were included in the June report and in our comment letters. For simplicity we will use the term "entity" as shorthand for an entity in an advanced alternative payment model.

The first principle limits the 5 percent incentive payment to clinicians in entities that succeed. This was designed to drive real change in the delivery system.

The second principle recognizes that success cannot be measured reliably unless there is a sufficient

number of beneficiaries attributed to the entity.

The third recognizes that unless the totality of Medicare spending is considered, the incentives can lead to behavior that is not optimal for the totality of patient needs. If only a subset of spending is measured, it would be deemed success although spending could go up in total, which would be bad for the program and beneficiaries.

In addition, to engage beneficiaries, entities can share in savings with them, the entity is given regulatory relief because incentives for overutilization are eliminated, and a single entity must assume risk rather than participants individually.

So those are your principles.

Now, in light of these principles, the basic design of the 5 percent incentive payment needs to be rethought. You could consider a change in law that would apply the 5 percent incentive payment only to the clinician's revenue coming through an advanced APM. This would make the reward proportional to one's A-APM participation. Currently, the 5 percent incentive is applied to a clinician's previous year's physician fee schedule revenue, but only if the clinician passes the

threshold of 25 percent of revenue being through an A-APM. This design creates uncertainty over whether the clinician will meet the threshold and is an all-or-nothing situation.

For example, a clinician with 24.9 percent of revenue coming through an A-APM gets nothing while one with 25 percent gets 5 percent on all revenues. So this kind of payment cliff does not seem equitable and is something we try to avoid in most payment systems.

In addition, you could consider changing the law to only award the incentive if the entity is successful in accordance with the Commission's first principle. So together these changes would be more equitable for clinicians and more likely to protect the trust fund.

Now, before we proceed, I have to take a step back to build on a somewhat technical point we mentioned earlier. Again, the concept, I think, in CMS' mind behind this was to make it possible for small practices to take on two-sided risk.

The final rule includes a revenue-based nominal risk definition in addition to the benchmark-based definition we are more familiar with. This is just a numerical example to get some idea of what any of that

means.

So the standard is the minimum amount that the model must require to be deemed at more than nominal risk and, thus, meet the criteria in law to be an advanced alternative payment model. On the slide we see a numerical example of how this might work. Let's assume this entity is attributed 1,000 beneficiaries under some advanced alternative payment model. And let us further assume the benchmark spending per capita is $10,000. Then the total A and B benchmark for that entity will be $10 million.

Finally, let's assume that the clinicians in the entity receive $500,000 in Medicare physician fee schedule revenue. That is about 5 percent of the benchmark A and B spending, which is about what primary care accounts for. We will also assume for simplicity that all of this entity's clinician revenue is through the advanced alternative payment model.

So how do the two standards compare? Under these assumptions, the benchmark-based 3 percent standard would be $300,000. The revenue based 8 percent standard would be $40,000. So this is much less than the benchmark-based standard. It turns out under most likely scenarios the

revenue-based standard will be less than the benchmark-based standard. In addition, if the practice received the 5 percent incentive on its revenue, which would be about $25,000, the resulting risk would be only $15,000. So the revenue-based standard can result in a very low level of nominal risk.

If the concept is to make it possible for small practices to take on risk that is more proportionate to their ability to absorb risk, this seems to be moving in the right direction, but maybe a little beyond.

The underlying fact is that there is a disproportion between a clinician group's revenue and the entity's benchmark because a primary care group, for example, has only about 5 percent of the benchmark as its own revenue. The other spending goes to other providers. That is a lot of leverage, which works fine if you are in a one-sided risk model, but can be too much to venture if you are at two-sided risk. In this example, a 10 percent loss limit -- 10 percent of benchmark -- which is lower than for most two-sided ACO models, would be $1 million, which would be twice the revenue of the practice.

So if we keep that last example in mind, here's a

possible design to make it reasonable for small practice entities to take on two-sided risk.

Again, we assume practice revenue of $500,000 coming through the A-APM, and now we set a risk corridor or limit on rewards and losses of plus or minus 20 percent of revenue. This is more than the 8 percent standard and is meant to drive more robust change, as you have discussed in the past.

The maximum reward in this example would be limited to $100,000 plus the 5 percent incentive of $25,000, or $125,000 in total. The maximum loss would be limited to $100,000, and as we discussed, there would be no incentive payment for poor performance.

This design would define the revenue as revenue through the A-APM in keeping with the redesign of the 5 percent incentive. It would have a revenue-based standard to qualify the model as requiring more than nominal risk -- although we would probably increase the 8 percent to something more, 20 percent in this case. And we would state the risk corridor -- that is, the limit for savings and losses -- in revenue terms.

It would scale the shared savings on Part A and

Part B performance in keeping with the Commission's third principle.

Finally, small entities would need to aggregate to reliably detect cost and quality performance. That aggregation could be voluntary, driven by the entities, or virtual, driven by CMS if the entities did not aggregate themselves.

The idea is to create an incentive that is large enough to motivate improvement but limit the loss to something a practice might take on. In most cases, the maximum loss would be less than 20 percent of the practice's total revenue because the revenue through the A-APM would only be a share of the practice's total.

So, in summary, the idea is to create useful incentives for better care, protect the trust funds, and accord with the Commission's principles.

We have outlined redesigning the current MACRA system. MIPS would require minimal or no clinician reporting and instead rely upon patient experience and claims-based measures that are more outcome oriented, and there would be comparability across clinicians. These measures might be made at an entity level or even an area

level. If clinicians did not like that, they might prefer to join an A-APM entity so that they could decide who they wanted to be measured with.

The 5 percent incentive payment would be based on the clinician's revenue coming through an A-APM, and it would also be made contingent on positive performance in the A-APM.

It would create a two-sided risk model for an A-APM that small practices might want to join, in which the risk would reflect the practice's ability to absorb risk and not put them at untenable levels.

It would need to choose between two alternatives for payment. First, pay could be proportionate. The advanced alternative payment model share would get bonus (if there was positive performance) and the remainder would get the MIPS adjustment. There would be no threshold and no eligibility determination, and this would greatly simplify the program and increase certainty. Or the second alternative would make a clinician with any revenue coming through an A-APM exempt from MIPS.

The idea is that a program redesigned in this way would create useful incentives for better care such as

stronger care coordination and better access to appropriate care. At the same time, it would protect the trust fund from handing out bonuses for meeting arbitrary thresholds, and it would accord better with the principles the Commission has maintained.

This is kind of an ambitious program to discuss after a long day, but if you would, we ask you to consider the following discussion points and let us know which, if any, you would like us to develop.

So how should MIPS be redesigned? Is it possible to go to minimal reporting?

Should the 5 percent incentive be made contingent on performance and only apply to revenue through an advanced alternative payment model?

Should a two-sided risk model be developed to make it possible for small practices to be in it, even if they can only bear a limited amount of risk?

And, finally, are there any other issues you would like to discuss?

We look forward to your discussion and would be happy to answer your questions.

DR. CHRISTIANSON: So, as usual, questions of

clarification first.

MR. PYENSON: Thank you very much, Kate and David. Terrific report on a very complex topic.

I have a question on what types of physicians you see as participating in Track 1+. This seems to be a mini MSSP with attribution and, therefore, primary care or primary care-type physicians are the ones affected. Is that the case?

MR. GLASS: That's what -- the model we just talked about would certainly be that, primary care-oriented. They actually came out Tuesday with a description and a fact sheet of the official Track 1+ model, which is something different than this, that we just described. It sticks with the 8 percent of revenue limit, and it doesn't have a risk corridor per se, so it's much more asymmetrical. The risk is very limited on the down side, but the plus side is 50 percent of whatever savings there are on the benchmark, so that can be really high.

So that, yeah, that could create a very different dynamic. That would almost certainly be primary-care oriented, because you wouldn't want any specialists in it, that would increase the revenue.

MS. BLONIARZ: And the other point is that Track 1+, there is a revenue threshold that applies for organizations of a certain type, so clinical organizations without a large hospital or large urban hospital. But what those things mean is not particularly clear, and we've had a hard time understanding exactly, you know, who would get that revenue threshold and who would go back to the default threshold, which, in Track 1+, is 3 percent of benchmark.

DR. SAMITT: So before weighing in on kind of the feasibility of revising the MIPS side, do we have a sense of how accessible and feasible it will be for clinicians to join APMs? Because one of the things we want to know is, will it be feasible for every clinicians who wants to be in an APM to get into an APM. Are there going to be vehicles for them to be able to do so?

MR. GLASS: Well, CMS seems to be wanting to make it very feasible for them to do it, to the extent of making these mandatory episode payment models qualify as advanced alternative payment models.

DR. SAMITT: I guess what I'm getting at is that then, ultimately, it's a clinician's preference, not a clinician's access to an APM that we're dealing with here.

MR. GLASS: I guess it depends how it eventually works out. Like the Track 1+ thing, how that's going to work. I would say that's a little hard to say right now, but it certainly sounds like, in many areas, they'd be able to figure out one to be in.

DR. SAMITT: One way or another.

MR. GLASS: Yeah.

MS. BLONIARZ: And CMS, also, in the final rule, was -- you know, announced that they intended to reopen models, such as Pioneers --

MR. GLASS: -- or Next Gen.

MS. BLONIARZ: Oh, Next Gen. Right. And, you know, so it seems like they're creating a lot of options, or have been planning to over the next year.

DR. MILLER: Can I just nail one thing down -- and I know we're in the first round. So your question was about what is it now, or what it would be in the reformulation?

DR. SAMITT: We've talked about -- and again, it's getting into Track 2 here, but we're talking about making MIPS less attractive than the current formulation. And one of the things we have to consider is if we're going

to make MIPS less attractive, with the hope that we're going to drive people toward APMs, that they can relatively easily join APMs if they prefer to. I'm just trying to assess to what degree there would be barriers to any physicians wanting to be part of an APM in one form or another.

DR. GINSBURG: It seems to me that if you're a specialist, in many specialties, I don't see many opportunities of APMs for you at the present, and I think it's going to take a lot of development to spread those opportunities, because it's probably going to involve a lot of distinct models, the same way that, you know, CMS came up with an oncology model.

So I think that the reality is that for the fairly large percentage of physicians, they probably don't have very extensive APM activities now.

DR. CHRISTIANSON: Let's try to go back to the list and I'll try to get the rest of you on. Right now I've got Alice, I've got Brian, and David. Okay.

DR. COOMBS: Thank you very much. So I have a question. On Slide 4, can you say something about preferential 3 percent versus 8 percent, whether or not

it's a physician-only APM versus a physician-and-hospital APM? Does that differentiate either one of those?

MS. BLONIARZ: No. There's no -- so models will have to meet those nominal risk criteria. There's no, you know, membership criteria, like I was -- we were trying to say to Bruce, on Track 1+. It can be any arrangement of providers in the model.

DR. COOMBS: Okay. So in the final rule, though -- I'm not talking about the Track 1+ ACO. I'm talking about the final rule --

MS. BLONIARZ: Right.

DR. COOMBS: -- as it pertains to the 3 or the 8 percent.

MR. GLASS: So the final rule just says here are two ways of doing it. You can either meet the 3 percent benchmark -- the model has to require that you have at least, at risk, 3 percent of the benchmark or 8 percent of the entity's revenue, and the revenue is A and B revenue --

DR. COOMBS: Okay.

MR. GLASS: -- clinician-only group, would, you know, just be B revenue.

DR. COOMBS: Okay. Is there any mention about

the ACO governance within the structure, in terms of how that looks to small groups that are incorporated into larger groups?

MR. GLASS: Well, this is more general. It doesn't even specify it's an ACO. It could be an episode payment model.

DR. COOMBS: Right. Right.

MR. GLASS: It could be all sorts of things.

DR. COOMBS: But in the case where we're talking about MIPS and APMs and groups being able to easily transition into APMs, I'm just thinking about whether there are other dynamics that may influence some of the small practices being a part of APMs.

MR. GLASS: Yeah. Certainly. I mean, yeah, there's a lot. I think taking on risk would be the major one.

DR. COOMBS: And then the other question is Part B drugs being included as a part of the risk.

MS. BLONIARZ: So it would be whatever the benchmark is. If the benchmark included Part B drugs, or if it's A and B, or if it's the entity's Medicare revenue, yeah, I don't believe there's any exclusions. It would be

all revenue, as David said, from A and B. So ACO with a hospital, it would be their inpatient revenue as well.

DR. CROSSON: Brian.

DR. DeBUSK: I have two questions. First of all, on Chart 6, you talk about eliminating or greatly reducing the clinician-reported measures, basically moving away from the PQRS toward some type of claims-based data. Has anyone looked at the delta between what we can get from claims, or what we can reasonably derive, and if it would give us an attractive set of PQRS measures?

And then, actually, I'm sorry. I have a second question and then I promise I'll turn the mic off. Well, sort of promise.

On pages 10 and 11, you know, you do describe a very novel model for how to shift risk, how to really scale down risk to a practice, to an individual practice. When, for example, a two-sided ACO incorporates, or applies and does its paperwork, I mean, one of the things I think it has to do is spell out its incentives and reward systems, and sort of the rules of engagement with physicians anyway.

Couldn't something like this just simply be captured in that ACO application? I still think there's

novelty. I like what you're doing, but couldn't that just simply be written into the ACO's agreement with that individual practice?

MR. GLASS: I don't quite follow your question on the second part, but, Kate, do you want to answer the first one? Let her --

DR. DeBUSK: Sorry. Two totally separate questions.

MS. BLONIARZ: So some of the background on PQRS and, you know, other measures that might be available. So PQRS is about 300 measures, and there's actually a variety of ways that clinicians report them, including registries and claims and other measures, and currently, in both the value modifier and in MIPS, clinicians will be selecting measures and reporting them.

One of the outcomes of that is that performance on most of the measures is extremely compressed, and for many measures they meet, you know, CMS's definition of topped out. And so, you know, when CMS has been looking at this and talking about it, they said, "Well, you know, one reason could be that, you know, we're just capturing high performers," and that may be true but it really does call

into question, well, then, what is Medicare -- how is Medicare assessing performance?

So I think what we've kind of gone to is given the level of burden that PQRS has, the measures all have very complicated specifications. They're not owned by the government, so the measure specs change periodically. Collecting and reporting that data might not be giving Medicare a great deal of information.

The flip side is to use claims-calculated measures, especially some of the outcome measures that Lydia has talked about, you may have a large group of clinicians for whom you cannot differentiate performance, and that's just what it is. And so I think that's where we're kind of saying, you know, you could do different things. You could talk about aggregating to groups, or local market areas. You could talk about extreme outliers -- that's another thing we've thought about. But, you know, you're going to face a limit on what you can do with claims, but, in general, I think we've kind of had the sense that the current process is really not giving the program any meaningful information.

DR. DeBUSK: I think the consensus is that the

current reporting system is broken. You've proposed a very, very intriguing idea. I want this to work. The question is, do we have the claims infrastructure to at least partially fill in the blanks?

And I guess my question, sort of correlated to this -- and I'll withdraw my question to you, David; you're off the hook because I think it's going to shake out over here with these guys -- but are there some modest changes or augmentations to the claims that we could do that would dramatically improve their value and lessen that gap?

MS. BLONIARZ: I think there are. I'm not sure I'd want to say what they are off the cuff, but, you know, we have talked about -- years ago, talking about adding lab values to claims, whether that would give you more information, you know, whether there's something in electronic health record reporting that you might be able to use. But, yeah, that's the idea.

DR. DeBUSK: Thank you.

DR. CROSSON: David.

DR. NERENZ: Okay. Thanks. Just a couple of quick questions on the example on Slides 10 and 11, and this may follow on to what you were asking.

Just to clarify. This is essentially purely hypothetical, right, in the sense --

MR. GLASS: Exactly.

DR. NERENZ: -- this doesn't illustrate a flavor of ACO --

MR. GLASS: No, no.

DR. NERENZ: -- it doesn't illustrate bundled payment, it doesn't illustrate any current named APM, right? It's just --

MR. GLASS: Well, it does say that it's a total A and B benchmark.

DR. NERENZ: Yeah, but it's not an example of any --

MR. GLASS: No, it's not an example.

DR. NERENZ: -- on thing that's -- okay. That's what I wanted to clarify.

Then, in your language in describing it, you used examples like what a practice could bear, or tolerable risk, or something. I'm just curious. Is there an evidence base upon which, like this up-down 20 percent is based? And I'm particularly interested, do we have any examples that you're drawing from that suggest that a small

practice would actually be willing, voluntarily, to get into something where they have to write a check for $100,000 to CMS if things to go bad? I mean, is that --

MR. GLASS: Well, I think the only thing you could talk about, right, off the top of my head, would be there were some practices that went into the ACO Track 2 and Track 3. I don't know if any of those were --

DR. NERENZ: Not small ones, though.

MR. GLASS: I don't know if any of those were small.

DR. NERENZ: Not this -- well, that's the point. This is so small --

MR. GLASS: Yeah, I don't think so, yeah.

DR. NERENZ: -- that they wouldn't qualify.

MR. GLASS: Yeah, because they need 5,000 beneficiaries. So the answer is no, we don't have them.

DR. CROSSON: Okay. Further clarifying questions?

[No response.]

DR. CROSSON: So let's move into the body of the discussion here, and we have two volunteers, Alice and David. I guess, Alice, why don't you start? David just

talked.

DR. COOMBS: Thank you very much. It's a great chapter and I think we're onto something with the potential recommendation that you have on Slide -- let's see here -- I think we're on Slide 6, the alternative to redesigning.

You know, there are a couple of things that are at bay here and I think the whole notion of the workforce and what it means for being able to carry this out. The measures that are being used are, as you have pointed out, are inappropriate for some specialties. Like, for instance, the ophthalmologist trying to look for measures such as smoking cessation. I mean, it's very hard for some of the specialties to kind of follow through with just fulfilling a check-off list, and, as you said, pay for reporting. It's like "I did that, Mommy. Can I have a cookie?"

I think that it's not what we want in terms of being able to measure quality outcomes, and I think that's really important going forward.

The whole piece of including, as a part of your risk, the Part B drugs, and then looking at the Part D and how the Part D is looked at, I think may be problematic.

On one hand, the Part B physicians who would -- physicians who do a lot of Part B versus what it looks for physicians who are not in that corridor -- you know, the oncologists, the rheumatologists, docs who are in that area -- and there may be some issues around what drugs are being used, but still I think it invokes a different type of patient panel compared to the non-rheumatologists and docs who are using some of the biologics. So I think that's an issue.

The thing that is interesting is how do we have subtle -- how do we have gradual changes without disrupting access with the Medicare beneficiaries? And so a piece of this is the assumption that we want MIPS to progress to a APMs. I think that's what we're saying. At least that's what the consensus is, is that that's a good progression. That reward and bonus of that 9 and 9, when I first looked at it I said, "Nine percent? Oh boy. You can make 9 percent? That sounds like really something good." And then the cumulative addition, that you assume that you're going to make it 8 for those four years or so, I think is probably an erroneous assumption, because of the number of providers that are going to be eligible for that bonus.

One of the things that I've asked is, you know,

what absolute raw number looked like, at the end of those four years, in terms of who actually gets bonuses, and will the negatives, on the down side, outweigh the positives, because that's the driving force for whether or not you've been severely -- adversely affected by it. It would make you turn around and look at APMs and say "how can I do it"?

I like the idea of having some kind of leeway where you lower the threshold and you allow doctors who have the 24.9 percent to participate in APMs. I think that's a really good idea.

And, like I said, the workforce, in terms of looking at the shortages and what that looks like for primary care, what that looks like for advanced nurse practitioners and PAs being able to participate in it, this all becomes important, especially in small groups, especially in small practices and how they fit in.

I was curious to know about that risk, the 3 percent or 8 percent, whether or not there was some kind of stipulation that you had to be a part of a large, integrated health care delivery system. And if that's not the case, then I think there needs to be tools for the providers that are out in the trenches. At one time, in

Massachusetts, we had 40 percent of our doctors that were in onesie-twosie practices, and that was about five years ago. So, Massachusetts is the most doctor-rich state there is in the country, and if it's the case in Massachusetts, I wonder what it would look like in the crescent of the Southeast Corridor, in terms of how this robust integration happens and what it looks like for patient access.

So I think my concerns are, you know, what the workforce looks like, both in, you know, the urban setting, the academic versus non-academic rule-settings, what it looks like with physician workforce, what it looks like with advanced nurse practitioners, and PAs. And there were two studies in Health Affairs that actually looked at how nurse practitioners and PAs are deciding. It used to be predominant primary care kind of transition from PA school and nurse practitioner, but now there seems to be a relocation into other specialties, for even the advanced practice nurses and PAs. So things are happening that actually changed the decision-making to pursue non-primary care, even in the non-physician clinician section.

So I'll stop there. I had a couple of other questions about, just specifically about what the portion

of clinicians looked like who received bonuses on that upside for those four years, because that really is a rate-limiting step.

MS. BLONIARZ: I can tell you for the first year. So CMS, because theirs was kind of this pay for reporting option, CMS estimates that over 90 percent of people will get an increase in MIPS, but as a result, the increases are extremely small.

DR. COOMBS: And so extremely small is the other question. If it's set up in such a way that you're not being penalized the first year, then what happens the second year? So right now, 2017, primary care doctors are looking at different ones of the parameters that they are going to be reporting.

As anesthesiologists, as the end of my case, I take it to the PACU. I have to actually say patient had no cardiac arrest, patient -- and, you know, these are the good things that happened, but those are the parameters. They're kind of gross big ones, and there are some other things that are probably as important that we probably should be paying attention to as well.

DR. CROSSON: David.

DR. NERENZ: Thanks.

I am going to focus mainly on some broader conceptual things recognizing that if we try to take time to deal with all the various technical details, we'd be here all weekend, and we wouldn't ever go home at night. It's a 2,000-page regulation. It's got all kinds of stuff.

You've done a really nice job, I think, of drawing some attention to some of the key problems, but we could go on forever on technical details.

Just as a couple small teasers, there's a feature in the APM side that strongly disadvantages multispecialty group practices against primary care. We don't have time to talk about that.

There's a feature on the MIPS side that I think strongly advantages primary care versus specialty care, and actually, if implemented, it would probably move a whole lot more money to primary care versus specialty care than anything else we're talking about. We don't have time to talk about that either. So there is just a ton of stuff going on here.

I will mention a couple of things I have some concerns or questions about. I'm sort of intentionally

leaving out the things you've done really well, but that's because when we do these things, the things that are in here tend to move forward, and they sort of go on their own with their own momentum. So I have to take the opportunity to raise a couple questions, but I like a ton of things I'm not going to talk about, just length of time.

Okay. Here we go. I've said this many times, and I have to say it again, and Mark knows I'm going to say it.

DR. MILLER: Would you like me to say it for you?

[Laughter.]

DR. NERENZ: Yeah. If you --

DR. MILLER: No, go right ahead.

DR. NERENZ: Well, okay. There's a number of features in here where we talk about pushing people to measure performance on the basis of an aggregate. Don't like the idea. Don't think it's a good idea. Never liked it. Still don't like it.

Let me say that I don't think it's good to measure and reward performance on the basis of the collective, and I use that word very intentionally because I think all the historical examples I can think of are not

good. You know I'd say it, so I said it.

But, for example, combining people in geographic areas and linking the rewards that way, I just -- no idea.

I agree with you absolutely that there should be some more careful thinking on the issue of more than nominal risk, that phrase, and you've done some good things in that area.

I might think about it slightly differently, though, and what I might do is sort of expand some of the examples in definition as opposed to what CMS has done in the more than nominal risk.

As an example, I personally would have been willing to put the one-sided MSSP models in there because, as we know from Zach's presentation, most of them now lose money. That's real risk. I disagreed with how CMS did that, and so I think that we could actually expand and essentially lower the bar in that sense.

But then what I also write in is a more clear consideration of who is bearing the risk because the rule is currently built on the idea that it's the APM entity that bears the risk. It is not necessarily the physician practice or the physician group that bears the risk, and I

would push more in the direction of that than link to the incentives that tie into that.

DR. DeBUSK: That's what I sort of fumbled in my question actually to David earlier was, normally, when you set up your APM, if you've got, say, a key group of physicians, you would want to pass a slice of that risk on to them. And that's what I was wondering. Could, for example, what you embodied in Charts 10 and 11 actually just be written in to say, a Track 2 ACO operating agreement?

DR. NERENZ: We're kind of on the same page. I was just imagining that as we think about improvements, we might say whatever financial incentives are linked to being in a risk arrangement could be made more tight in the sense that the physician practice or group being rewarded, say, with the 5 percent should be the entity at risk, not necessarily the larger ACO at risk. So, for example, a hospital at ACO may be structured that it's the hospital actually leading all the risk.

Okay. A couple more things to go, and then I'll be done. In a couple places here and elsewhere in our discussions, we've talked about various ways to push people

to two-sided risk. I just don't know how that's truly going to happen because many of the one-sided risk models are currently unattractive. We have no good working examples of people willing, actively, voluntarily to step into the two-sided risk models of the MSSP. It's a tiny, tiny fraction of those that are accepting two-sided risk.

You can force people in. You could declare everything else to be a felony punishable by law, but we don't have examples of how to do it. It's in here periodically. I just don't see how that's actually going to happen in practice because at least in their other features and structures, they are simply not attractive.

And the example you showed in slide 11, a model that has a very small practice writing a check for $100,000 to CMS. I don't know who is going to step into that or what.

In general, I'd like us to be thinking about more carrot-type incentives rather than stick incentives, and I think the way we have it framed out is a whole lot of stick incentives. We're going to move people in this direction because we're going to make the other direction less attractive. I'd like us to be thinking more about how do

we pull people into the areas we'd like them to be in by positive incentives.

And then, finally, last thing, on the issue of claims and outcomes data, I do have a great concern about that. I mean, it's sort of an attractive idea to reduce the reporting burden and focus on outcomes. I just don't think under current setup we can do it.

Many of the outcomes that are most important are just simply not captured by claims, and for those that are, like a need for a redo procedure, readmission, things like that, it is crucially important that there be good solid risk adjustment, detailed, wonderfully good risk adjustment, otherwise the result is unfair, and the claims data typically don't have that. It's the same point you made.

It's attractive in principle. Right now, I don't see how we can do it.

DR. DeBUSK: It is very attractive, and one thing I was going to point out earlier, just like with the PAC model, once you presented that PAC model in the June report and those coefficients were there on the page, it got real. You know, that's really what it took to get me over the

hump. I think if someone had just a general discussion around what it would take to make it real to bridge PQRS into that claims data, David, I share your skepticism, but I'm also an eternal optimist because I would love to see less physician data collection.

DR. CROSSON: We are going to go further with the discussion, but, David, I want to ask you one question for clarification. Then I want to just make one point.

I think I heard you say that you don't believe in measuring physician performance at the collective physician practice level; is that right?

DR. NERENZ: Except for those that they have voluntarily entered in that has its own coherent culture.

DR. CROSSON: Yeah. Okay. All right.

DR. NERENZ: But geographic area is my opposite view.

DR. CROSSON: That, I understand. So that would be sort of measuring performance at a collective level where there is no -- it isn't a collective. It's just a geographic assignment, essentially, and beyond that, there is no particular mechanism or entity that exists at least at day one in order to improve performance collectively.

DR. NERENZ: That to me is the worst, worst -- I think there's kind of a middle step that I do have concerns about, where, say, a cardiac surgeon may have a contractual affiliation with an ACO. The system may end up set up where that cardiac surgeon is measured and evaluated and paid by the performance of the ACO, and there's to me a complete logical disconnect between how good the cardiac surgeon is and how good the ACO is. They're just two very different things.

But, on the other hand, a small primary care group that agrees to work together has same infrastructure, same culture, agreed to be measured as a group, sure, I have no problem with that.

DR. CROSSON: That is, in fact, I think the only practical way you can measure physician performance.

But I just want to make one other point, and that has to do with whether or not risk assumption by a -- whatever you want to call it, a physician practice or an ACO or an AAP, is in fact feasible. I think we've got examples that have been in existence for a long time on the West Coast particularly where in fact in the commercial marketplace, depending upon the relationship between the

payer or payers and the practice and its size and capabilities and its ability to learn over time, where it has proven to be feasible and worked very well, both for the practice and physicians and the payers, personally I'm not convinced, as I think you're not, that the current models we have with respect to MSSP models at least provide that same level of environment for that kind of dynamic to thrive.

DR. NERENZ: Yes.

DR. CROSSON: So do you accept that?

DR. NERENZ: Oh, absolutely. And I think we agree.

I guess where I would just expand and paraphrase a little bit is I'd like to see our discussion enriched by using those examples and not to say just about what's feasible, but what's attractive about it? Why does that model even exist? Why did the group step into that arrangement?

We've talked about why they perhaps could in kind of a mathematical sense. I want to know why they want to.

DR. CROSSON: Okay. I'm trying to figure out how to structure the rest of the discussion here. Could we

turn to page 12? I think that may be a better place to work from. This summary doesn't have every detail of what you've proposed; for example, for MIPS. But it kind of has summary-level notions here. Could we try to structure the discussion around like relatively I kind of like that idea versus another idea? Would that work for people?

So I've got Jon, Craig, Rita, and Paul.

DR. MILLER: Can I just inject one thing into this?

DR. CROSSON: Yeah.

DR. MILLER: I'll let David get back to his seat.

In an aggregation, measuring in the aggregate, measuring in the individual, you guys are the Commissioners. I don't care, okay? But there has been a 15-, 20-year discussion about this, where it's like, okay, you can't do anything but measure me at my individual level, and the very thing I do, you have to tell me precisely how you are measuring me. And any of the physicians groups argue this.

Then they are upset that it is too burdensome, that the comparisons aren't fair, and you're moving nine and nine dollars around, and nobody is happy.

Right now, the reason the exchange between you and Kate was everybody gets a small thing is because, basically, it just stopped the process because it's too complicated.

So then, as an analyst, you're sort of like, "I don't know what to do, except go to a more aggregated level and measure." Then everybody says, "But this isn't me, and that's not fair." So fine, but at some point in time, somebody has got to decide how this is going to go.

And I'm going to throw just one last bomb into the middle of this. A few meetings back, Paul said, "Why are we measuring and paying for quality?" and I'll just ask that question. I mean, as long as this is so complicated and nobody can come to any agreement on this -- and any model you pick, you're going to have a bunch of unhappy people and a bunch of logical or analytical failure. Then maybe Paul's point should come into the conversation and say, "What are we doing here?"

And I may have built your point out past where you actually meant it, but what the hell. So I'll say that.

And then the only other thing I would say to all

of your points, David, they often feel to me that once you've put all the set together, you're sort of back where we are now. You're sort of saying, "Everybody is measured at the individual level. Nobody takes any risk. You give them carrots." Carrots -- let's be clear about this -- mostly means -- you said collective has special meaning. Carrot means money in Washington, and so if you give them money, where is your savings? You have to answer that question.

DR. COOMBS: Can I say something? I have to say something, please.

DR. CROSSON: Why don't you say what you mean? Come on.

[Laughter.]

DR. COOMBS: So there are two things at work here. One is if I am in a group -- and that's why I say ACO governance matters. At the Medical Society, we decided central principles within an ACO, and it has to do with ACO governance, how it trickles down to the little people in the village who go out and take care of patients. That's actually a very important piece of this whole process because in the ACO, they're establishing quality parameters

that they are checking out. You have to trust the institution of the APM to say we're going to do what's best for this community. That's one piece of it. They're going to look at the individual level.

On the large scheme of things, you are looking at how that ACO does it for that community. So those are the big outcome measures.

So I think that we have to be able to trust, and that could involve primary care and specialties and things of that nature, but with the APM, the whole reason why APM is supposed to be good is because they know what's best for the community. And the individual people who are working in the village are being evaluated by the ACO to see that they do what's right.

DR. MILLER: And, generally, what the Commission has said generationally up to this point is for the program to measure at an aggregated level and let the entity manage the individuals, but there were a few things that you said that were just a little bit slippery in there. You started saying ACO, which I can visualize, but then you said APM. And APM may not be the organizational structure that you had in your head, and I agree with what you said, that if

the measurement was around the entity and saying, "I am going to measure that at a macro level, then you manage your individual level. In fact, this Commission many times has made that point.

DR. CROSSON: Can I make -- I mean, okay. So we're getting a little tied up in language even here. Knock me if you want, but an APM is a payment model, okay? So when we talk about APMs in this context, we should be saying APM entity, and for the most part, although there are others -- there are other APM entities, other than ACOs --

DR. MILLER: If somebody defines it as a bundle, what she said is --

DR. COOMBS: Don't hit him.

DR. MILLER: I'm not going to hit the guy. Always through words.

[Laughter.]

DR. CROSSON: We're mostly talking about ACOs, and first of all, Alice -- this is not a point we talk about a lot, but she is dead right. This doesn't work, and if you want to look at the characteristics of why it works on the West Coast, it is exactly related to the nature of

the structure of the physician entity, and the degree to which the physician, through a governance process for the most part, buy into this whole system, and then, therefore, work to support its success or, in some cases, its failure.

But I have to believe here that -- and I don't think this is different from what we've historically said here at the Commission, which is that it's very difficult to impossible to measure, except for a few things, patient satisfaction, surgical mortality rates, maybe. But once you get beyond that at the individual doctor level, you can't really do it. You have to do it at the aggregated level, and in order to get that aggregated physician level to be able to actually not just get rewarded or punished, but to be able to take that experience and improve, there has to be some entity existence, some entity quality that exists.

And I even believe in the end, it has to be between the physicians and the hospitals, which not everybody agrees with. But that's what I think, and I don't know how you do it, otherwise.

So, to a large extent, we've been having this discussion here at the Commission since 2004, in my time,

trying to figure out how we help the nation get from where it is now and how we help the physician community get from where they are now in a disaggregated practice mode to something different. ACOs was the way, and ACOs have been partly successful but not completely successful, largely, to my mind, because of the nature of the design as it was constructed in law. I wish it were different, but that's what I believe.

Now we're both preaching. But my sense is that the key to quality measurement, because I don't think we can do risk and reward and payment for cost without balancing that out with quality. I think that's what Paul actually believes. I'm telling him that's what he believes.

DR. GINSBURG: When it's my turn, I'll tell you what I recall.

DR. CROSSON: You'll tell me what you really think.

[Laughter.]

DR. CROSSON: I don't think we can get there without dealing with both the structural aspects of this, the governance aspects, as Alice said, and the relationship

between that and how the payments is put together. And right now, we're dealing with a lot of models that try to do it, but they're not working.

So that's it. I'm sorry.

DR. MILLER: I think it was Jon's turn.

DR. CROSSON: Oh, Jon.

DR. CHRISTIANSON: Are you feeling better?

DR. CROSSON: I think.

DR. CHRISTIANSON: So my comment isn't on the group versus individual, but I like that you're tackling the measures that are in the measure set and trying to comment on which ones seem reasonable and which ones don't. And my own concern about measures that we see across Medicare are the measures where we ask a provider or a provider system to tell us if the patient is getting better, as an example, and we reward them if they tell us their patient is getting better. So, you know, trust, but verify. There's no way to verify that. And then we look at the data, and we get concerned about what we're seeing, and then we start blaming the provider for doing exactly what we incented them to do; whereas, we should be blaming ourselves and the Medicare program for proposing measures

that have a reward set that encourages behavior which you like to call "gaming."

So I really like that you're taking a look at those measures and putting a little spotlight on measures that can be -- you know, "gaming" is actually a soft word, in my mind. So you end up with data on quality that doesn't represent actual quality, and you end up spending more from the Medicare program than you should when you put those kinds of measures out there. And the reason we put them out there is they are so doggone attractive. We really want to know at the patient level whether the functional status is getting better, you know, in these sorts of measures that we really want to now about, but the only source of data tends to be asking the people who are treating the patients to go tell us whether their treatment is getting better and resulting in an improvement, and there's no way we can verify that, but we'll pay them if they tell us it is.

So those kinds of measures are very bothersome.

DR. SAMITT: So to start, this is awesome work. Give Brian all that you want to write about Part D. I'll take all that you want to write about this topic.

You know, at a very high level, and on page 12, I actually am very enthusiastic about everything on this page except for the last bullet, which I would not be in favor of, and let me say why.

My understanding of the whole MACRA legislation is it was to enhance the governance and accountability of population health, with the thought being that we would want more people to select APMs than we would to choose MIPS. And my understanding is the challenge we face is that the risk/benefit tradeoff is showing favor to MIPS and APMs. And I don't remember who used the expression that risk is not attractive under the ACO models. Well, attractiveness is all relative, and I think it's because the design of the model has not created the right attractiveness for the portion of the model that we would pick.

More specifically, to get to the specifics, I like the fact that we are proposing significant tightening of the MIPS model because, as you described it, it feels as if there's significant upside related to subjective or self-reported information, which does not -- which creates more security, frankly, to choose MIPS over APMs. And so

that seems that that needs to be fixed and repaired, and so I would be very much in support of all that you've suggested.

And, David, to your point about the concern about aggregating quality data, first of all, I agree, you can't pay for value without paying for quality. So we need a way to do it. But if clinicians, physicians, don't want to be at risk for quality outcomes in a geographic area where they may not know who the other clinicians are, they have the option of joining A-APMs where the APMs will be much more aligned and organized and governed with some degree of comfort that everyone else will also focus on quality, which creates yet another incentive to shift toward A-APMs.

I very much like the APM enhancements, and I hadn't thought about this, but the inclusion of the percentage of revenue that only applies to the A-APM I think is a real brilliant recommendation, because on the surface, what it encourages is more allocation of patients to the A-APM. If I get all of my revenues linked to the 5 percent bonus, I have no incentive to go just beyond the minimum threshold in A-APMs. Whereas, if you do it this way, I would probably want all of my patients' members to

be in A-APMs. So I very much like that.

I have three concerns that I should share. One is as it relates to claims-related quality metrics, especially for specialists -- and this would be predominantly, I think, for MIPS -- that to be fair we would need to know what those are and do they really exist. So that would be the one thing I would want to know more about.

The second is -- and we glossed over it earlier -- we need to assure that there are adequate A-APM options for specialists. So I know there's a methodology to create them, but I think that if we're going to disincent MIPS and incent APMs, we need to find a better vehicle for this to work for specialists.

And then the last thing that I'm concerned about are the principles regarding Medicare Advantage and not counting a group or a provider or a clinician's membership that is in Medicare Advantage or risk-paying Medicare Advantage relationships. For me, Medicare Advantage is even a better end state than APMs. And I'm just worried about a scenario where a clinician says, "I have a good bulk of my patients in MA, but now I'm getting this 5

percent bonus if I'm in fee-for-service APM. So you know what? I'm going to stop MA and I'm going to go back to something that is built more on a fee-for-service chassis." And, frankly, I think that's going in the wrong direction.

So I think the one easy modification there is, in addition to counting percentages related to A-APM patients, to count MA patients as well within the mix.

DR. CROSSON: Craig, first of all, thank you for bringing this discussion down to Earth -- back to Earth, actually. And you helped me modify my own thinking with respect to the notion of geographic quality measurement -- not that it is a process that should be sustained over time, but that it could be a transitional process. So I appreciate that.

DR. REDBERG: Thanks. So to pick up where Craig left off, I think it's certainly worthwhile for us to think more about alternative payment models and how to be more inclusive, because I think we want to move towards alternative payment models. But it has to be something meaningful. And I'm not -- I'm trying to think about how we could make it more aligned with some of the other things we've talked about today and in the last few months with

regard to high-value care and getting away from low-value care and having those kinds of behaviors be rewarded or being considered alternative payment models.

I think, you know, trying to -- I don't know that we should spend a lot of energy on finding something people will like because nobody likes change. You know, change is hard, and whatever, I think it's going to be hard, I think we have to make the rules clear. We have to stick to the principles. But I can imagine that, you know, every time you propose especially something that has two-sided risk, and that's what -- you know, and even psychologically, I'm not sure how many of the Track 2 or Track 3 ACOs actually wrote a check back to CMS. Did that ever happen?

MR. GLASS: It did happen, I think, but not often. And there were very few of them.

DR. REDBERG: Just even if there is like that -- and you were talking about a carrot. But I think hypothetically, if we were going to have a $100,000 loss, it's better to do it up front and then say, "If you meet these criteria, then you can get up to $100,000," than to have paid it out and then ask for it back. Nobody wants to -- psychologically, it's much worse to take something back

after you've paid it than to have not given it in the first place.

And in terms of these two alternatives for payment, I think it certainly makes much more sense to have pay be proportionate and not have that cliff, which doesn't make a lot of sense. I don't like the idea of a dollar in A-APM and you're exempt from MIPS. I think it makes more sense to be proportionate. That's a start.

DR. CROSSON: Thank you, Rita. Very clear. Now, Paul, you get to explain yourself.

DR. GINSBURG: Let me say the other things first. You know, your presentation was really good and had a lot of good ideas, particularly about fixing MIPS. And I had some thoughts about discontinuities, and this has come up in some others' remarks. I think we really want to try to avoid discontinuities, and one that others have said is the -- you know, and I really like the blend between MIPS and A-APMs as a way to do that. But I'm also concerned about one of the decisions the Commission made in June before I was here about saying that bonuses -- you know, A-APM bonuses only go to people who have succeeded in risk models, because to me that's another discontinuity. So if

you have, you know, a minuscule loss, you lose your entire 5 percent for that year. And I have just never been able to get comfortable with that perspective.

Also, a few people said it before. I think this lack of opportunity for specialists in A-APMs is a serious problem. Realistically, this all stems from the shortcomings in the ACO model, because the ACOs have very little incentive to engage many specialists in their models. So, you know, if you talk to some specialists, they'll say, "Well, none of the ACOs want us. We don't treat patients in the hospital."

So I think creating more opportunities for specialists, if you don't fix the ACO, it means more bundled payment approaches, coming up with bundles for certain chronic conditions. And that may be a good approach, but I think that the Commission might want to spend more time actually coming up with a concrete plan to actual develop APMs that work for most physicians, regardless of their -- you know, that are specialty specific.

Finally, here are my thoughts on quality. I think what Mark was recalling was something I said about MA

bonuses, star quality bonuses, yeah, figuring that there's really no need for star quality bonuses. It's great that CMS measures star quality. If an MA plan has a good rating, it will attract more beneficiaries. If it's actually more costly to achieve that good rating, they actually have the option to charge a higher premium to the beneficiaries. So, to me, it's like overkill having a star quality bonus from CMS.

I think on the physician services, since physicians don't get rewarded for higher quality, they may have higher costs producing it, then I think quality bonuses make some sense. The problem is that very few of the measures, quality measure that we have, actually give people much conviction that this is actually worth paying for. So I think that's where we are.

DR. REDBERG: Just on that point? When you said that "check the box" doesn't correspond to quality, I think that's a big problem with a lot of quality measures. And I'm not sure patient satisfaction is as hard a measure as we would like it to be.

DR. CROSSON: Just to be clear, I wasn't suggesting it was a hard measure. I was suggesting that it

was potentially measurable at the individual physician level -- not perfectly but better than other stuff. We'll have a discussion.

MS. BUTO: As I look at this whole system, I worry about the complexity of it and whether it's going to achieve anything. In other words, we could be exactly where we are with a lot more complexity, paying out a lot more money. I don't see anything really compelling that says the ball is going to be moved forward, at least not the way it's now currently structured. So that really worries me because Medicare has sometimes a way of getting into a system it can't get out of, and this has that feeling about it, that we could go down a rabbit hole and not be able to get out of it because more money's involved and people are invested in it, and there are vendors now that are selling the software and so on and so forth.

So I don't know what to do about that. And I really worry about the point that Craig was bringing up about the actual potential to inhibit the migration of individuals into MA. I think that's a possibility here, providers but also beneficiaries, if the benefits are made very attractive.

And I liked Paul's idea about what I call -- I think of specialty care case management, like there used to be primary care case management, where a lot of specialists serve as, in a sense, primary care physicians managing a chronic condition, and there ought to be an opportunity there for, you know, some bundled payment or some sort of ongoing risk taking by a group of specialists. So my comment.

DR. HOADLEY: So just a couple of quick things.

First, kind of going back to the exchange Dave and Jay and maybe a couple of others were engaged in about sort of where the examples of true physician group kinds of things exist and whether there has been anything to sort of look at -- I know in the West there were some regulatory structures that partly drove some of that creation, but if there's any history that tells us sort of how those came to work the way they did or any of the other examples, whether there's something to be learned about sort of what can seed an organization and cause it to sort of serve this better function, so that we're not in the business of just creating sort of structures of organizations that aren't really doing anything, which seems to be one of the

concerns we have here.

My other comment spins off of what Craig was saying about MA, and I guess one of the things I would wonder about in terms of your suggestion is whether all MA is the same and whether there are a lot of provider -- you quickly had a phrase about at-risk MA in the way you were describing it, and I just wondered -- it seems like a lot of -- there's a chunk of the MA world where the providers really aren't at any risk. They're just getting fee-for-service payments out of a managed care plan. And so if we were going to go down a route like that, I think we'd have to -- we'd want to at least think about whether we need to define something around that, the different kinds of reimbursement arrangements that exist in MA. So, obviously, in a Kaiser world or a -- although you could say that's a salary, that's not even necessarily that the physicians are at risk there. Certainly, there are others where there's a capitation, but there are others that are fee-for-service. So just having to -- if we want to go that route, we should think through what we mean by it.

DR. CROSSON: There is physician group risk, by the way, much in the way that Rita described.

DR. HOADLEY: Okay.

DR. SAMITT: But to Jack's point, it's not universal, so it depends on the relationship between the MA plan and the provider, and so you may need to get under the covers and tease it apart between the various subcontracting models between the plan and the providers to get --

DR. CROSSON: But that model is what you had in mind when you were talking --

DR. HOADLEY: Right [off microphone].

DR. CROSSON: That's what I -- and I easily jumped to that as well. I've got David and Alice and then -- I'm sorry, then Warner. David, yeah. I'm sorry, you weren't --

DR. MILLER: I thought you had your hand up, David.

DR. NERENZ: I did. I thought I was coming behind Warner. All right. Mark clearly knows far more than I do about what means what in Washington. I don't mean to dispute that. But just on the issue of carrots and dollars, I think we have an example in the current structure of where a carrot is not a dollar. If we think

about what it means to be on the APM side, you get the 5 percent increase. That's clearly a dollar carrot. But also you get a relief from reporting requirements. That to me is a carrot that's not a dollar. And I guess I'm just looking for that kind of thing, that if there's a certain work requirement, there's an effort requirement, there's something -- if we want to pull providers from one place to another place or one model to another model, I'd just like us to look as hard as we can at that kind of thing. And in that one example, I don't think it strictly has to be a dollar, but it is a positive thing. Life will be better for you if you are over here than if you are over here, not because we're going to make this one bad but because we're going to make this one good.

DR. MILLER: Yeah, and we as a Commission -- and you were present for all this -- said things like relief from regulatory requirements. So I do know carrots are not always just dollars, but in the context of your comments, I wanted to draw that out. So I actually appreciate the clarification.

I also want to loop you on some of this conversation, and I want to pick up on Craig's point. So

there was a moment there of harmony where --

[Laughter.]

DR. MILLER: Well, Jay and Craig seemed to be finding a place, and that was good. And Alice triggered it, and so, you know, this notion of, well, if there's an organized group and, you know, you measure it at that level, and then underneath it they manage the individual performance and physician, I think -- and I'm looking for your -- David, I can't see you. Warner's in the way again.

[Laughter.]

DR. MILLER: You're okay with that thought, yes or no?

DR. NERENZ: I just lost track, thinking about Warner in the way.

DR. MILLER: It's the same way with me. I look at him and then --

[Laughter.]

DR. NERENZ: Just a quick -- I think yes, but rephrase just --

DR. MILLER: So you're okay that if the physicians have collectively come together and organized, you would say, yeah, you measure at the aggregate level.

DR. NERENZ: Yes.

DR. MILLER: Okay, and then so the only thing I want to do -- and not to -- I don't want to reopen this, but I do want you to carry this in the back of your head. Think about what goes on in these conversations. There's consensus with that thought, and then what the system does and the law does and the regulation does and all this other complexity, goes back over to the other side and goes, okay, where everybody is not doing that, how are we going to measure quality for them? And then all these issues start to arise, and you have all these people saying, "I'm the individual physician. I'm not going to be in an organized thing." And everybody goes, "Okay. Now we got to figure out how to do that."

And when you think of some of the complexity, which I cannot figure out how Kate keeps organized in her mind, a ton of it is what's going on in MIPS. And the reality of MIPS right now is it's dead in the water because of those complexities. And that's what we grind tons of time on, and I just wonder sometimes how we're going to get out of this, because I do think at some level there is a collective -- well, to use that word which you don't like,

a collective understanding --

DR. NERENZ: I like it because it helps me make my point.

DR. MILLER: Yeah, I mean, a collective understanding -- agreed, and I am trying to do that -- a collective understanding that if done this way, everybody's good. Then we have all this other stuff that becomes highly complex when we move back out of that model and go, "Well, what are we going to do with everybody who's not in it?"

DR. CROSSON: You can't do it.

Anyway, Alice.

DR. COOMBS: I just wanted to say, Craig, at the beginning of this whole conundrum, when they talked about should MAs be a part of -- I just have to be rebased again, what the MACRA was about. It was about the SGR, which is a fee-for-service rule, and because it was about that, the MA had been on its way, in terms of the recruitment. This is about the SGR people, the SGR concept.

And so because of that, if you try to give an alternative to the fee-for-service world, in terms of not -- in other words, it's a progression toward MA. There

should be a progression anyway, right? It should be that natural progression as time goes on.

So this is really to address the fee-for-service world.

DR. SAMITT: And I agree with you, and it's more about the fact that I just don't want us to slide backwards, that if we've made progress toward MA, I mean, if we think of it as a trajectory to say we want to really move from fee-for-service to APMs to MA, or in that general vicinity, if the models are going to drive people the other direction, especially from MA backwards, it feels to me that we're working at counter purposes, and I may not know the answer as to how to factor that in, but it feels to me that there's some risk there that we need to attend to.

DR. GINSBURG: If I could add something to what Craig said, is that to me SGR affected the MA world the same way as it affected the fee-for-service world, because it meant that the MA plans had less in the way of benchmarks to work with to pay physicians, and I think there's a lot of evidence that, you know, the MA payment rates to physicians are so closely tied to fee-for-service

that it really flowed right through.

So I think the point Craig is bringing up is that now you put a 5 percent bonus, if it's easy, which it's not yet, in the fee-for-service world, and I think he's right that that would have a tendency to pull people back.

DR. CROSSON: Warner.

MR. THOMAS: Just one comment on Craig's point. I mean, I think the idea of looking at credit for MA, especially organizations that have risk there, is -- I think it will incent them to go more down the road of doing more in the ACO or, you know, two-sided ACO type of model, if you can get them -- you know, provide credit for that as well, or get them more involved in the MSSP and have opportunity on the up side there.

Commenting on Slide 12, I just think that -- I'd like to actually see us have -- redeploy resources from this system into the ACO model to make it more attractive because, ultimately, I think that's the direction we want to see folks going, with the large enough primary care groups that can take, you know, two-sided risk, or take upside risk in a -- you know, versus this, where there's, you know, pretty significant dollars on the table without a

tremendous amount of risk, you know, quite frankly. And I think if we can make the ACO track -- and I don't know a lot about the new model that's coming out, but as we learn more about that, I think making that more attractive, that's the direction we want to go. I understand we have to have a model for smaller practices, and maybe we look at the ACO as being really more of a model for larger groups, but it seems as though if we could continue to evolve and perfect that model, that it, directionally, is where we want folks to go, and there's just so much complexity with what's being done here.

I agree with Craig's point. We don't want folks to go backwards and think that, oh, well, I don't need to kind of head towards the risk or take responsibility for global payments because I can just, you know, go in this direction and, you know, have pretty large upside and relatively little downside and evolve back into a fee-for-service mentality.

So I would encourage us to continue to evolve more dollars and more effort to perfecting and creating a glide path for folks to move down the risk path on the ACO model, and to make it more attractive. I mean, to make it

attractive to get folks in. I mean, to not be able to have first dollar savings if you created, I think is a challenge for most organizations. Even if you get a little piece of it, it creates the right incentive.

So that's just another viewpoint on that situation.

DR. CROSSON: Okay. I'm going to try -- sometimes this is easy, sometimes it's not -- this particular one is difficult. I think I'm going to try to describe what I think -- where I think we are and what we could do, and then you can applaud or throw things, because it seems to me that -- and I'm working off slide number 12 here -- with the exception of the last bullet point, that I heard a number of people say they didn't like that, and I think I understand that -- that we have some suggestions here from the staff with respect to MIPS and A-APMs that generally make sense.

However, if all we were to do was to write up something and say "here's some ideas," then I think we would be under-representing, by a large percent, the discussion we've just had here. So it seems to me, you know, whether we go forward with a chapter with

recommendations, or without recommendations, or wherever we're going to end up, because I'm not sure yet what that is, it would be critically important to describe the fact that there is a direction that this Commission has been suggesting for a long time now, more than 10 years, and we'll call it roughly delivery system reform and payment reform, that we think creates a better path for the Medicare program, for the whole country health care system, but particularly, in this case, for the Medicare program. And why that is, and we can reach back to, you know, the ACO chapter in 200, or beyond that even.

And then, also say that, you know, there has been progress in that direction but it's been halting, and not successful in some circumstances. And I would include in that some of the ACO designs, although there are some better designs that have, unfortunately, just not had enough time to be properly tested. I think we can bank that point as well. But also with respect to the implications of MACRA, which was, to my notion, as Alice said, well-intentioned. It was trying to fix another problem in the fee-for-service area. But in the way the law was written, the way it was structured, the way it's

being implemented, it has some potential ramifications that are negative for the general direction that we've been interested in for a long period of time, and I think ought to describe what those are, and then, having done all that, say, by the way, here are some positive, constructive suggestions to fix MACRA, which would require legislation, in some cases, and could be employed by CMS, in other cases, that would get us to a better situation than where we are, given the fact that this is sort of what we've got right now.

But, you know, overall, we really think that, you know, fundamentally, we need to take, you know, a much more effective approach, and I couldn't describe it right now. But I think David's point that we could look at examples that are successful in the commercial marketplace and ask why they're successful, I think that's a good point -- that we still have a vision, and we think we can get there. And maybe that's it.

I mean, so -- I'm seeing thumbs and bobble heads and things. Okay. All right.

Do you still -- Kate and David, do you still wish to continue your employment --

[Laughter.]

DR. CROSSON: -- on the Commission? You're not going job-seeking?

DR. MILLER: See, they don't know that the others are getting paid.

[Laughter.]

DR. CROSSON: Yes, Kathy.

MS. BUTO: So going back to sort of A-APMs and MIPS, are we at the point -- I understand the context and that sounds really good. Are we essentially saying that on MIPS that, you know, we don't think it potentially is going to work the way it's structured? And I think we still need to fill in the blank as to what we think should happen. So there were some good suggestions in here, but I think we're going to have to come back to that, is I guess what I'm saying.

DR. CROSSON: Yeah, and I think, you know, we've heard some people say what you just said. Then we've got the --

[Laughter.]

DR. CROSSON: -- then we've got the practical issue whether we just, you know, sit there and watch a

dysfunctional thing unravel, or whether we try to make some recommendations, which are constructive, and, you know, might begin to push policymakers in a different direction, which is, I think, what we want to do.

DR. MILLER: And if I were, you know, eventually -- we've got to write this, and so I think I would counsel -- I don't know that I would push to try and get recommendations on this, one, because we have a bunch of other things that, you know, you're going to have to work your way through Part B starting tomorrow and through the rest of the spring, for example, and you have some heavy lifts for the remainder of your season, if you will. You know, think about it and I'm sure you'll be happy to hear this is only two more meetings in the cycle after this.

So the way -- if I had to write this today, and part of what we were trying to do was react to the very visceral response that you guys have had to MACRA as a general thing. Like how does this work? It's very confusing? Where are the signals? And to the extent I understand them, they may not even be going in the right directions.

And, you know, we could write this in a way where

we say, look, there are these concerns. That's our driving motivation. Pick up everything that you have talked about here, but also, you know, say that there are other ways of viewing this. I mean, there is this philosophical problem that the policy process has tried to approach, time and time again, and say this is a way you could get over it, but we understand that the counter-arguments are this, so that at least, you know, everything is on the page, and just try and write and say this is a thing, and not sort of try and get everybody to recommend and agree.

So if I had to write it today, that's what I would try and do, and try and capture some of David's equities there, so he feels like he's heard.

[Laughter.]

DR. MILLER: No, I didn't mean that in a smart-alecky way.

ATTENDEE: I can just keep talking.

[Laughter.]

DR. CHRISTIANSON: I wasn't even trying to be a smart aleck.

DR. COOMBS: [Speaking off microphone.]

DR. MILLER: Yeah, exactly, but just try and

write it that way, because I don't know how much air time we're going to have to come back to crank through these things. That's what I'm worried about. We have a lot of items, you know, already lined up for this spring.

DR. CROSSON: So a paper with suggestions. Is that what you're saying? I think -- I mean -- go ahead, Jack.

DR. HOADLEY: I was just wondering, what are the next sort of process from the point of view of regulations? I mean, obviously, legislation could happen at any time, or more likely not happen. But regulatorily speaking, sort of where are the next intervals to -- for CMS to change the process?

MS. BLONIARZ: I would say the regulatory cycle this summer, you know, that they do physician update, end of year, and they've set the rules for '17.

DR. HOADLEY: So we're really talking about a chance to either say some things in a narrative sense, in a June chapter, that can then be used -- either be communicated to CMS, obviously, in various formal ways.

MR. GLASS: Yeah. So the measurement period has started already, for a lot of this, and the payment changes

show up in 2019.

DR. HOADLEY: Right.

MR. GLASS: So, yeah, there's not a lot of -- you have to move fairly quickly --

DR. HOADLEY: Would they be tweaking --

MR. GLASS: -- and they're also defining this Track 1+ as we speak, or just already did, and all that's happening.

DR. HOADLEY: But there's some ongoing sense they could change -- I mean, have they -- is there any sense that they've sort of locked in certain things that there will be an unwillingness to change up until that sort of 2019 first payments go out, or is there a sense that this is --

MR. GLASS: Well, you know, obviously there's a lot of things happening --

DR. HOADLEY: And there's a new administration.

MR. GLASS: --in CMS and CMMI.

DR. HOADLEY: Right. Maybe that's an unanswerable question.

DR. CROSSON: There's also the PTAC process, which is going on simultaneously, right? Did they have a

timetable for a report, or is going to dribble out, or what?

MS. BLONIARZ: No. I think they're meeting quarterly, and in their last meetings they were talking about the process for submitting models and reviewing models and what that would mean once they're -- you know, they approve a model and move it to the secretary. But that was the last time I paid attention.

DR. NERENZ: Just to sort of build on that and clarify, I know somewhere, several minutes ago, the phrase "dead in the water" was used. It might have been in a slightly different context --

[Laughter.]

DR. NERENZ: -- but it sort of carried the impression -- I hope people don't get it -- that somehow this is on hold or it's not -- it's exactly the opposite. MACRA, MIPS, everything, this went fully 100 percent live ten days ago, right? So this is on. This is happening.

DR. MILLER: Right, but the measurement this time in MIPS is kind of -- is it working the way that it didn't work?

MS. BLONIARZ: It's fairly perfunctory to just

clear the bar for the first year.

DR. NERENZ: Right, but it is indeed live and active right now.

DR. MILLER: Okay. Are we done?

[Laughter.]

DR. CROSSON: Okay. Kate and David, thank you so much for that.

We're now going to move on to the public comment period. If there are any members of our guests here who would like to make comments, please step to the microphone so we can see.

We have one. Anyone else?

MS. WILLIAMS: I'll be quick. I want to go home too.

DR. CROSSON: Hold on. Just one second. I just want to see. People are moving. I'm trying to get a sense.

[Pause.]

DR. CROSSON: Okay. This is an opportunity to make comments about the material that has been presented today, this afternoon particularly.

Just a small note that this isn't the only way.

You probably know that, that there are other ways to provide input to the Commission.

We would ask you to identify yourself and your organization, if there is one, and limit your comments to two minutes. Thank you.

MS. WILLIAMS: Hi. Deb Williams, Pfizer.

I just wanted to clarify for the record here. I'm looking at 30.2.5. That is the protected classes section in the Part D manual.

Just to clarify, actually plans, in fact, can do in the protected classes, prior auth and step therapy, but not if the patient is already on the drug. That means, effectively, the protected classes only apply to people who come into a plan on a drug, say like clozapine, or who come into Medicare, say like on a drug. Is that clear? I just want to clarify that because it was implied that nothing could be done, and this is stifling, but in fact, it's for people with schizophrenia, if they're on the drug and they're stable, this can't be prior auth or step therapy.

Thank you.

DR. CROSSON: Thank you.

Seeing no one else at the microphone, we are

adjourned until 8:30 tomorrow morning.

[Whereupon, at 5:18 p.m., the meeting was adjourned, to reconvene at 8:30 a.m., Friday, December 13, 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, January 13, 2017
8:32 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

[8:32 a.m.]

DR. CROSSON: Good morning. It's time for us to begin our work. We have two presentations and discussions today. The first one's going to be on Medicare Part B payment issues, and we've got Brian, Nancy, and Kim. Who is going to begin? Brian, okay. It's all yours.

MR. O'DONNELL: Good morning. In this session, we are continuing to examine ways to address the rapid growth in Part B drug spending. In particular, we will be discussing a package of policy reforms that the Commission has been developing over the last two years and that was most recently refined based on the Commission's feedback from the October meeting. The Chairman's goal for our discussion today is to solicit further feedback, with the intent of having draft recommendations ready for our March meeting.

Before I begin -- the slides are not working.

[Pause.]

MR. O'DONNELL: Got it. Sorry about that.

DR. MILLER: Would you do me a favor? Just a little closer to the mic?

MR. O'DONNELL: Sure.

DR. MILLER: Okay.

MR. O'DONNELL: Before I begin, I would like to thank Sydney McClendon and Joan Sokolovsky for their contributions to this work.

So, in terms of background, I know you all have seen this slide before, but I want to highlight a couple of items from it, as they help motivate our discussions today. First, Part B drug expenditures grew rapidly from 2014 to 2015 -- the most recent year for which we have complete data. Second, this growth rate is part of a longer-term trend. From 2009 to 2015, growth in Part B drug expenditures averaged 9 percent per year, which far outstrips the growth in the economy and many other health care sectors over the same time period.

While Kim, Nancy, and I will provide more details on the specific policy reforms, this next slide gives some broader context for how our package of reforms could fit together. As this figure shows, our first set of reforms is aimed at improving the current ASP system and can be implemented almost immediately.

The Commission has also expressed substantial interest

in a longer-term reform, which is the creation of an alternative, voluntary program that providers could choose to enroll in instead of remaining in the traditional buy-and-bill system. The design of the new market-based program, which we refer to as the Drug Value Program, or DVP, is informed by Medicare's experience with the competitive acquisition program for Part B drugs, with several key differences. For instance, the DVP would be structured differently to give private vendors greater leverage to negotiate lower prices, using tools such as a formulary, and create more incentives to improve provider efficiency through shared savings opportunities.

As part of the transition to the DVP, the current ASP add-on of 6 percent could be slowly reduced over time. This would give providers an incentive to enroll in the DVP.

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

As we discussed in October, only manufacturers with Medicaid rebate agreements are required to report their ASP data. Some entities, such as repackagers and manufacturers of drugs that are considered devices by Medicaid, 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.

A policy reform for the Commission to consider is requiring 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.

One question for the Commission to consider is whether repackagers could be covered by this new provision. Excluding repackagers could limit the administrative burden of this policy (as many repackagers do not currently report their ASP data), ensure sales are not double counted (as repackagers' sales would already be included in another manufacturer's submission), and could provide an incentive for manufacturers to find the most efficient way for its drugs to reach consumers.

Our next issue is drugs that are paid at 106 percent of wholesale acquisition cost, or WAC+6. WAC is a drug's list price and, unlike ASP, does not incorporate discounts. New single-source drugs and the first biosimilar to a reference biologic can be paid at WAC+6 for nearly three

quarters because ASP is based on the first full quarter of data and there is a two-quarter lag due to data reporting.

Our analysis found that for a subset of new, high-expenditure drugs, small discounts were common while the drugs were WAC-priced. During the October meeting, the Commission discussed the possibility of reducing the WAC add-on percentage to account for those discounts.

In response to feedback from the Commission suggesting potentially larger reductions to the WAC add-on percentage, we re-ran our analysis on a larger group of drugs, which includes the top 50 drugs in terms of 2015 Medicare Part B spending.

For this larger group of drugs, discounts were similar to those we presented in October.

Given our findings and the preference expressed by the Commission in October, a policy reform for the Commission to consider is reducing the payment rate for WAC-priced drugs by 3 percentage points. This percentage represents the high end of the discounts we observed in our initial analysis of new, high-expenditure drugs.

In addition, to maintain parity to ASP-priced drugs, the WAC add-on percentage could be further reduced if the

ASP add-on is reduced. For example, if the ASP add-on was reduced by 1 percentage point -- going from 6 percent to 5 percent -- then the WAC add-on could be reduced by the same amount -- going from 3 percent to 2 percent.

Nancy will now take over with a discussion of the ASP inflation rebate.

MS. RAY: Thank you, Brian.

The next policy to improve the current system is the ASP inflation rebate. Growth in the ASP+6 payment rates are driven by manufacturer pricing decisions. There is no statutory limit on how much Medicare's payment for a product can increase over time.

For example, in the last year, about half of the top 20 highest-expenditure Part B drugs had price growth of 5 percent or more. A policy that could be considered would be for Medicare to require manufacturers' rebates when ASP growth exceeds an inflation benchmark. Such an approach is commonly used. For example, the states collect rebates from manufacturers under the Medicaid drug rebate program.

In October, we talked about some of the design elements for an ASP inflation rebate, and we've added some more details based on your discussion.

The savings from rebates could be shared with the beneficiary by basing cost sharing on the lower inflation-adjusted ASP.

The provider add-on payment could also be based on the inflation-adjusted ASP to minimize potential for large price increases to inflate provider add-on payments.

There was concern about CMS administrative resources to implement a rebate. To reduce the work involved, low-cost drugs could be excluded from the inflation rebate policy. Doing this might make sense since 10 percent price growth on a $10 drug is less of a concern, for example, than on a more expensive drug.

Also, duplicate discounts could be avoided, meaning that the ASP inflation rebate would not apply to Medicare utilization already subject to a 340B discount or Medicaid rebate.

Finally, an inflation benchmark would need to be chosen. It could be CPI-U like the Medicaid inflation rebate, or an alternative could be considered. If an alternative is chosen, a principle that could be considered is that the inflation benchmark be in a similar range to the annual payment updates received by Medicare providers.

Now let's discuss a consolidated billing code policy. To promote maximum competition, brand drugs and associated generics are in one billing code, and all biosimilars associated with the same reference biologic are paid in one billing code. By contrast, we do not have maximum competition for most single-source drugs and reference biologics because they are paid under their own billing code.

It is widely recognized that separate billing codes do not promote optimal price competition, and your briefing paper provides two examples that demonstrate this point.

First, while Medicare's payment rate for the biosimilar Zarxio has declined by roughly 20 percent during the six quarters since its launch, Medicare's payment rate for its reference product Neupogen has remained about the same.

Second, although we have only one quarter of data, Medicare's payment rate for the biosimilar Inflectra is 22 percent greater than Medicare's payment rate for the reference product Remicade.

The Commission has held that Medicare should pay similar rates for similar care recognizing clinical

differences.

That leads us to the policy of giving the Secretary the authority to place products with similar health effects in the same billing code and pay them the same rate based on the volume-weighted ASP for the products in the code. This policy could be considered for a reference biologic and its biosimilars. This policy could apply beyond biosimilars to therapeutic classes in which there are several products with similar health effects. During the October meeting, we discussed how the Secretary could determine what products to group together. To group the reference biologic and its biosimilars, the Secretary could rely on the FDA approval process to determine what products to group together.

Implementing this option beyond biosimilars would require the Secretary to have a process to identify products with similar health effects. It would be important that such a process be transparent, solicit input from clinical experts, beneficiaries, other public and private payers, and stakeholders, and be designed to avoid conflicts of interest.

During the October meeting, Commissioners raised the

notion of including a medical exception process. We have added more details about such a process under which Medicare would pay for the higher-priced product if the clinician provided justification that the product was medically necessary due to the beneficiary's condition. Some could argue that an exception process might be needed if some clinicians would not supply the higher-cost product to a beneficiary with a medical need for a particular product.

On the other hand, some might contend that an exception process is not necessary because the clinician would continue to have the choice to select the product most appropriate for the patient. In addition, similar to other average-based payment methods, clinicians would earn more net revenue than they otherwise would on lower-cost products under the consolidated billing code policy, and that additional revenue could help offset the cost of a higher-priced product if needed by a particular patient.

We are seeking feedback from Commissioners about this issue. If deemed necessary, then such a process would need to be transparent, predictable, and timely. Providers could submit medical justification to Medicare's

administrative contractors. The process could be coupled with Medicare's existing appeals process. Your briefing paper discusses the possibility of creating an expedited process for such appeals.

To address the concern that the exception process might create incentives for the use of higher-priced products, the clinician's payment from Medicare when an exception is granted could be set at the higher-cost product's ASP without an add-on payment. The beneficiary's 20 percent coinsurance could be based on the coinsurance of the consolidated billing code payment rate, not the higher-cost product that is furnished under the exception.

Now Kim will talk about the Drug Value Program.

MS. NEUMAN: The policies that Brian and Nancy just discussed would seek to improve the ASP payment system. Now we are going to talk about developing a second system, which would be a voluntary, market-based alternative to the ASP system.

Although the alternative system, which we are calling the Part B Drug Value Program, or DVP, would be voluntary for providers, it would be important to create incentives for providers to enroll.

The current 6 percent add-on in the traditional buy-and-bill system may make that system more attractive to providers than the DVP.

As a way to transition to the DVP program and encourage providers to enroll in it, a policy that could be considered is to reduce the ASP add-on in the buy-and-bill system gradually over time.

As you'll recall, in October a number of Commissioners expressed interest in creating a voluntary alternative to the ASP payment system that would create more incentives for provider efficiency and create pressure on manufacturers to offer lower prices. Commissioners asked for more detail on how such an alternative might be structured, and so we're going to walk through a potential approach now.

In general, the policy would give the Secretary authority to create a Part B drug value program that would use private vendors to negotiate prices and offer providers shared savings opportunities.

The design of this program would be informed by lessons learned from the CAP, but structured differently to increase vendors' negotiating leverage and encourage

provider enrollment.

So here are some more specifics on how the DVP might work.

First, enrollment in the DVP would be voluntary for physicians and hospitals. Each year, these providers would decide whether or not to enroll in the DVP. Those that chose not to enroll would remain in the buy-and-bill ASP system with the potential improvements discussed earlier and with a reduced or eliminated ASP add-on.

There would be multiple DVP vendors, so providers would have a choice of which entity to work with. Each provider would choose one vendor.

The program would have a GPO-like structure.

DVP vendors would negotiate prices with manufacturers and facilitate the availability of those prices to providers through a network of distributors and wholesalers.

The DVP vendors would not ship product to beneficiaries. Instead, providers would buy drugs from distributors or wholesalers at the DVP negotiated rate for their Medicare patients.

Medicare would pay providers for the drugs at the DVP

negotiated rate without a percentage add-on.

Providers would continue to be paid for drug administration services under the physician fee schedule or the outpatient prospective payment system.

An important feature of the DVP program would be shared savings opportunities for providers. If the DVP program resulted in lower total cost of Part B drugs, enrolled providers would share in those savings.

Provider eligibility for shared savings could be contingent on both cost and quality in order to avoid incentives for stinting.

Beneficiaries would also share in the savings. If DVP prices are lower, beneficiaries would save because their cost sharing would be based on that lower price.

Commissioners talked in October about the importance of the DVP vendors' compensation being structured in a way that creates incentives for vendors to negotiate discounts with manufacturers and to reduce the total cost of Part B drugs.

With that in mind, the vendor could be paid an administrative fee and potentially shared savings. Shared savings could be contingent on whether the vendors reduced

the total cost of Medicare Part B drugs and whether the vendors engaged in efforts to promote quality or met other performance standards.

An important aspect of the DVP would be the use of tools to increase vendors' negotiating leverage with drug manufacturers.

First, DVP vendors would be permitted to use a formulary. Criteria would be developed for what is an acceptable formulary, and CMS would oversee the vendors to ensure they met the standards. There would also be an exceptions and appeals processes in case a beneficiary had a need for a drug not on the formulary.

Second, prices under the DVP program 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. This would be especially helpful for situations where drugs that are not on the formulary are provided under the DVP program through an exceptions process.

Third, DVP vendors could be permitted to use other management tools, for example, step therapy or prior authorization, and possibly some of the newer purchasing approaches that some private payers are exploring like

risk-based contracts or indication-specific pricing.

While a formulary and some of the other tools I just discussed would increase vendors' negotiating leverage for drugs that have clinical alternatives, the vendors may have little leverage for drugs without close substitutes. Given this, arbitration could be considered for use in the DVP program to facilitate DVP vendor and manufacturer negotiations for high-priced drugs without close substitutes. There's more discussion on arbitration in your paper, and we'd be happy to discuss it further on question.

In October, Commissioners raised the question of how DVP prices would affect ASP.

DVP prices could be excluded from ASP. This would give DVP vendors more leverage with manufacturers since DVP prices would not carry over into manufacturers' other lines of business like commercial plans that often pay based on ASP.

Finally, in terms of developing and implementing the DVP, it will take time to develop the program, and the complexity of doing so varies across classes of drugs. There could be benefits to phasing-in implementation of the

DVP, beginning with a subset of drug classes. This could help address the complexity and allow CMS and DVP vendors to learn from experience over time.

Now that we've walked through each piece of this potential package of reforms, let's step back and look at how the pieces would work together.

As we've said, the idea would be to move to a system where providers have a choice: enroll in the DVP or remain in a buy-and-bill ASP system.

The DVP would take time to be developed, so while it's being developed, Medicare could take action to improve the existing ASP system. These improvements would apply to all providers initially and to providers that choose not to enroll in the DVP once it's operational.

The ASP improvements seek to do the following:

The policy to strengthen ASP reporting is about getting more information to ensure accurate payments.

Modifying the WAC add-on is about paying a more efficient rate for drugs before ASP data is available.

The policies of the ASP inflation rebate and consolidated billing codes are about putting downward pressure on ASP and spurring price competition.

Now, turning to the DVP, you can think about it as being similar to the new payment models being developed in Medicare. With the DVP, the goal would be to encourage providers to enroll in this new model that has better incentives for provider efficiency and that uses private vendors to obtain lower prices from manufacturers.

So that concludes our presentation. We'd be happy to answer any questions.

In terms of the discussion, it'd be helpful to get feedback on the potential policies we just discussed as it's the Chairman's goal to work toward draft recommendations for the March meeting.

DR. CROSSON: Thank you. Great presentation.

We will now take clarifying questions. Bill Gradison, Amy, Paul.

MR. GRADISON: In situations where the WAC would be used because the ASP was not yet available, have you considered, retroactively, using a retroactive rebate system so that you didn't have to get into this question of changing the percentages?

We're talking, as I understand it, usually about two or three calendar quarters of data, and I'm just curious

whether you had looked at that possibility.

MR. O'DONNELL: So, yes, we did look at that, and I think it's kind of an option for the Commission to think about, but I think what we discussed was that we are trying to balance the administrative complexity with kind of the money that we'd get out of it. And so, as part of our package, we're already setting up kind of one rebate program, and we didn't know whether kind of this amount, which is certainly much smaller than the other program, would be worth it to set up that type of system.

DR. CROSSON: Amy.

MS. BRICKER: Your reference to excluding repackagers, so would they be reimbursed at their originating products?

MR. O'DONNELL: So the way it would work would be that if a manufacturer sold to a repackager, the manufacturer would include those sales to the repackagers in the manufacturer's submission, ASP data submission.

MS. BRICKER: So everyone would be -- all of those parts would be reimbursed to the same level?

MR. O'DONNELL: Right. So whether the products were channeled through a repackager or not, it would be priced the same, so yes.

MS. BRICKER: Okay.

The second question I have, with respect to the inflation adjustment, can you just walk through the flow of dollars, assuming -- you can use whatever numbers are easiest, but if the product is $100 and it's experienced at 10 percent inflation, so it's $110, who is getting paid what and when? I understand that the beneficiary's price or cost share would be off of the $100, but I'm just not clear on how the flow of dollars works.

MS. NEUMAN: Okay. So let's think of an example. Let's say that the actual ASP is $105, but the inflation-adjusted ASP is $100. So how it would work is that the beneficiary's cost-sharing would be based off of that $100.

The provider's payment would be -- it would be 100 percent of the $105 plus 6 percent of the $100. So that the 6 percent add-on is based on the lower price, but they get the full 100 percent of the ASP. And I will backtrack on that. That was confusing.

Starting over on the provider, the provider would be paid 100 percent of the $105 plus 6 percent of the $100. So the 6 percent add-on is on the lower price, okay?

MS. BRICKER: So the provider benefits from the

inflation?

MS. NEUMAN: They do not.

So if inflation adjustment did not exist, the provider would be paid 106 percent of $105. The way that this is set up currently is instead the -- so that would be $105 plus $7, let's say.

Now, the way this is set up is the provider is going to get $105. So the ASP folks are going to 6 percent of the $100, so they're going to get $6 instead of $7. So they're not -- they're getting a little bit less add-on payment than they otherwise would get because their add-on payment has effectively been inflation-adjusted.

MS. BRICKER: But they're buying the product at $105.

MS. NEUMAN: They are buying the product at somewhere around $105, right, because the ASP is the average across the market, and providers vary in terms of what they purchased it at. And then they get 6 percent add-on on top of that in general.

MS. BRICKER: And the manufacturer is going to be billed the $5 in this example to be refunded back to Medicare at some point in the future.

MS. NEUMAN: That's correct.

MS. BRICKER: At the end of a year, presumably.

MS. NEUMAN: Yeah. There would be a lag period. You'd need to count the -- yeah, it would be in that range. Yep.

MS. BRICKER: Okay. And we can talk further. I think we need to think about the cash-flow implications of the benefit paying out kind of credits that it's not receiving from the manufacturer for -- typically, these things can -- by the time at the end of the year, and then there's probably going to be a quarter that you're going to report out the inflation adjustment. And then there's some cash-flow hit that comes back from the manufacturer. So you could be 18 months out before you ever get that inflation adjustment back from the manufacturer, if I'm understanding the proposal correctly.

DR. MILLER: That's right, but the money would be coming back to the Treasury. So who is the cash flow? It's the cash flow of the Treasury or the provider that you're worried about?

MS. BRICKER: I'm worried about --

DR. MILLER: Or someone else?

MS. BRICKER: -- all of the stakeholders sort of in

this example. So the physician is presumably buying this at $105.

DR. MILLER: And so they are being reimbursed what the price is that they are facing.

MS. BRICKER: Mm-hmm.

DR. MILLER: So I don't see a cash flow there.

MS. BRICKER: Well, then you're giving money back, then, if I understand, to -- from the manufacturer. The Treasury is out, then the dollars.

DR. MILLER: Correct. The cash-flow problem, I think -- and, Kim, you track this carefully. I think the cash-flow problem is just the Treasury. The Treasury has to wait 12 to 18 months to get its money back.

MS. NEUMAN: Yes.

DR. MILLER: Okay.

Well, I'm sorry. I just wanted to --

MS. BRICKER: That's right.

DR. MILLER: All right. I'm sorry. Back to you.

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

MR. PYENSON: I mean, there is a liability issue on the part of the manufacturer, and that's been a financial

reporting issue. I don't know if that's what Amy is referring to, unlike the coverage gap discount program. So there's some complexity there.

DR. CROSSON: So it would have to be booked. Is that what you're saying?

MR. PYENSON: Yeah, yeah.

DR. CROSSON: It would have to be booked. Okay.

MS. BRICKER: Well, they would know what their inflation was tracking at. I'm less worried about them not being able to book that from an accounting perspective, but the Treasury, that's presumably a lot of money that you're waiting on the manufacturer to reimburse. And it would just be -- it would be interesting to see what the magnitude of that is that we're expecting, and maybe there's another way for us to think about it.

DR. CROSSON: I mean, that's absolutely true, but that's money the Treasury is not getting now.

MS. BRICKER: Understood.

DR. CROSSON: Right.

DR. MILLER: And now I understand. At first, when you said cash flow, I was thinking provider, and so that's why I wanted to zero in.

And, actually, there is an example in the paper of the amount of dollars that might travel back to the Treasury under some very, you know, assumption types of things. So we could give you magnitudes of dollars very, very easily, I think, but all hypothetical in the sense of if you set inflation here, right, that type of thing.

DR. CROSSON: Okay. I've got Paul, Kathy --

DR. HOADLEY: Jay, on this point?

DR. CROSSON: Yes, Jack.

DR. HOADLEY: I mean, presumably, because Medicaid has been doing an inflation-based rebate, we would have some experience there in terms of getting the information and sort of how any aspect of cash flow back to government is working on that. So I wonder if there's some information we could get on how that part of that's played out to help answer this.

DR. CROSSON: So for clarifying questions, I have Paul, Kathy, Jack, and I saw Pat. Anybody else so far? Warner and Bruce, okay.

Paul.

DR. GINSBURG: Yeah. I wanted to bring up the issue of the sequester, and the clarifying question is really how

do we deal with it because, if I'm correct, the 2 percent sequester that's been going on for some time now, it's not a 2 percent reduction in the 6 percent markup, but it's really a 2 percent margin in the 106 percent total. Is that correct?

MS. NEUMAN: Yeah. It's a 2 percent reduction to the providers, a total payment from the government, so 1.6.

DR. GINSBURG: Yeah. Okay. So, basically, the currently sequester reduces the 6 percent margin to 4 percent or slightly less than that.

And my sense is that some of the physician opposition to the innovation centers Part B proposal demonstration was really -- would not have happened if not for the sequester in a sense that if you're going from 106 to 102, that's okay, but if you're going from 104 to 100, given the fact that some people may -- I'm just saying that I think the possibility that the sequester will still be in effect really casts a pall over proposals like WAC+3, and we just have to think about what wording we're going to use, saying that this is our proposal. We realize that if a sequester is still in effect, we might have to make a temporary change. But that's what I want to bring up.

DR. CROSSON: Let's see where we are. Kathy.

MS. BUTO: I just wanted to go back to Amy's point a little bit, which is, at one point, we had two options to achieve the inflation limit. One was this rebate approach, which is somewhat complex, regardless of whether Medicaid is doing it, and just putting an inflation limit on ASP increases, ASP plus 6 percent increases, I guess, ASP increases, which is -- I mean has the benefit of the beneficiary, complexity of the beneficiary only paying 20 percent of the lowered amount is immediate. The government doesn't have to go back and collect that inflation rebate. It's just built into the rate, et cetera, and I'm just curious why we've preferred this approach to that approach. So that's my first question.

And I guess the second one is around the arbitration process, and if you could just explain a little bit more about how that would be executed in your mind by the vendors and CMS, just a little bit of clarity around how you think that would work and could work and time frames around how long it would take to come up with that kind of process and develop a price.

DR. MILLER: I'm getting the look, Kim. Do you want

me to take the first one?

MR. NEUMAN: On the inflation, sure.

DR. MILLER: And I think Kim is just looking at me because there was some interpretation of 17 comments going on here.

So what I thought we were trying to do here -- and, Kim, you know I'm leading this; you better be close order -- is the biggest concern that the Commissioners seem to have is that the beneficiary not carry any more liability than they would have to carry, and so we have constructed it that the beneficiary pays 20 percent of the inflation amount. That's one thought.

The second thought, if I understand your proposal, is if the government's amount to the provider also was held to the inflation point, then the provider could be facing a price that's higher than that and not getting reimbursed, and our takeaway was that was something -- and that's why when Amy raised her cash-flow issue, I immediately started thinking, well, I thought we had sort of worked through that issue. And so the cash-flow issue in a sense was converted to the government, and because there was a Medicaid precedent, the idea was the rebate would be the

way to kind of capture all the equities as much as possible. Bene is held harmless. Provider is held harmless. Manufacturer pays the government on the back end.

MS. BUTO: I mean, I guess I'm saying, Mark, that sounds right, but getting the bene -- doing the machinations to get the bene to pay a coinsurance on a lower fee than what the provider is doing, applying the ASP+6 to the lower amount, not counting the actual price increase, these are complexities that you wouldn't need if you just set the payment rate with the inflation limit, in my mind, anyway. I'm just asking what the rationale was.

And I think we've seen from the evidence that these guys have provided in the past that providers have nicely compensated for things like the sequester already. I mean, whether it's providers or manufacturers, the pricing manages to fall out in a way that they're accommodating those kinds of adjustments.

So I'm not sure why we're going out of our way to accommodate the provider in this situation. I'm just trying to figure out why we have taken that other option off the table. It's a lot simpler.

DR. CROSSON: Kathy, I have to admit I'm a little bit confused. When I first heard you say that, I thought you were saying simply that Congress would pass legislation, and it would say to pharmaceutical manufacturers, "You cannot increase your price more than 5 percent year by year." That's not what you're saying.

MS. BUTO: No.

DR. CROSSON: What you're saying is that the physicians --

MS. BUTO: Yeah. It's like --

DR. CROSSON: -- purchasing the drugs would only be reimbursed at last year's price --

MS. BUTO: Correct.

DR. CROSSON: -- plus 5 percent, irrespective of the actual ASP. Is that right?

MS. BUTO: Well, it was the other option that we had on the table until, I think, this meeting --

DR. CROSSON: Right, right.

MS. BUTO: -- which was that the payment rate would be limited by inflation, whatever inflation index we chose, and that would then fall out to the beneficiary copay would be at that lower rate.

Yes, the provider might be under some pressure, but I think we are willing to put some of that pressure back on the provider. It does add complexity to the calculations, to the recoupment of money, et cetera, et cetera, that I'm just asking. It just doesn't seem necessary if you can go the other route. That's my point.

DR. CROSSON: I understand the point. Thank you.

Jack.

MS. BUTO: Oh, the other one was the arbitration process, and if you could just kind of give us a little clarity on that.

MR. O'DONNELL: Right. So I'll walk through -- there's a lot of inflexion points for the Commission to think about and policymakers to choose. So I'll walk through kind of an example of how it might work and then note some decision points along the way.

So I think the way that we are conceiving about it is that there would be certain drugs would be eligible for arbitration, and so I think in our minds, it was these kind of high-cost sole-source drugs.

So let's say a new drug that's sole source and high cost comes onto the market, and the DVP vendors wouldn't

have any leverage to negotiate. So, at that point, you would want the arbitration process to step in to kind of come to an agreed-on price.

So it will take time. So for a time period, you will be paying the drug, largely how we have been, on ASP because the arbitration process will take some time. So how it might work is that the vendor or the vendors collectively would call for arbitration on this given drug, and so the arbitration would be between the vendor and the manufacturer. So one of the inflexion points was whether that negotiation between one vendor and the manufacturer would be applied to all vendors in terms of pricing.

So you'd have this arbitration panel, which we discussed in your package, could be set up of three neutrals. We go through a little bit about how you select that, and then there would be a period of -- you know, let's call it months -- that the manufacturer would submit kind of a package of effectiveness research to the arbitration panel and some pricing proposals, and the arbitration panel would consider this and potentially look to a kind of independent fact finder to help it out. And then, at the end of that process, they would issue kind of

a ruling.

So the only thing -- yeah, go ahead.

MS. BUTO: Yeah, a quick question.

MR. O'DONNELL: Yeah.

MS. BUTO: So you're saying this arbitration process would really apply just to the DVP or to the rest of buy-and-bill as well?

MR. O'DONNELL: So we are thinking about it as a tool and the DVP.

Just a note on the arbitrator, there are -- and we note them in the paper. There are ways to kind of make the process more efficient, so limit the options that the arbitration has in terms of what it can decide on, and you can also -- policymakers can also set criteria. So you can kind of highlight or prioritize certain priorities, like if a drug is a breakthrough, you can prioritize that in the criteria that you give the arbitrator. So you can kind of line up kind of a set of rules for the arbitrator to make a decision on that could expedite the process.

DR. CROSSON: So one example of this -- and it's probably an extreme example -- is Major League Baseball. So, when there is a salary dispute, an arbitration is

called for. There is a process for developing a neutral arbitration panel -- I won't go through that -- and the player or player representative comes in with a salary request. The Major League Baseball team comes in with what it wants to pay, but in this particular model, the arbitrator has only once choice -- arbitration panel, rather, has only one choice, and that's to pick one or the other, not find a medium in the middle.

Now, that's a strange dynamic, but what has proven to be the case is that because both parties have some risk of having one or the other decision that they don't want, then it tends to actually limit the instances of arbitration because usually, in most cases, essentially a private arrangement is developed prior to the arbitration process. That's just one model.

Okay. Jack.

DR. HOADLEY: Just one addendum on your last comment, the State of New York in its balanced billing law has also adopted a similar kind of arbitration process for determining the payment rates for out-of-network providers who are billing in emergency and other situations, so that's another precedent for that.

My clarifying questions, I have two of them. One is, when you talk about the GPO model, you sort of framed it in terms of drugs coming through distributors and wholesalers, and I don't know to what extent the Part B drugs are being delivered to providers that way or through direct arrangements with manufacturers. I don't know if we know how much is done different ways and, in fact, does it matter in terms of playing out how this GPO model would work. It seems like it might not matter, but I was just wondering about that.

MS. NEUMAN: So I don't have figures for you on that breakdown of direct versus indirect, but we can look and see if we can find that. I think this model would have to accommodate that in some way, either going straight through the direct method and applying in that way, or bringing them through the distributors and wholesalers. The intent -- right? -- is to keep the system as it is today in terms of --

DR. HOADLEY: Right.

MS. NEUMAN: -- not monkeying with the distribution system. So a goal might be to try to make it work exactly how it works today through the various channels. We'll

look at that more.

DR. HOADLEY: Right, yeah, just to make sure that if there are direct sales from manufacturers that that could -- and it seems like it should, but just an "I" we need to dot.

When you were talking, Brian, about the arbitration, you mentioned vendors acting alone or collectively, and I had been thinking about that, whether we would expect the multiple DVP vendors to each have a separate arbitration going on or whether this would be sort of one process for all. And have you thought through sort of the pros and cons of that choice?

MR. O'DONNELL: So we've thought about that a little bit, and I think largely what we were thinking about was just the efficiency of it all. And so, you know, we were thinking of this as having multiple, obviously, DVP vendors, and the arbitration process will probably take, you know, a non-trivial amount of time. So we were thinking that, you know, if you have -- if one DVP vendor calls for it and it's using the pricing to apply to all the other vendors, it might be more efficient. I think that's where our thinking was heading. But it's certainly a

decision point.

DR. HOADLEY: Okay. Thank you

DR. CROSSON: Okay. We're still on clarifying questions.

MS. WANG: This is a question on the consolidated billing codes. I think it was great that you included some thought around the exceptions process and all the rest. I'm a little bit confused, though, and this is a very simplistic kind of question. Consolidated billing codes have to do with how Medicare decides to pay for things. An exceptions process has to do with like medical necessity and medical judgments, and I'm a little worried about -- in addition to the fact that it's complex to administer and set something like that up, is there any reason, if there's a consolidated billing code situation and a clinician decides that a different -- you know, a different Part B drug, a higher-cost, whatever, is appropriate for his patient, that you shouldn't just go to the end point that you suggested, which is let them prescribe that drug, just don't pay an add-on, pay it at cost? And I know that there were efforts to protect the beneficiary at the lower -- I feel like these are layers of complexity. Would that

destroy the idea of consolidated billing codes? Skip the appeals process, skip all of the calculations about what's the lower coinsurance and all the rest, and just let the clinician make a clinical judgment that they want to prescribe something that's more expensive, but don't pay an ASP add-on. Does that work? Maybe I'm not understanding.

DR. MILLER: So am I getting the look or do you want to answer it? Which way do you want to go, Nancy?

MS. RAY: So I think one of the reasons to go through a medical exception process was to, I guess, make sure that the medical exception was justified, that any other incentives that the provider might have in prescribing the drug would, you know -- the medical director at the MAC could evaluate that.

DR. MILLER: I would have said two things, that one, which is, you know, to the extent this is -- and I would really defer to people like Jack and Amy and Kathy on this. To the extent that you see the medical exception as something of a management tool also, rather than just having stuff running through, if truly, you know, there's a management function there on the part of the program, maybe you do want an exceptions process, number one. But I have

to say I don't have any inherent hostility to the idea. I would defer to others on that component.

And then the second thing I would have asked is: But is it somewhat inflationary in the sense that if you let a lot of exceptions go, even though you're not paying add-on, I think you're raising -- all else equal, you're raising the underlying ASP. And that's with two seconds of thought in public, which, you know, I don't like to do.

MS. WANG: Okay.

DR. MILLER: But my sense is those would be my first two responses.

MS. WANG: But there would be an inflation adjustment constraint on that exception drug. I just -- unless -- do you --

MS. RAY: Right, but just to be clear, just to clarify Mark's point, it would be -- the payment rate would increase because more of the higher-cost product was being used, not because of a price growth that would be taken care of under the inflation rebate. That was your point which --

DR. MILLER: I think that's exactly -- no matter the fact that I didn't really understand what I was saying,

that's what I --

[Laughter.]

DR. MILLER: Right. You got it [off microphone].

MS. WANG: Okay. I just wondered whether there was a simpler way to handle that without getting into the management of clinical decisionmaking, because, you know, the reason that we're talking about this, I think, is to try to address what is perceived to be an incorrect potential incentive to prescribe at higher levels because of the way that the ASP+ works. And now we're kind of getting into management of or judgment over clinical decisionmaking, and Part B drugs are complicated. I think there are a lot of doctors who in good faith feel like their patients might need different drugs than what might be in a bundle. So I think that that's a comment more than a question.

The second question that I had on the DVP, can you just explain a little bit more? Because I want to make sure that I understand. I think that the -- and, by the way, I love pictures, so I love the timeline that shows this sort of splitting in these two sort of parallel systems.

If the intent is to try to provide incentives for docs to get into the DVP, what do you see as the reason that docs would go that way? You know, what caught my eye is there's no more add-on. So they're getting -- yeah.

MS. NEUMAN: So there's a couple of components. As you said, the traditional ASP system, the add-on, would be taken down so that there's not the revenues that are currently there in that system that make it as attractive. And then on the DVP side, there would be shared savings opportunities for the providers. So to the extent that vendors are able, where there are clinical alternatives, to take prices down below ASP for a particular product, then the providers would share in those savings in a way that is not possible under the ASP payment system.

MR. THOMAS: Just a couple of questions. On Slide 3, you reference a 9 percent growth since 2009. Do you have any idea what components of that are volume versus price?

MS. NEUMAN: That 9 percent growth rate, about half of the growth is due to an increase in the price, and that reflects both an increase in the price of existing drugs as well as shifts to newer higher-cost products.

MR. THOMAS: Okay. And can you just briefly remind me

how the WAC is calculated? What's included in that calculation? If it's overly complicated, never --

MR. O'DONNELL: No. It's really simply. WAC is just the list price that the manufacturer puts out. And so until ASP data is available, which can be six to nine months, you just pay the list price.

MR. THOMAS: And then the ASP is really just the trailing six to nine months of what the average price is that they sell in the marketplace.

MR. O'DONNELL: Right, so when the ASP pops up, it reflects the small discounts that receive in the WAC. But, yes, you're right.

MR. THOMAS: And remind me again, what is the average discount from the WAC to the ASP, roughly?

MR. O'DONNELL: So we found the range for kind of the new high-expenditure drugs we looked at, the range was anywhere from 0.7 to 2.7 percent.

MR. THOMAS: Okay.

MR. O'DONNELL: So 3 percent would kind of -- is the high end of that and putting a little bit of pressure on them.

MR. THOMAS: Okay. And did you look at other

alternatives? Because it seems like what we want to try to look at is how do we protect the beneficiary but also look at escalation of price. Were there other -- did you consider other simpler ways to basically control escalation of price? Or do you think there's other simpler ways to control escalation of price?

MR. O'DONNELL: Well, so the launch price is kind of outside of both the WAC and the ASP inflation rate, so that's --

MR. THOMAS: Right, but ongoing.

MR. O'DONNELL: Yeah, other than the WAC and the inflation, I think those were the two things we considered.

DR. MILLER: Warner, is there some thought that you --

MR. THOMAS: Well, I'm just trying to -- well, this is clarifying, so now I'm -- I do have thoughts.

[Laughter.]

MR. THOMAS: Wait until we get to Round 2, Mark. I've got a lot of questions when we get to Round 2.

DR. MILLER: Sorry. I was way out of line there.

MR. THOMAS: I'm just trying to, you know, follow the process. Just real quickly, on the DVP, so -- and I'm just trying to understand this. So essentially it seems like

you're setting up a GPO-like structure, yet -- you know, large systems and there's GPO. Why do you think that DVP would be different or more successful than current GPO or purchasing processes today? I'm just really trying to understand the logic behind it.

MS. NEUMAN: So the DVP would have certain tools that would be applicable to Medicare Part B drugs that currently don't exist, so the ability to create a formulary where there are drugs -- where there are clinical alternatives, pick one over the other, would give leverage to negotiate in ways that currently may not be there. Then there's also other tools that we've discussed that could sort of enhance the leverage.

MR. THOMAS: But presumably, providers today have formularies and whatnot that they use today, correct? I mean, how would this be different than, you know, a system that has a formulary that uses certain drugs or changes certain drugs out? I'm just trying to understand how this would be different.

DR. CROSSON: I'm sorry --

MS. BRICKER: He's thinking from a hospital -- from a hospital's perspective, they have the formulary, and that's

what they're going to prescribe. And are you suggesting that there wouldn't be new entities created, but whoever your GPO is today would have additional resources potentially to -- or levers versus creating another set of organizations that then you have the regular GPO and then this other G --

MR. THOMAS: Right. I'm just trying to understand what tools would this new DVP-GPO would have that is not currently in place today with -- you know, maybe not a single physician practice, but with larger entities or larger groups, I mean, they presumably look at efficacy of drugs and trading out drugs for, you know, different price drugs and whatnot. So I'm just trying to understand what would be different in the DVP.

DR. CROSSON: What's that? You --

DR. DeBUSK: I just [off microphone] --

DR. CROSSON: You want to answer? Okay. Go ahead.

DR. DeBUSK: I do think the DVP --

MR. THOMAS: He really read this chapter backwards and forwards, I knew it.

DR. DeBUSK: Not like I did Part D.

[Laughter.]

DR. DeBUSK: I think the DVP, to your point, it really would be a specialized GPO or something that could be done within a GPO. I think the novelty -- and I do want to compliment you guys. There's some real novelty here in that, for example, they have to start -- the starting price is the ASP, and any concessions don't count against the ASP calculation. And I think there's some real novelty there because that does give the DVP a nice level starting point to basically price-minus these -- to do deals at price-minus.

I also think this arbitration mechanism is another fascinating tool, because just having that -- I mean, imagine the existing GPOs having this new set of tools that they could build, again, formularies, the ability to exclude drugs, all that. But I think if you're starting at ASP and going down from there, but the drug company knows this isn't going to hurt their overall market price, I mean, this is almost the opposite of what you see in GPO agreements today that have things like most-favored-pricing clauses, which really is just a way of keeping a price up at a high level. So this is really the antithesis of that.

The one thing that I would say, this idea of stripping

the markup out of the reimbursement, I don't think that's going to work as well as we would expect, because imagine as a provider you'd hate to be penalized based on the vendor -- on who you purchased your product through or what GPO agreement you accessed. Plus I'm not sure a claims mechanism could even do that anyway. I mean, are we set up to do a Part B drug claim that the actual rate of the claim varies based on the source of the supplier? Okay. So we can do that today.

But the thought is, if you just -- if you strip the markup -- or if you lift the markup in the reimbursement, whether they bought from the DVP or not, you could always walk the ASP down over time. But I think when you start paying administrative fees back to the DVP vendors, you're going to get into some of those same agency issues that you run into the GPO where the higher the price is, the more they make. So what I would rather do is spend that money on the ASP markup, walk the markup down, and then let the shared savings be the source of additional money.

MS. BUTO: Brian is getting into Round 2.

MR. THOMAS: I just have two very quick --

DR. CROSSON: Okay. I want to bring this back to

clarifying questions. Having said that, I just want to make one comment. So I don't think the intention here, Brian, is to pay an administrative fee based upon the dollar volume. Right? So the intention is, I think, a little different from what the mechanism is that you rightly described in the GPO market right now. So, Warner, you have two more --

MS. BUTO: Jay, can I just on -- there's one other thing that I think I wanted to mention to Warner about his comment --

DR. CROSSON: Yeah, I think, Bill, Kathy was --wanted to speak first on this point, and then you.

MS. BUTO: Okay.

DR. CROSSON: Is that right, Bill? Bill?

MR. GRADISON: I wanted to ask a question or two about the arbitration, whenever that's appropriate.

DR. CROSSON: I'm sorry. So you just want to get in line. My mistake.

MS. BUTO: So I just wanted to -- the other thing, Warner, that I think is different here is not that the entity is different; that Medicare has no ability right now to pay a different rate than ASP+6.

DR. CROSSON: That's right.

MS. BUTO: So what this does is it provides another entity, whether it's an existing GPO or other, to set different payment rates for drugs in Medicare. So essentially it's more like what gets done rather than is this entity different than what's out in the private sector.

MR. THOMAS: Right. When we get to Round 2, I'll just ask why don't we just do that for the existing entities, but I'll wait for Round 2 to do that.

[Laughter.]

DR. CROSSON: Thank you for that clarification, Kathy. Warner, you're still on questions.

MR. THOMAS: So getting back to the consolidated billing codes, how difficult do you think that is to implement? I mean, just kind of on the surface, it seems like it would be relatively easy to implement that. It seems like a great recommendation. But how difficult, based on what your research found, would that be to implement?

MS. RAY: Right, so I think for the reference biologic and the biosimilars, CMS can rely on the FDA process. So I

think that is straightforward.

I think for other drugs and other biologics, I think there is a little bit of complexity there, and I think that's where CMS can reach out to clinical experts -- pharmacists, clinicians, and so forth -- and also look to see what private payers have been doing.

MR. THOMAS: And would you see that basically like when you're going to get something approved, like you would have to say, look, I'm opting into this billing code because that's the disease or that's the treatment I'm trying to address? Is that kind of the thinking behind this? Or how would -- as far as which code they'd be in, would it be as part of the approval process?

MS. RAY: You mean the FDA approval process?

MR. THOMAS: Yeah.

MS. RAY: No. Well, I mean, at least as of right now, the FDA approval process is a distinct process that just focuses on clinical efficacy. I think under this process it would be the Secretary, again, getting input from clinical experts --

MR. THOMAS: Okay.

MS. RAY: -- and reaching some judgment about which --

about grouping drugs that treat a given condition.

MR. THOMAS: Okay.

DR. MILLER: Just to say it a little differently, when the drug came to Medicare for reimbursement, that would be the point where the decision is made into which category it goes, and I think the first part of her response is the FDA, for biosimilars, has made a determination of what it's similar to.

MR. THOMAS: Right.

DR. MILLER: And so there the category should be clear. The second part of your conversation was what about the rest of those determinations.

MR. THOMAS: Right. Okay. And, lastly -- and this just -- I probably should know this, but I apologize. So besides Part B drugs, what is the other largest payments kind of in the Part B program besides drugs? Physician fees?

MS. RAY: Yeah.

MR. THOMAS: Okay. All right. I thought that's what it was.

MS. RAY: Physician fee services.

MR. THOMAS: I just wanted to check. Okay. Thank

you.

MR. PYENSON: Thank you very much. I've got several questions, and I'll try to make these real questions and save the comments for alter.

The first one is on choice of inflation factor, and Consumer Price Index got mentioned or alternatives. And just some of the thinking, how we think about the choice of an inflation factor comes to mind. Do we think that drugs are a consumer -- Part B drugs are a consumer good or are they more like a wholesale product or a producer product? Let me pause there on the second part to that question.

MS. NEUMAN: So we haven't really taken a position on that. The reason that we've used CPIU in a lot of the analysis is that the Medicaid inflation rebate is based on that factor, so that was the motivation as a starting point.

You could consider a range of other things, and as Nancy said, also think about how these rates compare to the updates that providers get in the other sectors.

MR. PYENSON: Well, thank you.

In the world of drug pricing, there's been some dramatic differences in the trends for generic drugs and

brand drugs, and I'm wondering if that's a differentiation that needs to happen here, how you think about that.

MS. NEUMAN: So that is something we gave a lot of thought to, and the way we tried to address it is to think about excluding from the policy, drugs that were low in cost, and whether they were brand or generic, if they were low in cost, then you might not be as concerned about inflation. And so it sort of gets at your brand and generic issue in general, but if there were an expensive generic, the policy could then still apply.

MR. PYENSON: Thank you.

I think I will move on to my next question, which is, as others have noticed, the DVP does not -- the pricing is not reflected in ASP deliberately. As we think about that, it struck me that the Japan system of pricing actually has like a DVP concept, where that pricing is, in fact -- seems to be driving the overall price, their limits, and I am wondering if you thought about how that might -- could work.

MS. NEUMAN: So we haven't looked at that, but we can look at that and come back to you.

MR. PYENSON: Okay.

DR. MILLER: That's specific to the Japan point, and others, again, who know more about the drug industry should respond.

There is this concern that if you put the entity and say, "We're putting you on point to negotiate the drug," and the manufacturer knows that that negotiation is going to inform whole sets of other lines of business -- and, again, this is a decision, just to be clear, but the concern is that they are less likely to give the DVP a low price because it will inform the rest of your business.

I think you're turning that on your head and saying, "Yeah, I know," and it should. It's sort of what you --

MR. PYENSON: Well, it's an option.

DR. MILLER: Right.

MR. PYENSON: Another question on how a DVP could make money, whether you thought about the analogy to the PBM industry and how it makes its money or has made its money, which has largely been the spread in generic pricing. So it sounds like that's off the table. Did you consider that as a source of DVP profitability?

MS. NEUMAN: So the way the DVP was structured in this GPO model currently is that they negotiate a rate, and then

the provider buys it at that rate, and Medicare pays the provider that rate. So there's no dollars flowing to the GPO through this transaction.

From your prior conversations, several Commissioners were concerned that we get the incentives right. So, as a starting point, we thought about more like an administrative fee, not conditioned on the amount of dollars flowing, but on the work it takes to make this operational, and then shared savings, potentially, as a second piece to the extent that it saves.

If there are savings on generics, as you're suggesting, then that potentially could drive that shared savings piece.

MR. PYENSON: Okay. Thank you.

Last question, just on that, what portion of Part B drugs is generic? I think that was in an earlier report.

MS. NEUMAN: I don't know that we have a specific percentage for you. It is very low, though. Like the biologics, for example, account for nine out of the top ten Part B drugs, so it is a small chunk, generics, relative to the other.

MR. PYENSON: Okay. Thanks.

And last question, whether you think there is enough volume or margin here for a DVP to go at risk in some form.

MS. NEUMAN: So we haven't looked at that specifically. It's something we could think about.

MR. PYENSON: Okay. Thank you.

DR. CROSSON: Okay. Rita.

DR. REDBERG: Thank you.

Thanks. There was a lot of work and creativity, and I really liked the options in the chapter.

I have clarifying questions about repackaging and WAC. Just repackaging, how common are the use of repackagers, and what is their effect on price?

MR. O'DONNELL: Right. So we did note that we don't think repackagers are as common in B as they are in D, and so even to the extent some of them are in B right now, a lot of them don't report, so that's one issue.

Sorry. What was the next one?

DR. REDBERG: What is their effect on pricing?

MR. O'DONNELL: Oh, right. Because there's relatively few that kind of report right now, I don't know that the effect is really large right now in aggregate, but I think what we are concerned about is that if -- right now, most

of them are not mandated to report, and I think what we were concerned about is if we turned around and mandated them to report, you're saying, okay, you're kind of baking in a spread into the ASP.

So I think the way we were thinking about it, it was more of a kind of future concern for what kind of impacts our policy could have going forward.

DR. REDBERG: My other question, it's hard for me to understand how the WAC is determined. I know the manufacturer sets the WAC. Like you have a set of criteria on page 30 for what arbitrator. That would seem what arbitration could use, like how a clinical benefit presses of comparable drugs, but just my observations of prices, the starting prices seem all over the place to me. Maybe what the market will bear sometimes seems to play into it. Is there any predictability to WAC before it's announced?

MR. O'DONNELL: I mean, not to my knowledge. My knowledge, it's a list price from the manufacturer.

DR. REDBERG: Just related to that, because the example on page 11 -- and you mentioned it today too -- Inflectra is a biosimilar, but Medicare is paying more for the biosimilar than for the brand? I don't understand

that. You need to explain that to me.

MS. RAY: Yes. The --

MR. O'DONNELL: So I'll talk about -- so we brought it up in the WAC section, but I'll talk about why, ultimately, Nancy talked about it.

So Inflectra, we looked at Inflectra. The biosimilar is 22 percent higher than the reference product, which is surprising in and of itself, but when we were coming, I looked from a WAC perspective. I think there's two issues.

Immediately, it is paying a high price for the biosim relative to the reference, and what could be happening is that there could be discounts occurring, so that the net price when the ASP shows up is equal to the reference product or somewhere near the reference product. In that case, a WAC policy could try to get at it, but a combined billing code, if it was in a combined billing code, it would come in at the reference price, and so the price would be 18 percent lower.

So it came up in our WAC issue, but there's that issue, and there's also the issue of going forward, the competition between the two drugs. So the consolidated billing code deals with that problem a lot better, if

that's clear.

DR. REDBERG: Okay.

So getting back to it, there could be discounts, and who is getting the discounts?

MR. O'DONNELL: Right. Currently, the Inflectra is WAC price, so we don't know what the discounts are. So we'll know in probably six months or so. So that would be if a provider was buying it right now. They're getting paid WAC+6, and the price that they're buying it for, there could be a relatively large discount happening, but we don't know.

DR. REDBERG: So then the provider is accruing the benefit of the discount, but Medicare is paying more than the reference.

MR. O'DONNELL: It could be, yes.

DR. REDBERG: It's possible.

Thank you.

DR. CROSSON: Okay. Thank you.

Kathy. Sorry.

MS. BUTO: I did my Round 1. Thank you.

DR. CROSSON: You did your Round 1. Okay.

Bill Gradison.

MR. GRADISON: My understanding is the reason for the arbitration, it's a new product that has no competition; is that correct?

MR. O'DONNELL: So you can think a lot of them will be new products, but I think it was the sole source.

MR. GRADISON: Sole source. Pardon me. "Sole source," that's the proper word.

May I assume, then, that as soon as that arbitrated -- the price that came out of arbitration would only apply until a competitive product came on the market?

MR. O'DONNELL: Sure. So I think you can think of in the arbitration process that there would be -- the price that's agreed upon would be time-limited in some way, shape, or form, whether it be a year, whether it be until another produce came on. You know, that's a decision, but yes, it would be time-limited in some way, shape, or form.

MR. GRADISON: Thank you.

DR. CROSSON: Okay. Good questions.

So now what we're going to do is I'd like you, if you could, put up the last slide, the discussion slide. I'm going to ask for efficiency here. We've had a long question period.

Essentially, what we're going to do is we're going to have opening comments first by Jack this time and then Amy, and then I want to go as efficiently as we can around the table. And the questions for the Commissioners are on that list, and I would just point out that for consolidated billing codes, we actually have two options. You can see that better on your page No. 10. One has to do with combining the reference biologic and the biosimilars, and the other has to do with combining drugs that have the same health effects, so there are actually two options there.

And what I'd like to see is "I like all of these things," "I like these," "I don't like that." Particularly, with respect to things that you think should not be included in the package, why?

I'll probably start at one end and go to the other end, but we'll start first with Jack.

DR. HOADLEY: So I'll try to make my comments sort of in that same framework and just kind of go through these things.

I think on the improved reporting, I think we're in a good place there, in my mind, including the notion of exempting the repackagers. That seems to make sense to me.

On the WAC+3 percent, I think, again, there's a good policy being laid out there. I think the logic is sensible. Obviously, it would be nice to be able to address some of these launch prices in other ways, but this is kind of what's possible within the system.

On the inflation rebate, sort of thinking back to Kathy's comments a few minutes ago, I mean, I think that the notion of the approach that you've outlined here is to put the penalty, as it were, or the burden on the manufacturer rather than on the provider, and I think that's what has made sense to me. It is more complicated. If we really thought, if we were confident that we would get a price response from the manufacturer by simply limited what's been paid -- and we did see that on the sequester, then that would get us to the same result in a simpler way. But I guess having the confidence that that happens is what is less clear.

So, given that there is a precedent for this kind of approach in Medicaid, I think I do like this particular approach. You've got the notion of protecting the beneficiary in there, and that's good. I think the notion of exempting the low-cost drugs does seem to be a sensible

way to keep this the simpler system.

I would, for the moment, be happy with the CPIU again, just following the Medicaid precedent. It sort of works there, but I'm not opposed to hearing about other notions of what the index would be.

On the consolidated billing, again, I like the approach. I believe that we're much more likely to see an impact of this policy on the biosimilars. I think it's worth trying to -- probably worth trying to do this for the other categories of drugs. I think, practically speaking, the process is going to get difficult. There's going to be challenges in getting agreement that these two drugs are equivalent, and I think it may well be that there will be relatively few cases that make it through that system.

So you could argue that it's not worth trying to do that if we think the other tools will sort of handle those situations, but in principle, I think it's the right thing to do, so I would probably tend to include it in the package.

Pat raised the questions about the exceptions process, and this is different than a formulary where a drug is not

covered if it's off formulary. Here, the drug is covered. The question is what price will be provided to the provider -- or paid to the provider who chooses to use that drug. So I think, in theory, we shouldn't have to have an exceptions process.

The issue, as you guys raised it, is the right one. If providers simply say even though there's an averaging -- and we've got lots of averaging in our payment systems in lots of places, but this comes up. So, in this particular case, maybe the price difference is pretty wide, and they're saying, "I'm going to take such a hit by using that more expensive drug that I'm simply not going to offer it to the beneficiary, even though I know it's the right drug."

Now, a physician has to be willing to sort of say, "I'm not going to do what's right by my patient," to sort of get to that point, and so that does -- and you kind of feel like you may need an exceptions process for those reasons. I think that's a bit of a challenge still, and I still want to think through that, that set of options, because, again, it's not a question of the drug is uncovered. It's just a question of what price that drug

will come at.

On the question of sort of the reduced ASP add-on, we had a lot of discussion of this over a number of meetings. I'm not convinced that we should only use this as sort of a phase-in to get to the DVP as opposed to -- and, thus, delay the potential savings we could get out of taking some reduction in that 6 percent more rapidly. So I would still like to consider doing that less phased in or doing that now and still thinking about how it has an impact and relates to the DVP.

There's obviously a lot of issues inside the DVP. As I've said in past meetings, I'm not convinced that this process is going to work, but you've put a lot more specificity around it. So it does feel like it's worth putting out there and trying to see if it happens or trying to set it up to happen.

I do think, to respond on a couple of the specific items -- you talk about multiple vendors. I would not want to see a situation where there are like 15 different vendors doing this, and the providers just have no clue as to who am I supposed to go to. So it seems quite likely that we would want to limit the total number of vendors

that could enter this. I'm thinking maybe it's like a number like three or something like that. I'm assuming you're thinking of national vendors as opposed to kind of regional ones. I don't think there's any reason it needs to be localized. I don't know enough about the structure of the existing GPOs, but that's kind of how I thought of it.

The shared savings concept, again, I understand the logic for going there, but one of the things I'm wondering about is are we expecting a utilization impact in addition to cost, and what would that mean? In the materials, you sort of talked about potential for having some impact on utilization. It does seem like we'd probably need to think about both on that, and on sort of a structure of a formulary, how this is going to play out in different categories of drugs.

So, on cancer drugs, typically, oncologists are looking at making all kinds of decisions off an array of drugs. There are a few cases where there are sort of direct comparisons, and so the formulary concept might apply. There are a lot of others where this is just all part of the array of choices that people make, and so I

don't know overall how many of the cancer drugs would fall into natural candidates for a formulary. Rheumatoid arthritis might be a little different because there are some multiple options, although you get caught up in the B versus D, some of the products.

The biosimilars does seem like a clear case, although we have another way of handling that with consolidated billing.

But the same thing on the utilization impact and cost impact for a shared savings. On these different categories of drugs, are we thinking that somehow this mechanism is going to discipline overuse of chemotherapy, and that that would be part of what was going on, or really what is being anticipated? Is the shared savings really mostly about the cost savings that is created by the negotiations as opposed to some kind of utilization impact? I think that's something that may need a little more thinking through.

And then, last, on the binding arbitration, I guess I raised the question about should it be separate, or is there one sort of arbitration? What's the logic for two or three different organizations ending up at a different price in that sole source? Why would an arbitrator sort of

get to that? So I think that's a detail to be thought through.

I like the concept, and I said yesterday I think it's something that potentially ought to be considered for Part D as some kind of secretarial authority there, but I think the idea that this is a way we can get at pricing for sole-source drugs, where the existing system has no ability to bring down prices, this may.

I think I've covered all the things that I've made notes of, so I'll stop at that.

DR. CROSSON: Thank you, Jack.

Amy.

MS. BRICKER: So there's a lot here, and it's very complex, as I think we've all gathered. So a couple things. You know, I've only been on the Commission for six months, but I see that we go to great lengths to ensure fairness to all stakeholders. And I'm not sure in all cases we need to focus -- while we need to understand the impact to all stakeholders, I think this is how it becomes so complex. We over-engineer sometimes our recommendations to make sure every single person is going to be fine and not harmed. And because of that, you don't really allow

market forces sometimes to play out because there's so many safety nets. So I'll just caveat that with the rest of my comments.

I believe, yes, we should require ASP reporting. I would be more aggressive and suggest that if manufacturers don't, then their drugs are not eligible for reimbursement. I wouldn't go through the civil penalties and all the rigmarole. If you don't send it, your drug's not going to be eligible for reimbursement.

I would not give exception -- build an exception process. Again, I'm in favor of consolidated billing codes, but to points that have previously been made, there are winners and there are losers in all businesses. Some things you make a lot of money on; some things you don't make a lot of money on. And it is what it is. So I wouldn't necessarily be in favor of going to great lengths to try to figure that out.

With respect to how do you consolidate the billing codes, I think we could just rely on therapeutic classes, so all beta blockers or -- you know, that's one way to do it versus requiring some separate panel of people to determine what is consolidated and what's not, just looking

for some simplicity.

With respect to the DVP, I'm interested in who we think would meet all of the requirements that we've outlined. So as Warner pointed out, there are plenty of GPOs that already exist today. They don't go so far as to implement step therapies or prior authorizations, to my knowledge. So it's sort of a hybrid between buying institutions and then PBM or health plan-like functions, and I'm a little confused on how that might play out. And should we instead focus simply on the finances of this Part B versus also weaving in clinical components, which, again, make it very complex. There's reference to quality in the DVP and if the providers demonstrate quality, then they get more shared savings. This just gets really, really complicated.

So I would like to see us, if we go down the path of shared savings, it's just that; there's shared savings payment. I don't -- not focusing on whether or not the provider has demonstrated quality in their practice. Again, just trying to simplify.

Today GPOs collect admin fees from manufacturers, so we wouldn't need -- if it exists in the same way, we

wouldn't need to figure out another way to benefit the DVP, especially if you pull back all these other -- like, you don't have to worry about the prior auths and the step therapies. Something else for consideration.

Lastly, with arbitration, consistent with my theme, I'd like to see us not try to boil the ocean, and I don't know that arbitration -- I'm not in favor of the arbitration just because I think it's -- what is the administrative burden? What is the cost to the system? What is going to be the turn-around time? And I know we have a problem with respect to sole-source products, but as I mentioned yesterday, I would like to see us provide incentives to manufacturers to bring competition to the market versus trying to create a system that doesn't exist today for us to go to court. I just don't know how these things play out and what the length of time that we'd spend doing those sorts of things versus just, you know, nudging another manufacturer to come to market.

So thanks.

DR. CROSSON: Okay. Thank you, Amy.

Could I just see hands of Commissioners who want to make a comment in this phase? So it's pretty much

everybody. Again, we've got about -- if we're going to stick to the schedule, we've got about half an hour, which is going to be difficult. So I would ask you -- and we'll start with Bill Hall, so a warning. We'll ask you to be referencing what's on the slide and be as efficient in your comments as you possibly can.

DR. HALL: So I was just commenting to my seat mate here, what is it that we're really trying to do here? I'm a little fuzzy on that. But it seems to me that there are at least two major goals here. I think the obvious one is to rectify pricing in the Medicare system. But the other we really haven't mentioned, do any of these manipulations really have a direct correlation to quality of care for the patient population that is most affected by Part B? And we've talked a lot about rectifying some of the internal operation here, but I think at some point we ought to say -- and if this, then what is the real advantage to the consumer on this? I don't think we've really taken a very careful look at that.

Rectifying pricing I think is very straightforward, but I think we always have to add the other thing. What's in it for the consumer?

DR. NERENZ: Thanks. Just a very quick comment on the +3 part of that bullet up there. It seems to me the logic here is that we feel that the current +6 provides an incentive to prescribe more expensive drugs, and the +3 is designed to reduce that incentive. Now, is that a fair summary of --

MR. O'DONNELL: So I think we're going with the +3 is that +3, given the historical discounts, is really akin to ASP+6. So we are trying to seek out parity between WAC-priced drugs and ASP-priced drugs.

DR. NERENZ: Okay. Well, and maybe that just cuts off my comment, because it seemed like when we were doing this a year ago-ish, we weren't talking about WAC. We were talking about going down from +6 to +3 to reduce the incentive. Yes?

DR. HOADLEY: The ASP add-on [off microphone].

DR. NERENZ: The ASP add-on? Was that -- okay.

DR. CROSSON: Not the WAC.

DR. NERENZ: Okay. Well, I'll just do this quickly, and then you can ignore it if it doesn't make sense. It seems to me that the difference between +6 and +3 is not only going to mean nothing in terms of incentive, it may

actually make things worse.

The issue is, first of all, that 3 percent of a big number is still more than 3 percent of a little number. So the incentive to prescribe more expensive drugs is still there. It doesn't change. It could be worse than that. If I'm a practice manager and I know from my accounting that the +6 gives me a certain finite number as part of the bottom line, and then this is going to be a cut, I may not just sit and take it. I may want to restore that. How do I restore that? I prescribe even more expensive drugs because I've got to get that money back. And that effect on the program is even worse than where we started.

Or I can prescribe just more drugs total because I need to build my +3 on a larger pool of prescribed drugs. Either way the program ends up spending more than we do now. So I would caution that. The behavioral economics here are not going to be just straightforward. And this focus is purely on the difference between +6 and +3. It's not a WAC issue.

MR. GRADISON: Rather than go down all of them, let me just mention the few that I do have concerns about.

First of all, with regard to the inflation cap, if

there is to be an inflation cap, I certainly don't think it should be below the MEI. I mean, to say that this number should -- that the increased price for these products should be less than everything else in the health care system, I find a bit of a stretch, and I haven't heard any justification for going that far.

I don't like the inflation cap. I've talked about that before. I think from a manufacturer's point of view, you really have to analyze it for the factors that they would take into account in making decisions which are based largely in the long run and in the short run on return on investment. And I can spell out -- and would be happy to if anybody would like me to -- circumstances in which this kind of a limit would actually mean the products just wouldn't be offered anymore because the facilities from which they were being built -- which were being used for the existing product could far more profitably be used for a certain new product. So, anyway, I'm probably beyond redemption on that point.

But with regard to arbitration, I want to give a lot more thought to that. I certainly think we need far clearer definitions than we have so far of what the

arbitrator can take into account. I've got a new product. I think -- I'm hopeful, have reason to believe -- that in the course of -- if the proper course of using this product is followed, it will save the lives of X numbers of people who have hepatitis C. So I go in there, and I say it's an expensive product, but there will be 10,000 more Americans living a year from now if this is available at the price I'm asking. How do you factor that in? We talk about clinical benefit. But I'd like to hear a whole lot more about what the -- because, otherwise, I think it gets extremely arbitrary.

A final thought. I'm sorry if this seems irrelevant. I remember Ronald Reagan talking about when he was head of the Screen Actors Guild, and he said, when it was time to negotiate wages, he said, "We go in there and ask for the moon, and the management would offer green cheese. And then we'd really begin to bargain." And maybe that's kind of not so bad.

MR. THOMAS: I'll be brief. First of all, I would concur with Amy's comments around the data reporting, and essentially if folks don't want to report data, then they can't get reimbursed for their drug. I just think we've

got to take a much harder line there.

On the WAC+3 percent, I think my only comment there is -- and the same with the ASP+6 -- I think if we were looking at the whole idea around controlling pricing, I think what we ought to think about is some sort of index that we tie to to control any sort of increase going forward. So I know there's the issue of how we actually set the initial price, but then as we look at this going forward, I think there needs to be some sort of cap tied to some sort of index so pricing does not exceed a certain amount on an annual basis. And I think that that should be considered in whether it's WAC or ASP pricing, this inflation idea I think just needs to have some sort of cap tied to an index in place.

I think consolidated billing codes are a good idea. I think once again the idea of having an appeal is not a good one. To me, you ought to get it in a billing code. It ought to be determined as you're going through the process of being approved and being reimbursed by Medicare.

As far as the DVP program, I would -- I think there's components to that that make sense. I would like to see us take those components into an existing structure, either a

PBM or existing GPO structure, versus creating a new entity that I think just creates more complexity and makes it more challenging. I think we have most of that structure already in place. I'd just like to see us take the components in that program and have it put in place on the structure. And I agree with Amy that we don't need to necessarily reimburse that group, that there are already reimbursement mechanisms in place, and we ought to handle it that way.

But to me, the most important thing is we ought to think about how do we cap inflation going forward as it relates to just kind of arbitrary price increases, whether it's in Part B, Part A, or other areas. I just think that's -- or Part D. I think that's important.

DR. GINSBURG: A lot of interesting comments about manufacturer response, and I think this is something we need to try to learn as much as we can about experience so far. In a sense, to the degree that there is a vigorous manufacturer response, it may mean that we don't have to worry about negative aspects of the sequester, of the inflation rebates, and there's less need for an exceptions process if in a sense if the manufacturer is faced with,

well, doctors aren't going to use my drug for a lot of their patients, I better keep them whole and do that.

I think DVP is a very promising idea, and I think we should think in terms of not so much tacking it onto an existing entity, but think about does it resemble more a health plan/PBM or a GPO, and just in informing us as to how to specify it. And I think once we get to specifications, if this were enacted, then in a sense organizations can bid to be designated as the DVP, and, you know, we'll see if GPOs or health plans or PBMs are the ones that come forward with the best proposals to do that. So we're not going to be creating a new organization from scratch because I think a lot of these skills already do reside in organizations.

I'm uneasy about this notion that this DVP that we create would be the entity to negotiate with manufacturers. You know, this can be extremely controversial, and I'm wondering whether we're fooling ourselves to think that we can do it this way as opposed to just having CMS be negotiating with manufacturers on some type of authority that Congress might give at some points -- probably not too soon.

And the final thing is I think consolidated billing is really important, and I think we can very quickly -- I mean, basically this is a potential of holding back all of the potential cost savings from biosimilars unless we can actually get some type of a mechanism where physicians would respond to, yes, the biosimilar costs less, I'm confident in it, I'm going to go for it.

MS. THOMPSON: Thank you, and I thank all of you. I just want to underscore Amy's comments as she opened this discussion about there being winners and losers and keeping our recommendations in the context that that is very much a part of our reality, and also reflecting on a comment that Paul made yesterday in the Part D discussion that we are indeed in a different time, and I think different times call for different kinds of recommendations. And I think this is certainly a very different time.

I think for the first time in my experience -- I, too, am a rather new Commissioner -- we're having discussions that broach on direct negotiation with direct manufacturers on behalf of the Medicare program and the Medicare beneficiary. And whether it be through the DVP or whether the DVP becomes an arm of the Secretary, I just find while

this is a rather new concept I think we're in the process of developing, I find it very encouraging.

So I am quite supportive of all these recommendations, and thank you for your good work.

MR. PYENSON: Thank you to the authors. I am supportive of the package of improving the ASP system. My concern is with the viability of the DVP and is there enough money there, is there enough potential savings given the margins of running an organization that anyone would want to participate in that. And I think the answer is yes if we start modestly, and I wasn't able to look up the numbers, but I suspect there's enough money in generics and that there's enough potential margin and enough ability to negotiate down the price from ASP for generics to make this work if we start there. And part of my thinking there is that, you know, many chemotherapy drugs are generic, and there's lots of other very good drugs there. And that's -- although generics are and always were low-priced, that's how the PBM industry made most of its money on pushing it down even lower. So in the absence of that in Part B drugs, I suspect there's large potential margins.

Thank you.

DR. CHRISTIANSON: I agree with Paul about the importance of combining these drugs in pricing categories, and so I just -- I mean, Jack commented that it was kind of small potatoes potentially, and it is now, but I think it's still consistent with our principles. And I think so often what we do is making recommendations about changes to clean up messes, and this is a chance to get ahead of something. So I'm in favor of that.

I'm a little bit dubious about the rebate policy. I think we need to understand how manufacturers would respond in terms of their pricing behavior. I'm generally dubious about rebate policies in terms of what they actually generate in terms of savings.

And so that sort of raised another issue. I would love to know what the staff predicts to be the impact on Medicare spending of all of these different components of ASP before I would say, okay, I'm in favor of all of them or I'm in favor of some of them.

And on the DVP, I think we should go ahead and continue to explore that, but maybe temper our enthusiasm a little bit. Again, I think the ability of these groups,

particularly when you have a great number of them, to negotiate lower prices for Medicare is -- I'm skeptical about how effective they'll be. I think it's a lot like buying a car. There's a manufacturer's price, and then there's the price that the manufacturer ultimately thinks it's going to get after negotiation with you, and I think you just adjust the initial price to make sure that after the negotiation you get down to the price you think you're going to need on that product.

And then shared savings under these arrangements is quite complicated. We know that from the private sector. We know that there's disagreement oftentimes that result in fairly substantial lawsuits between health plans and PBMs around who gets the shared savings, how much were they, and so forth. So I think there's lots of issues around how these DVPs would work that would temper my enthusiasm about what they would actually accomplish for the Medicare program, but I do think we should continue to explore, and I think we're just in the very initial stages, as some of these comments suggest about how these things would actually work and what they would look like, and I think we need to know more about that before we can make a judgment

about whether this makes a lot of sense or not.

DR. CROSSON: Thank you. Amy -- I'm sorry -- Pat.

[Laughter.]

DR. CROSSON: I did it again.

MS. WANG: As a general approach, I think it's very important to delink improvements in the ASP system from DVP and try not to kind of sync them up, of changing ASP in order to incentivize DVP. I think that they should each be freestanding, strong proposals, because I don't know about -- you know, I'd hate to put all of my bet on the DVP because it's a new thing.

I agree with the comments that have been made about ASP reporting. I think Paul's comments about kind of sensitivity around the sequester for any changes in the WAC+3 or the ASP add-on are important. Something for the inflation rebate or a cap, as Warner suggests, I think, is very important to try to make concrete and real.

My personal preference is to try to take the dock out of the middle of those things. I understand Kathy's point. It assumes a lot of elasticity and manufacturer pricing, and she may be correct that if you took that approach, the prices would just come down. But I'm a little concerned

about putting clinicians in the middle of that. So even though the mechanics are more complicated, I'd rather do it the way it's described.

And the same comment for consolidated billing codes. Definitely in favor of both options that were listed in the paper. To the extent that there is an exceptions though, again, I would try very hard to allow clinical decision-making to happen in the best interest of the clinicians. Your doctor, you're his patient. You know, I want my doctor to make the best decisions for me. What this is supposed to do is try to take the incentives, the financial incentives out of it.

So if there is a way to allow that to happen, pay the exception drug at cost, without the ASP add-on, excluded it from the ASP average calculation to blunt the impact of the inflation, I would be in favor of that.

DR. MILLER: Can I ask you one quick thing?

MS. WANG: Yes.

DR. MILLER: Because you set that ball in motion. Is it also true if there wasn't an exception process you'd be okay? Because you sort of set that ball in motion, so I'm just curious.

MS. WANG: Yeah. I think that there should be exceptions.

DR. MILLER: Oh, okay.

MS. WANG: I do.

DR. MILLER: I wondered where you settling.

MS. WANG: I mean --

DR. CROSSON: No, no. You keep on your roll.

MS. WANG: Okay. All right. So, you know, improving the ASP system, like, you know, concretely and sort of regardless of what happens to the DVP is something that I think is important.

As far as the DVP is concerned, I think it's an interesting concept. I don't know whether it has a high likelihood of success but I think it's very much worth continuing to sort of detail out.

I don't know enough -- I'd like to know more about whether the introduction of some of these medical management tools -- formularies, step therapy, all that kind of thing -- is something that the DVP would be sort of an effort to create a unicorn, because nothing like that exists now, and if that's true, I think that's too ambitious and should be -- I think that the main focus of

this should be on pricing. The two most important features of that are the ability to set the ceiling price, the ASP, to start, and the second is, whether it's an arbitration process or something else that allows, you know, more direct negotiation with manufacturers. Those are important features that this would have over the current system.

DR. CROSSON: Thank you, Pat. Craig.

DR. SAMITT: I like a lot of what I've heard, but in all honesty I don't believe that we've gotten bold enough into making recommendations to address this problem. We talked yesterday about the looming risk of unsustainable drug cost inflation, and what I'm worried about when I hear all of these things is, have we really done simulations to understand what we think is going to happen with each of these interventions, and whether it's going to address the problems we're trying to solve?

So I as I was thinking of what we're trying to solve, we want better pricing for drugs; we want to avoid unnecessary or harmful prescribing; we want to have prescribers, when it's appropriate, to select the most appropriate agents. At least those are the three things we want to try to accomplish for Part B, and I just worry that

the list that we've got just scratches the surface and, at most, addresses some of the pricing issues, but perhaps doesn't address the others.

And so I think that we can strengthen both sides of the model here. On the ASP enhancements, you know, we referenced sort of the need to decrease the ASP add-on, but it's kind of very vague, and to what degree will clinicians still prefer the ASP approach, because it's always going to be more lucrative than the DVP approach.

And so it feels to me that if we really want -- if we believe the DVP is going to have the right complement and support of all that we're going to accomplish, then it feels like we need to be a bit more aggressive on the ASP side, and maybe we do require a reduction in the ASP add-on just so that there isn't any kind of potential perverse incentive for excessive or harmful prescribing or ineffective agent prescribing.

And the one thing that I know we've discussed in prior meetings, that I feel is missing, is there is a lot of innovation happening regarding the use of clinical pathways for Part B prescribing, and the appropriateness of prescribing is really not addressed in anything that I've

heard. So it may be easiest in the DVP, but what if an enhancement to DVP is a requirement that clinicians who use the DVP adhere to clinical pathways for prescribing, and the incentives that would go with that, to prescribe the most evidence-proven, effective agents for the diseases that they treat?

DR. CROSSON: Thank you, Craig. Kathy.

MS. BUTO: I would just pick up on Craig's last point and say I think those clinical pathways should be required of physicians in buy and bill, because --

UNIDENTIFIED SPEAKER: [Inaudible comment.]

MS. BUTO: Yeah. The burden, if you will, or the requirements one side shouldn't -- for quality and medication management shouldn't be tougher if you choose the competitive DVP option.

So I support a lot of this, and I want to just say, I think the chapter is very well-done. I mean, I was telling the team that they've really done a lot of thinking, and I think we all appreciate it.

I support a lot of the package but not all of it. So I support ASP data reporting requirements there, and I heard Amy say if they don't report let's, you know, not

cover the drug. I mean, they've never even been asked to report, the group that we're talking about. So the experiences, if you ask them to report or require it, they're going to report.

WAC+3 percent, listening to Paul, I'd just say we want to make sure that's appropriate, and given sequester, maybe it is. Maybe it should be lower.

Back to the ASP inflation rebate, I really do feel that the payment limit approach is superior and will be more easily implemented. I would just suggest that we have a conversation, maybe just to inform ourselves, with CMS staff, about how to do some of these things versus others. Yes, they do this for Medicaid but it's the Medicaid team that does it. It's a whole different construct in care.

Consolidated billing codes, I have serious reservations about consolidated billing, along the lines that Pat suggested. I feel that the approach is supportable for biosimilars and reference biologics. So where FDA has made a determination, I can see that being implementable and justifiable.

We say we're trying to take the perverse incentives out of ASP by combining, but if you take out -- if you base

the payment level on a weighted average of what's in the pot, the incentives will be to physicians who worry about losing money overall, on average, to always prescribe a lower-cost drug.

Now, I agree. Most physicians will not do that if they think that's not appropriate, but I worry about it. I think there is the issue of clinical appropriateness that needs to be injected here, and I also don't think this will be done for very many drugs, and by the time it gets executed, there will be competition that drives down pricing.

So when I think about all the other stuff we're doing with ASP, which is to lower ASP, potentially put in a DVP competitive model that has prior auth and other tools, I just think that this -- I would urge against it.

I agree with whoever said we ought to look at gradual reduction of ASP, regardless of whether or not it's paired with the DVP transition. And I would like to see more on the DVP approach. I don't think we have enough information to judge whether it would make a difference or could actually lower overall pricing, which is the goal.

I'd like to see more, as Craig said, more about

appropriateness, about treatment protocols injected into that program, as well as the buy and bill, because I don't think -- we really are focusing on pricing and we sometimes forget the issue of appropriateness. So I want to make sure that's still in there.

DR. CROSSON: Thank you, Kathy. Alice.

DR. COOMBS: So I have a strong feeling about the ASP inflation rate, and I'll say it long, strong, and hard. We have actually, on every single industry -- hospital industry, physician industry -- we have something tied to the updates, the percentage increase. Why are we tiptoeing around the manufacturers, or the WAC, or whatever you call it, the base price of drugs, and not addressing this whole notion of the 5 percent increase per year? I feel very strongly unless we do that we're having different kind of approaches to other industries versus this industry. I think that, for me, is a first and foremost on the table.

I do support one aspect of the consolidated billing codes but I don't support the health effects in that a lot of the times when you substitute, you have to consider what you have to do when you substitute, in terms of monitoring a patient. For instance, if you had methotrexate in a

substitution for some other drug, and then you have to do a lot of follow-up with liver function tests and things of that nature. So I think the health effects is a serious concern for me in terms of consolidated billing.

I think one of the things with the DVP program I question is the CAP environment did not allow for a lot of CAPs to exist, and I think we had one or two. And so why would there be a lot of GPO-like structures that would exist suddenly? What, in this environment, would allow that to flourish? That would be the main question I would have, and if there would be some kind of tie to the GPO parent structure, whereby drug shortages would evolve, because as an anesthesiologist, believe it or not, at one point we had a shortage on glycopyrrolate, atropine -- atropine is a nightshade plant. I mean these are basic drugs.

So I worry about too few GPO-like organizations that are available, and, you know, when you have a very small number of vendors, well, people who would participate in this program, you might have problems with access and storage, and that was one of the issues with the CAP program, is having enough drugs on the shelf so that the

oncologists would not have a patient show up one day without having access to whatever kind of oncology drug.

And then, lastly, I do agree with just the intelligence and support that's necessary for, you know, the right drug at the right time. I think that physicians, especially oncologists, they have standardized protocols. They're not going off somewhere having these perverse incentives to use more a more expensive drug. I think that when you twiddle down so much the ASP, and in consideration of what Paul said with the sequester, you get to the point where doctors see the advantage of hopping onto the hospital, and I said this before, in that if you drive doctors into the hospital, oncology doctors, particularly, then you've really changed the paradigm for cost, in terms of facility charge, and that, to me, is a major issue.

But the first and foremost, and I'm just going to say the manufacturer's price and the inflation rate, I feel strongly about that.

And the other things, I don't feel that strongly about but that, I think -- that's a tyrosine hydroxylase.

DR. CROSSON: Thank you, Alice. Brian.

DR. DeBUSK: I like all the ideas presented on Chart

19. I really appreciate the way that we're using a multi-faceted approach. I like it because I don't think there will be any one single idea that gets us there.

I do want to comment on the DVP. I think you have assembled -- I think it's off to a great start. I mean, I think you have assembled some really good ideas here. Again, I mentioned earlier, the novelty of being able to buy in at ASP as the starting point, it not being incorporated into ASP calculations.

I just want to reiterate what I cautioned earlier. I think not synchronizing the ASP mark-up to DVP-sourced drugs versus drugs sourced outside the DVP does hobble the program a little bit, and I'm not proposing that we put more money in it. What I would propose is that this administrative fee -- which, Jay, I apologize earlier. I heard admin fee, and in my world that's just a percentage of -- yes. So I would propose, though, that that administrative fee -- I think the money is there but I'd much rather see that take the shape of mirroring the ASP markups.

Now I still support drawing down the ASP markups from 6 percent, but I would keep them synchronized with the DVP,

and again, I worry that you're going to take this really nice tool set and accidentally hobble it by always making it lag 6 percent, 4 percent, 5 percent, whatever we set it to, behind its non-DVP-sourced counterparts.

The final thing I want to mention is I do like the fact that you're describing it as a tool set, because I think there will be GPOs. I would expect a distributor. You know, you may see a distributor that comes along -- a wholesaler -- that say, "You know, I want to use this as a starting point to try to build something that looks more like a GPO plan." I could even see a large, large health system that says "I want to adopt this tool set, and use this as the starting point for my negotiations."

So I like the fact that you haven't tied the tools to any specific delivery vehicle yet, because I don't think we need to create these new entities from whole cloth. I think there are plenty of different entities out there that could house these tools.

DR. CROSSON: Thank you, Brian. Rita.

DR. REDBERG: Thanks. I also like a lot of the ideas in the drug value program. To pick up from what Craig said, you know, I think it's really important to address

drug pricing. You noted Part B spending and that just Part B has grown percent since 2009. But there are other big problems in our use of drugs, even the Part B drugs that are not addressed here, like, you know, did beneficiaries need the drug in the first place? I mean, none of that is addressed. You know, it's clear a lot of oncology drugs now, and perhaps related to the ASP+6 or other things, but they're being used in patients who would be better off without them, what I mean is there's absolutely no evidence that they're ever going to get any benefit, and we're talking about very toxic drugs. So that's a big problem that's not addressed in the drug pricing proposals.

So I do like the idea of improving the ASP data reporting, and as I said, the ASP and the WAC, I don't know what resources we have, but I feel like there is, right now, no kind of logic to the setting of drug prices. They're set very high, to me. If you look at production costs, costs of research, the drug prices come in way higher than one would expect. So this is a start but I think we also need to think about addressing that problem.

I do like the consolidated billing codes a lot. I mean, as a clinician, I don't see problems with the

consolidated billing codes, and certainly the example, you know, I find it astounding that a biosimilar could come in higher than the reference price, the brand-name drug, and I know if consolidated billing code starts to get at that. I mean, I know Kathy seems much more sanguine about competition than I am, but, you know, the paper cited, on page 20 in the mailing materials, competition between two or more brand-name manufacturers does not usually result in substantial price reductions. I mean, we don't see competition -- I don't see competition leading to lower prices, particularly, lately, in the drug pricing area.

I do agree with my fellow Commissioners that we definitely need to reduce ASP add-on transition more rapidly, but again, we didn't address all the problems. And finally, I'm not crazy about the exception process. I think it's kind of messy and it's addressing a problem that isn't really there, and could better be addressed in sort of the way we set up the program.

That's it. But I really admire the work you did here.

DR. CROSSON: Okay. Thank you, and thank you to the Commission for helping us with the efficiency of this discussion.

This is my ninth year on the Commission, and we've dealt, over that period of time, with a lot of issues. I can't think of one -- maybe there's some -- but I can't think of one that was a more serious issue, a more pressing issue, and a more complicated issue than this one, and I think our discussion bore that out.

I really appreciate the depth of thinking that we heard here. I think it's going to be very helpful to the staff. It is our intention to come back in March, distilling your comments, and come back with a set of potential recommendations that we can discuss again in March, and vote on in April.

We will have more information for you. We had a lot more requests for information. We will get you as much in-depth information as we possibly can on some of these options. That said, there's a limit to how much we can do in terms of saying how exactly this going to work in the second and third order ramifications of some of these ideas.

As you know, our recommendations, for the most part here, will go to the Congress and go through the legislative and regulatory setting process. And so, to be

perfectly frank, it's really not possible for us to anticipate, you know, all of the details that would be created here. What we're trying to do here, and several people mentioned this, is to create a new dialog, a new set of ideas here, which are, in fact, in many ways, groundbreaking, and when you break new ground sometimes the ground can be hard and you have to really jump hard on the shovel, or some metaphor like that --

[Laughter.]

DR. CROSSON: --that escapes me at the moment. But it's a messy process when you're trying to create new ideas, particularly new ideas which are both complex and controversial at the same time. That's what we're trying to do.

Again, because we are faced here with a problem, and a number of Commissioners have said that and emphasized it, which is both quite serious and for which there is a lot of interest in the country, and really, a heart-felt search for solutions to this problem. It's impacting not just the industry that we're involved in, trying to support, but the Medicare program itself, and individual Medicare beneficiaries who bear the out-of-pocket costs for

pharmaceuticals, both here in Part B and Part D.

We will spend more time, probably next year, on Part D, but our work for this spring is to refine these ideas and come forward with a set of recommendations that we can all support.

Thank you for the work. Thank you to the staff, of Brian, Kim, and Nancy, for excellent work, and we look forward to having you come back in March. And we'll move on to the next presentation.

[Pause.]

DR. CROSSON: Okay. We are going to return once again for a discussion we've had for a number of years, which has to do with the concern, I think, that we have as a Commission and I think increasingly in the country about whether or not the pipeline for primary care physicians is, in fact, as robust as we need it to be for the country.

We can't solve that problem, all of it, here at the Commission. The Medicare program can have an impact but not totally, but it's something that I think we have addressed in the past, and we would like to continue to address and try to keep this issue at the top of the list of attention for both CMS and the Congress.

And then I'll stop, Ariel, and not give your presentation.

MR. WINTER: You're doing good.

DR. CROSSON: It looks like Ariel is going to start. Please go ahead.

MR. WINTER: Good morning. Kevin and I will be presenting this morning.

So the goal for this session, as Jay said, is to discuss next steps the Commission might take to support primary care for Medicare beneficiaries. This presentation follows up on a session on primary care from our November 2015 meeting. At that session and at several subsequent meetings, Commissioners have expressed strong interest in doing more to address primary care. And I want to thank David Glass and Kate Bloniarz for their help with this work.

So here's the outline for today's session. We will describe how the fee schedule for physician and other health professional services underprices primary care, discuss prior Commission recommendations to improve payment for primary care, present three options to better support primary care, and highlight some key design issues for

these options.

Primary care services are underpriced in the fee schedule for the following reasons. Primary care is labor intensive, which limits the potential for efficiency gains and volume growth. By contrast, efficiency gains are more likely to occur for other services due to advances in technology, technique, and other factors.

Relative value units, or RVUs, should go down for these other services over time to reflect these efficiency gains. And under statute's budget neutrality rule, RVUs should go up for other services, including primary care. However, the process for updating the prices of services often does not account for these efficiency gains. Further, some specialties can increase their volume of services more easily than primary care clinicians.

And we see evidence of this in the growth and the volume of clinician services per beneficiary from 2000 to 2015. Growth in the volume of tests during this period, as shown by the purple line, was twice as high as growth in evaluation and management services, shown by the orange line. And the growth of other procedures and imaging was more than 50 percent higher than growth of E&M.

The Commission has expressed concern that mispricing in the fee schedule contributes to an income disparity between primary care and specialty physicians. This chart, which we showed you last month, is based on physician compensation data from 2015.

As in prior years, average compensation was much higher for some specialties than for primary care. The specialty groups with the highest average compensation were radiology, with an average of $560,000, and the nonsurgical procedural specialties, with an average of $545,000. By contrast, average compensation for primary care physicians was about $264,000.

Previous Commission work showed that such disparities also exist when compensation is adjusted for the number of hours worked by each specialty, and these disparities may give medical residents an incentive to choose specialty care over primary care.

Another reason the fee schedule is not well designed to support care coordination and primary care is because it is oriented towards payment for discrete services.

For the most part, these services have a definite beginning and end. By contrast, primary care requires

ongoing non-face-to-face activities. Examples include managing the practice's clinical team, reconciling medication prescribed by multiple providers, and developing and updating the patient's plan of care. Such care is crucial to a more coordinated and efficient health care system.

Over last several years, the Commission has made several recommendations to rebalance the fee schedule and provide more support for primary care.

In 2008, we recommended that the Congress create a budget-neutral bonus for primary care services that would be funded by reducing payments for other services. The bonus would be applied to each primary care service billed by an eligible practitioner.

In response, PPACA created the Primary Care Incentive Payment program, or PCIP, which existed between 2011 and 2015. It provided a 10 percent bonus on payments for primary care services provided by eligible practitioners; however, it was not budget neutral.

In 2011, we recommended repeal of the sustainable growth rate and higher updates for primary care than for other services.

In 2015, MACRA repealed the SGR, but it did not provide a higher update for primary care services.

We also recommended that CMS regularly collect data to identify overpriced services, which are more likely to be procedures and tests, and establish accurate prices for them.

In addition, the Congress should set an annual numeric goal for reductions in the RVUs of overpriced services. This goal should be equal to 1 percent of fee-schedule spending for each of five years.

In 2014, Congress established an annual target for reductions to overpriced services, although the annual goal was less than we recommended, and it was for a three-year rather than for a five-year period.

Finally, the Commission recommended in 2015 that the Congress establish a per-beneficiary payment for primary care to replace the expiring PCIP program.

Although the Commission's recommendation would replace PCIP, it would retain certain elements of this program. Namely, it would keep the same definition of primary care services -- office visits, nursing facility visits, and home visits -- and the same definition of primary care

practitioners

Initially, funding for per-beneficiary payments should be equal to the amount of PCIP payments, which were about $700 million in 2015.

The policy should be budget neutral. It should be funded by reducing fees for all fee schedule services, other than primary care visits furnished by any clinician.

The goal of this policy is to begin moving primary care from a fee-for-service payment approach to a beneficiary-centered payment approach, which should support investments in care coordination.

As Jon has pointed out previously, the additional funding for primary care would be paid to practices and other employers of primary care clinicians, which may use the funds for purposes other than care coordination or increasing compensation for these clinicians.

Since making this recommendation, several Commissioners have expressed interest in doing more to support primary care. At the November 2015 meeting, we discussed other models that would increase beneficiary-centered payments for primary care providers. Based on your discussion at that meeting, we have developed three

options for your consideration.

Option 1 would maintain the Commission's recommendation from 2015 to establish a per-beneficiary payment for primary care based on the amount of payments in PCIP program, which were about $700 million in 2015.

Option 2 is to increase the total per-beneficiary payments to $1.2 billion, using the $700 million from Option 1 plus $500 million from the MIPS exceptional performance bonus.

Option 3 is to allow primary care practitioners in all two-sided ACOs to receive a portion of their payments for primary care visits as an up-front payment in addition to the per-beneficiary payment they would receive under Option 2.

And I want to point out that Options 2 and 3 are not mutually exclusive.

So we'll start with Option 1. Based on $700 million in funding, we estimate that the per-beneficiary payment would equal about $28 per year or almost $3,600 per clinician, on average.

It would be funded by reducing fees by 1.3 percent for all services other than primary care visits.

This funding method is budget neutral and would help rebalance the fee schedule between primary care and specialty care.

There would be no beneficiary cost sharing because it's difficult to ask beneficiaries to pay cost sharing for non-face-to-face services.

This chart shows how the per-beneficiary payment under Option 1 would be funded. The white rectangle at the top represents the 11 percent of fee schedule spending on primary care visits provided by primary care clinicians.

Next, the light gray rectangle in the middle of the chart represents the 17 percent of fee schedule spending on primary care visits provided by specialists.

Payments for the services in these top two rectangles would not change.

The dark gray rectangle at the bottom represents the 72 percent of fee schedule spending for all services other than primary care visits, and the per-beneficiary payment in Option 1 would be funded by reducing payment rates for the services in this bottom rectangle by 1.3 percent.

Option 2 would provide about $1.2 billion per year to primary care practitioners through per-beneficiary

payments. It would include the $700 million from Option 1 plus $500 million from the MIPS exceptional performance bonus.

As David and Kate discussed yesterday, MACRA provides $500 million per year over six years to reward clinicians who reach the MIPS exceptional performance standard, but we have serious concerns about the MIPS program, and it might make sense to shift this $500 million in funds to primary care.

The per-beneficiary payment under this option would be about $49 per year or a little more than $6,000 per clinician, on average. And as with Option 1, there would be no beneficiary cost sharing.

Options 1 and 2 raise important design issues. Under the Commission's prior recommendation for a per-beneficiary payment, we did not consider risk adjusting the payment because it would be small, at least initially, but as the payment gets larger, you may want to consider risk adjusting it so that clinicians who treat patients with more care needs would receive higher payments.

On the other hand, risk adjustment may not be necessary because most of clinicians' payments would still

come from fee-for-service, and practitioners who provide more services and higher-intensity services would receive more money from Medicare.

Another issue is how to attribute beneficiaries to primary care practitioners so that only one practitioner receives a payment for a given beneficiary.

Under the Commission's prior recommendation, the preference was to attribute beneficiaries prospectively to a practitioner based on where they received the plurality of their primary care visits in the prior year.

An alternative approach would be to encourage beneficiaries to designate a main primary care practitioner in advance. This approach could encourage beneficiaries to think of their primary care clinician as the person responsible for their overall care.

A third issue is whether to require practitioners who receive a per-beneficiary payment to meet certain practice requirements, such as 24/7 access to care.

When the Commission made its prior recommendation, we did not support practice requirements because the per-beneficiary payment was not considered large enough for clinicians to make substantial investments in practice

changes.

The Commission was also concerned about mixed evidence that practice requirements improve quality and reduce spending, but if the per-beneficiary payment increases, you may want to reconsider this issue.

Finally, there may be an incentive for practitioners who receive a per-beneficiary payment to refer some of their attributed patients to other providers for primary care visits. This could lead to higher overall spending and less care coordination. However, practitioners who engage in this behavior would be less likely to have beneficiaries attributed to them in the following year.

This takes us to Option 3, which would apply to primary care practitioners in all two-sided risk ACOs. Two-sided ACOs include next-generation ACOs, ACOs that participate in Track 2 or Track 3 of the Medicare Shared Savings Program, as well as ACOs that will be participating in the newly announced Track 1+ of the MSSP.

And this option has two elements. First, these practitioners would receive the per-beneficiary payment under Option 2. This payment represents new money for clinicians that they would not have received otherwise.

The second element is partial capitation. PCPs could choose to receive a certain share of their expected fee-for-service payments for primary care visits as an up-front lump-sum payment, and the remaining share would be paid on a per-visit basis.

The up-front payment would be based on each ACO's historical level of spending for primary care visits by primary care practitioners.

To finance the up-front payment, Medicare would reduce the fee-for-service payment for each primary care visit. Therefore, clinicians in ACOs would not receive new money for this up-front payment. Instead, they would be shifting some of their own revenue from fee-for-service payments to an up-front payment.

This up-front payment would give ACOs and practitioners more flexibility to invest in the infrastructure and staff for care coordination activities, and there would be no change in beneficiary cost sharing under this option.

This table illustrates how Option 3 would work under the assumption that primary care practitioners in a two-sided ACO chose to receive 20 percent of their expected

payments for primary care visits as an up-front per-beneficiary payment.

The average practitioner would receive an $81 up-front payment per beneficiary per year, as shown in row 1. And, by the way, if you increased the withhold to 40 percent, this amount would double.

In addition, like all other PCPs, each clinician would receive an annual per-beneficiary payment from Option 2, which is about $49. So the total per-beneficiary payment is $130 per year. Assuming the average number of beneficiaries treated by primary care practitioners, which was 126 in 2015, the total payments per practitioner would be about $16,000. About $10,000 would come from the up-front payment in the first row. This money comes from the payments that PCPs would have received for primary care visits, so it does not represent new money. About $6,000 would come from the per-beneficiary payment in the second row, which does represent new money for the practitioner.

So here we describe the rationale for only allowing partial capitation for primary care practitioners in two-sided ACOs, rather than all PCPs in fee-for-service Medicare.

First, attribution would be simpler because beneficiaries would be attributed to an ACO based on the current methods for attribution.

Second, this option reduces the need for risk adjustment because ACOs with higher historical spending on primary care visits would receive higher per-beneficiary payments.

Third, it reduces the need for practice requirements related to quality and spending because two-sided ACOs are accountable for both quality and total spending.

Finally, this option reduces the incentive for primary care practitioners to refer their patients to specialists or to providers outside the ACO because the ACO would still be accountable for spending on those services.

So, to sum up, we have proposed two goals: rebalancing the fee schedule by increasing spending on primary care and giving primary care clinicians more resources and flexibility to invest in care coordination.

And we have described three options to accomplish these goals, which are shown on the slide, and as a reminder, you could choose to do both Options 2 and 3.

So here are three questions to help guide your

discussion: How large should the per-beneficiary payment be? How should it be financed? And should Medicare allow primary care practitioners in two-sided ACOs to choose a partial capitation payment method for primary care services?

And that concludes our presentation. We'd be happy to take any questions.

DR. CROSSON: Thank you. Thank you, Ariel.

I just want to reiterate one point here, and that has to do with our definition of what the problem is that we are trying to address. I think there is an issue here with respect to equity among specialties, and that's important, I think, for itself. We try to promote equity among providers here as a matter of principle, but to me, as important as it is, I think, to individual physicians, it's a secondary issue.

So the question we have, I've been trying to address for a number of years, which is do we have an erosion of the pipeline for adult primary care physicians such that soon, if not already, but certainly accelerating in the next five to ten years, many Medicare beneficiaries will simply not have a primary care physician. They won't be

able to find them because they're not going to be present in practice, and do we really want to have that situation and have beneficiaries have essentially no choice as to where they receive their primary care services?

Well, let me just stop at that point. I think it's important also, perhaps, to remember that we're not even dealing with a steady state because the budget-neutral add-on payment that we had recommended and had been implemented in law disappeared about 12 months ago. So we actually have a situation right now where, on the margin, the primary care physicians' payments for Medicare have been not increased but actually reduced compared with what they were over the previous five years or so.

So we can't solve this problem in total, but to the extent that we can make some recommendations to at least return the trajectory for primary care physicians to choose this particular -- I'm sorry -- for senior medical students to choose adult primary care as a reasonable and appropriately remunerative career for themselves, then I think that's something that we need to do.

So we'll start with clarifying questions. Jon, will you --

DR. CHRISTIANSON: Sure. I have a couple of thoughts on clarifying questions, I guess. I think most of what this chapter is about is how to pay for primary care in a way that results in more effective care delivery. So I'm agreeing with Jay in the sense that I don't think we're talking about changes that are going to really materially alter this distribution of incomes. But if we can make primary care delivery more effective, maybe that will attract people to the field that might not like just simply billing for E&M and operating in that way.

So, in a sense, I find that first -- not the first slide, the slide that shows the distribution of incomes a little -- you know, takes us in a different kind of direction. I would prefer that we just focus this on this is a better way to pay for primary care services.

I think, you know, my feeling for a while has been that we should consider undertaking an endorsement of a full revision of the RBRVS process and schedule, because we say we are in favor of value-based purchasing arrangements that are all built on a flawed fee-for-service schedule and give us the wrong benchmarks, or benchmarks that to me seem to be the wrong benchmarks. And I think that's a whole

different kind of issue. But what we have here is how do you pay for primary care in a way that physicians can deliver it more effectively. And so that's what I -- I would like to see that focus.

You also talked then about -- I mean, we've concluded in the past that we don't -- because of the small amount of dollars, that we don't want to tie this to certain recommendations. And I've agreed with that in the past. As you suggest here, going forward, if the dollars get bigger, at what point is that a possibility, and you at one point in the chapter say, well, we have other folks on this journey; we've got two Medicaid program examples. Actually, there are quite a few private health plans that are changing the way that they pay for primary care. It would be really helpful in the chapter if you could talk about that, and particularly at what point in terms of the percentage of the physician payment for primary care do you start seeing things tied to particular requirements.

So in the private sector, is it also true that there are no -- nothing is asked in return for the money? If the goal is to improve primary care, we kind of say let's give you more of the money on a capitated basis and do with it

what you want. Is that the way other programs operate that are moving in this direction, particularly in the private sector? I think that would be interesting to know as a next step in terms of moving forward in this chapter.

So who wants to make comments besides me? Let's go right --

DR. SAMITT: Is this Round 1 [off microphone]?

DR. CHRISTIANSON: This is Round 1, I guess, but it better be targeted Round 1.

MS. BUTO: You always start on that side [off microphone].

DR. CHRISTIANSON: Let's start over here. You don't want to be the first person? I don't always start on that side.

[Laughter.]

DR. CHRISTIANSON: Clarifying questions.

MS. BUTO: Very briefly, do you have an idea of how many physicians are eligible for payments under number 1, number -- well, number 1 and 2 are, I assume, the same -- and 3? In other words, does 3 really get at a substantial number of docs, or is it -- when you boil it down to ACOs, primary care, are we really down to a small number? That's

my question.

MR. WINTER: So under Option 1 and 2, it's about 200,000 clinicians that meet the PCIP definition of an eligible practitioner, that is, their insurance specialty is like family medicine, internal medicine, and 60 percent of their fee-for-service allowed charges are from primary care visits. To put that in perspective, that's about 21 percent of all clinicians who billed Medicare in 2015.

In Option 3, I don't have a sense of that yet. That's something we can look into. It is probably small because there are very few two-sided ACOs right now. One thing to keep in mind is that when CMS announced the Track 1+ model, they projected -- estimated that about 70,000 practitioners would be participating in that new model, which is, you know, a little less than 10 percent of all practitioners.

MS. BUTO: Just a related question. Did you look at the number of physicians who might qualify if you used APMs instead of ACOs?

MR. WINTER: All APMs are advanced APMs.

MS. BUTO: Advanced APMs.

MR. WINTER: Advanced APMs, so that would include the mandatory bundled payment models.

MS. BUTO: Right.

MR. WINTER: The cancer, the oncology care model.

MS. BUTO: I think it would be --

MR. WINTER: Yeah, we'd have to look into that.

MS. BUTO: Yeah. It would be limited to primary care physicians, right, not specialists?

MR. WINTER: And CPC+2, yeah. So what we can say is, at least for CPC+, there are two tracks, and they're open to a maximum of 2,500 practices per track, so 5,000 practices total. They have not yet publicly announced how many practices would be participating in 2017, although the program just started two weeks ago. And they have not said how many practitioners would be expected to participate. They have said the number of practices, but not practitioners. So we'll have to look into that some more.

DR. MILLER: Can I just say one thing? Maybe this was behind your question. It doesn't -- these aren't mutually exclusive. Was that clear? So if you picked Option 2, or 1, you would get the number of physicians that Ariel said, and then, you know, whatever Option 3 said or was changed to on the result of --

MS. BUTO: Right, but I guess behind my question was a

thought that if Option 3 ought to try to capture the physicians who are taking risk because this adds another ability or opportunity to take risk in managed care. So APMs should get at that, but, anyway.

DR. MILLER: The other clarification for other conversation, not to go too far down this road, we were pretty deliberate about saying two-sided risk ACOs. We could have a conversation about how much risk is involved in some of those other A-APM models. Sometimes there's risk, but they're playing with the Federal dollar as the risk, and so there would have to be some conversation. But, of course, whatever you guys wanted to do, we could make that option do.

DR. HOADLEY: So on Slide 14, you note that beneficiary cost sharing would be unchanged, and so I had a couple questions about how that would work, and if you can go to Slide 15, actually, I'm also trying to think about the mechanics of what's going on here.

So the physician would be getting this up-front payment that's calculated as a percentage of their estimated average fee-for-service payments?

MR. WINTER: Yes.

DR. HOADLEY: Is that going to be done at the individual physician level? Is this sort of across the universe of --

MR. WINTER: So the notion we had is to do it at the ACO level.

DR. HOADLEY: At the ACO level.

MR. WINTER: But you could think about doing it at the practice level within the ACO. I think once you get down to the practitioner level, there's going to be some noise involved.

DR. HOADLEY: Right.

MR. WINTER: So you probably want a higher group than that.

DR. HOADLEY: Okay. And so then when an actual visit occurs, let's suppose it's a $100 visit, and so you're going to reduce the payment to the clinician by $20, using this 20 percent, so that's $80. Is the notion of the cost sharing being unchanged that they will still pay $20 cost sharing based on the nominal $100 visit or --

MR. WINTER: Yes.

DR. HOADLEY: Okay.

MR. WINTER: That's been our assumption -- that was

our assumption, and you can certainly discuss that, was that they would pay the same cost-sharing amount that they would have paid previously, even though it's a larger percentage of what the clinician is actually getting on a fee-for-service basis.

DR. HOADLEY: Right. Yeah, so, I mean, I get that, and I do think there would be some issues of what that looks like. So somebody understands that 20 percent coinsurance, and now what would the EOB look like? Would the EOB say this is an $80 charge and I'm paying $20, and it looks like I'm paying 25 percent? So there are some mechanical things that presumably could be worked out, but I think --

MR. WINTER: Yeah, and just as a parallel or as a precedent for this approach, under CPC+ for Track 2 practices, they are required to take a portion of their E&M payments as a partial capitation advanced up-front payment amount. And the way the cost sharing works is just as I described it here.

DR. HOADLEY: Okay.

MR. WINTER: The beneficiary pays the same cost-sharing amount that they would have paid previously, even

those it's going to be a larger percentage of the amount that's paid on a fee-for-service basis. And that's just to make all the math come out the way it should in terms of cost sharing.

DR. HOADLEY: Right. So, again, maybe there's some precedent in how sort of what do EOBs look like and how the communication goes to the beneficiary, that they understand that there's complicated math, but they're being left alone.

And I assume that there's no sort of reconciliation. I mean, this is an up-front payment. If it turns out that they do fewer visits, that's fine, it doesn't change what the up-front payment --

MR. WINTER: So I think that's a design question for you to think about it, whether at the end of the year you want to do some reconciliation to make sure the dollars, you know, add up, that they're not getting overpaid or underpaid.

DR. HOADLEY: I mean, one could make the argument, I suppose, that because you're getting this up-front payment, you made it possible not to have to see the patient as many times because you were doing some other kind of

coordination, or more times because you wanted to monitor some particular condition.

MR. WINTER: Right.

DR. HOADLEY: So, anyway, okay. Thank you.

DR. COOMBS: I had a question regarding the graph on the send-out on page 15, and I know we worked through this before, Ariel. We did the numbers last year. What happened with the residual non-primary care doctors was that the effect was negligible in terms of percentage points. Didn't we calculate that?

MR. WINTER: Are you referring to the chart I just put on the screen?

DR. COOMBS: Yes.

MR. WINTER: Okay. Ask that again, please. I just didn't catch that.

DR. COOMBS: So didn't we calculate that the impact on the residual specialists was minimal because of the large number?

MR. WINTER: Oh, the impact like per physician, per specialist?

DR. COOMBS: Yes.

MR. WINTER: I don't recall, but I imagine it would be

minimal because the overall reduction --

DR. COOMBS: Because of the numbers, okay.

MR. WINTER: -- on a portion -- a majority of their payments is 1.3 percent. So it would be less than that.

DR. COOMBS: Right. And then the other question I had --

MR. WINTER: It depends on the mix.

DR. COOMBS: Was there any consideration -- because a lot of times we think about disproportionate share hospitals -- for a larger -- so some family practitioners, some clinicians have very, very large percentage of Medicare beneficiaries under their panels. So I'm wondering if there's a way to incorporate some kind of consideration for those providers who have extraordinarily large percentages of their panels that are Medicare. And I know we've not talked about this in the past, but they're like disproportionate share providers, if you will, in the trenches. So that was one of the --

MR. WINTER: Is the thought that they would get a higher per beneficiary payment because they treat more --

DR. COOMBS: I don't know. I'm just throwing it out there as a consideration.

DR. MILLER: I was having the same thought, but just to clarify, before we get to that. So if you had a bigger panel of patients, you --

DR. COOMBS: You should --

DR. MILLER: You would get more dollars. You would get dollars for each one of those patients.

DR. COOMBS: And you could have your CCM on top of that, your chronic care --

DR. MILLER: Your what on top?

DR. COOMBS: Chronic care management.

DR. MILLER: Oh, right. Sorry. I see what you're saying.

DR. COOMBS: And then one last question. In terms of the MIPS 500 that comes across, that would be the total that would be allocated to primary care?

MR. WINTER: So what we're talking about here is the portion of MIPS that is for the exceptional performance bonus.

DR. COOMBS: Right.

MR. WINTER: So for those practitioners that achieve 25 percent -- they're in the 25 percentile above the performance standard, we would take -- we're proposing to

take all that money and put it in a per beneficiary payment for primary care. That's the proposal. But there is money in MIPS -- but there's other money in MIPS that still remains, but we're taking a portion -- the money that's allocated for this specific payment for exceptional performance practitioners.

DR. COOMBS: So what percentage is the residual that's left after the 500 leaves? Do we know that?

MR. WINTER: I don't know. I'd have to consult with my colleagues and get back to you.

MR. GLASS: It's budget neutral [off microphone].

MR. WINTER: It's budget neutral? Okay. So the amount of money -- the remainder is budget neutral. So the rewards -- the bonuses that go to higher-achieving practitioners are offset by money that's taken away from lower-performing practitioners.

DR. DeBUSK: Are there other programs, for example, like a CPC+Track 2 that have design elements in it that we could steal? I mean, first of all, I think we need to address this as quickly as possible, so I would worry that complexity could introduce delay, which we wouldn't want to do. But are there some redeeming or some intriguing

elements of something like a CPC Track 2 that we would want to incorporate into this design?

MR. WINTER: Besides CPC+Track 2, which is just getting off the ground, so we don't have any experience yet from that, Pioneer ACOs since 2014 have had the option of doing something very similar to what we're talking about in Option 3, a partial capitation approach. And what we've heard is about two or three ACOs have chosen this option between 2014 and 2016. We don't have any information yet in terms of how that's affected their performance in terms of spending, quality, and so on. But that's something hopefully CMS will release more information about.

And then for the next generation ACO program, there's a similar option for ACOs that they can take up to--they can take a certain percentage of their total expected fee-for-service payments, not just E&M payments, as an up-front monthly payment, and that would be offset by reductions to fee-for-service payments they would get throughout the year. So it's a similar concept, but it's all services, not just E&M, and the next generation ACOs are just getting off the ground.

DR. DeBUSK: So it could be, say, a stepping stone to

familiarize the primary care physician and maybe even make them more comfortable to join an A-APM?

MR. WINTER: Well, the way we thought about Option 3 is that this would only be available to practitioners in two-sided risk ACOs, which are a subset of A-APMs.

DR. DeBUSK: I was thinking Option 1, Option 2, getting them more used to --

MR. WINTER: Oh. I'm sorry.

DR. DeBUSK: Getting them more used to a per member per month type payment --

MR. WINTER: Yes.

DR. DeBUSK: -- may be a nice on ramp to some of these more advanced models.

MR. WINTER: Yes, correct.

DR. REDBERG: I just want to be sure I understand how you define primary care practitioners, which I think you said in answer to an earlier question, if you were somehow boarded in internal medicine or listed as internal medicine or family medicine and had 60 percent or more of your visits as E&M, is that correct?

MR. WINTER: Yeah, so we've adopted the PCIP definition, which is actually based on our prior

recommendation from 2008. So it includes physicians who are self-identified with Medicare as specializing in general internal medicine, family medicine, pediatrics, and geriatric medicine, plus at least 60 percent of their fee-for-service allowed charges are related to primary care visits, which are E&M services for office visits, nursing facility visits, and home visits. So we've adopted that PCIP definition.

DR. REDBERG: I'm not sure how I would -- you know, I'm a cardiologist, I'm boarded in internal medicine. I don't know how I'm listed to Medicare, maybe because I don't know what the university does. I'm sure 60 percent or more of my billing for Medicare is fee-for-service. So would I be a primary care practitioner or do I determine that?

DR. HAYES: When you initially applied to bill Medicare, you would have selected a specialty for yourself, and it could be internal medicine, it could be cardiology. It was whatever was done. But for purposes of this, the only physicians who were eligible are those who checked the box that said internal medicine or the other specialties that Ariel mentioned. So that's the key step in the

specialty designation part of the process. And then the rest of it has to do with how you bill. And it's not fee-for-service but it is, rather, billing for certain types of E&M services, the office visits and nursing facility visits and so forth.

DR. REDBERG: Right.

DR. HAYES: So it's a combination of what specialty designation you selected and how your billing pattern looks over the previous year.

DR. REDBERG: Right. If it's more than 60 percent E&M or --

DR. HAYES: E&M, right.

DR. REDBERG: And can I be listed as more than internal medicine and cardiology?

DR. HAYES: There is an option on the application for a secondary and I think even a tertiary specialty designation, but this latches onto the first one, and that has to be internal medicine.

DR. REDBERG: Okay. So if I understand it correctly, I could be considered a primary care practitioner under this --

MR. WINTER: Depending on how you designated yourself

with Medicare, your specialty.

DR. REDBERG: I'm going to check that. I think it's internal medicine with cardiology as secondary.

MS. BLONIARZ: You are listed as a cardiovascular [off microphone]. Your additional specialty is internal medicine.

DR. REDBERG: My additional -- okay. And then my other question --

[Laughter.]

DR. REDBERG: It doesn't affect how I feel about this program. I'm just trying to understand, because there is, as you know -- I mean, some of my patients I think consider that I'm their primary care practitioner and some I'm clearly seeing as a second opinion. But whatever it is, I'm still billing under that E&M code, and I just don't know, you know, so then how would it determine if that was a primary care visit or not. That's really what I was trying to get at.

The other, is this like on Table 1 and you had it on the slide as well, but you used 126 beneficiaries treated by a primary care practitioner? That just seemed -- I mean, I realize that's just Medicare. It just seems --

that's only two or two and a half patients a week? Where was that number coming from?

MR. WINTER: We used claims data and we divided the total number of unique beneficiaries who received a primary care visit from an eligible primary care practitioner. We divided that by the number of eligible primary care practitioners in 2015.

DR. REDBERG: So it does make me wonder about our definition, because I think a real, true primary care practitioner is seeing a lot more than that, so there must be people that are seeing a lot less than that in your definition --

MR. WINTER: Yeah, there --

DR. REDBERG: -- and I just wonder where that's coming from.

MR. WINTER: Yeah, there's a variation and we can --

DR. REDBERG: Yeah.

MR. WINTER: -- around that, around that meaning. We can come back to you with more data on that.

DR. REDBERG: It could be that standard deviation.

MR. WINTER: Yeah, we can get you that. Sure. We were using the average, the mean, really, to model what the

impacts would be, but clearly there would be a variation in terms of the total dollars received, based on the number -- total beneficiaries you are -- that are being attributed to you.

DR. REDBERG: Thanks. I just think that definitions are important. The rest I'll come back to in round two. Thank you.

DR. CROSSON: We're doing this linearly. I think I saw Pat.

MS. WANG: Just a couple of quick questions. If it's in here I apologize for not catching it. If you just took the $1.2 billion, and however it is, you know, sort of provided to primary care doctors, whoever they are, what is the effective increase in the fee schedule rate? So we have a fee schedule today for primary care visits. If you add $1.2 billion to it, whatever form, is it a 5 percent increase? Is it a 3 percent? If you were just to translate it into a fee schedule increase.

MR. WINTER: Yeah. So the $700 million was -- that comes from the PCIP program, which was a 10 percent bonus on each eligible E&M service that was billed. Okay? So it's going to be higher than 10 percent because we have a

larger pool.

MS. WANG: Okay.

MR. WINTER: So we're like 15 percent, something like that. Maybe a little higher.

MS. WANG: Okay. So this --

MR. WINTER: But again, we're not -- but just to be clear, we're not paying this on a per visit basis. This is going to be paid on a --

MS. WANG: No, I understand that.

MR. WINTER: Okay.

MS. WANG: I just want to get a sense of what -- you know, proportionally, what this money represents.

The second question is, you know, notwithstanding Jon's important observation and comment about the slide on page 5 of relative incomes, I would note that the non-surgical, non-procedural is not -- is more like primary care on that chart than it is like the others.

On Slide 11, is the 72 percent of specialties, so-called, that would be funding the $500 million, does that include the non-surgical, non-procedural, cognitive specialties like neurology? Like, would they be taxed to fund primary care?

MR. WINTER: So the dark gray rectangle is a service-specific basis, so it includes procedures, imaging tests, and certain other E&M services, regardless of the specialty that's billing for it. So these could even be billed by primary care practitioners, as well as these other cognitive specialties that you're talking about, and it would still be -- those services would still be subject to the 1.3 percent reduction. So it's a service-specific definition rather than based on the specialty that bills for the service.

MS. WANG: Okay. And the final thing, this is just in response to Alice's question about high DSH hospitals, I don't know whether this is true, but, you know, practitioners practicing in HPSAs used to be eligible for a fee schedule dump. I don't know if that's -- but it's not insignificant. I think that still is in effect, maybe?

DR. HAYES: I mean, the HPSA bonus would remain in place. It's a bonus on, you know, payments under the fee schedule for services furnished in a health professional shortage area.

DR. CROSSON: Okay. So we're still doing questions. Bill.

DR. HALL: I just wanted to add a footnote to what Rita had said about what did we mean by a primary care provider. I think as we go forward in our discussions, this is going to be an absolutely critical thing, and I'll say more about it as it gets further along.

DR. CROSSON: Questions? Bill Gradison.

MR. GRADISON: I understand, very clearly, that there are no practice requirements built in. Nonetheless, I interpret this as at least a nudge in the direction of wanting to encourage more coordination of care, wanting to be sure people get paid, one way or the other, for non-face-to-face interactions, and also adding some kind of 24/7 access, which often would be done in a group by sharing who's on call, given nights and weekends. In a sense, while it wouldn't be a formal change in the standard of care it sort of moves in that direction.

The reason I mention that is that I just wanted to get your reaction. My sense is, directionally, this would mean that somebody who's really active in this practice and is trying to do the right thing, if you will, won't be able to see as many patients, simply because they'll have to spend more house per week, at least initially, to do these things

that are presumably not doing today. And I just wanted to get your reaction to that assertion.

MR. WINTER: It could be that they end up seeing the same number of patients per week but they use this per-beneficiary payment or partial capitation payment to hire care managers and other clinical -- non-physician clinical staff to manage that caseload, and so that they're using -- they could be treating the same caseload, the same number of patients, but they're able to treat them more efficiently and effectively, because they have this additional amount to invest in hiring staff and infrastructure.

MR. GRADISON: But that, of course, doesn't increase their take-home pay and the appeal of this type of primary care. Well --

MR. WINTER: I hear what you're saying.

DR. CROSSON: Questions. Warner.

MR. THOMAS: Just real briefly, did we think about any sort of modification in the per-beneficiary payment based upon the number of Medicare patients cared for? I mean, just thinking -- you know, incenting folks to take care of more Medicare beneficiaries.

MR. WINTER: Yeah. We did not consider that in our -- in that recommendation from 2015, or in the recommendation on the bonus. It was not going to vary based on the number of beneficiaries treated, but it's something some of you might want to talk about.

DR. CROSSON: Questions. Coming up this way. Sue.

MS. THOMPSON: Back to the definition of a primary care provider, because I'm noticing in your definition it also includes nurse practitioners and mid-level providers, physician assistants. Do we have a sense -- this comes back out to the scope of the problem we're trying to solve -- do we have a sense, across the country, what the percentage is, and the growth, in terms of the role of the nurse practitioner in the primary care setting? I know in rural parts of the country it's quite prevalent, but do we know, at a national level, what's happening with that trend?

MR. WINTER: Yeah. So at the national level in Medicare there's been a steady increase in the number of APNs and PAs treating Medicare beneficiaries. It went up from 3.2 per 1,000 beneficiaries in 2013 to 3.6 per 1,000 beneficiaries in 2015. One caveat to keep in mind is that

some of these NPs and PAs could be working for specialists rather than working in primary care, and we don't have that information from our data.

We could certainly look at the literature and see what it says about your specific question, which is the number -- the growth in the number who are practicing in primary care.

MS. THOMPSON: I think it illustrates the scope of the issue --

MR. WINTER: Yeah.

MS. THOMPSON: -- and also, there's sort of an implied consequence to a growing number of nurse practitioners in these roles. So I just wanted to call that out.

DR. CHRISTIANSON: I think that's really important, and one of the things you won't find data on but just anecdotally is you're seeing large systems now that are starting to accept risk actually purchasing or building out their own retail clinics, which are staffed by advanced practice nurses as the first entry point into primary care. So if that becomes less anecdotal and more of a trend, I think it has even more implications for what you are raising.

MR. WINTER: I'm glad you asked that question because I should have mentioned earlier, when Rita asked about the definition of primary care practitioner. It also includes nurse practitioners, clinical nurse specialists, and physician assistants. I should have mentioned that before.

DR. GINSBURG: If I could add one thing. In a sense, with the way you started off that conservation, Jay, about your concern about the primary care workforce in the future, we're seeing the answer right now, and it's going to be a nurse practitioner, physician assistant workforce.

DR. CROSSON: Well, I understand the trend, and my only thought here is, you know, having just gone -- going back to both my clinical career and my medical group management career, I think it's important to have both physicians and nurse practitioners and other providers available, for a number of reasons, at least with respect to the way medicine is practiced today. For the most part, if you're talking about night coverage and things of that nature, that's generally performed by physicians -- not entirely, but generally speaking.

And secondly, I think it's important -- it will be important in the future that beneficiaries -- that the

supply of providers is diverse enough so that beneficiaries will have a choice as to whether they receive their primary care services from a physician or a nurse practitioner. At least that's my own personal opinion.

DR. GINSBURG: Jay made the comment, just saying, you know, the Medicare program, which influences payment throughout the system, has underpaid primary care for so long, that in a sense we're seeing the inevitable response to it --

DR. CROSSON: Yeah. I understand that.

DR. GINSBURG: -- which may not be a good response.

DR. CROSSON: I understand.

DR. HOADLEY: Jay, on that point --

DR. CROSSON: Yes, Jack.

DR. HOADLEY: -- have we looked at, or is straightforward to look at what share of E&M services are being delivered by primary care physicians versus MPs, PAs?

MR. WINTER: So E&M, primary care?

DR. HOADLEY: I mean, yeah, I think that's what I'm thinking of.

MR. WINTER: We can look at that. We can look at that in the data.

DR. HOADLEY: And putting a trend and see whether -- I mean, it's another version of answering Sue's question.

MR. WINTER: Sure. We can look at that.

DR. CROSSON: Bruce.

DR. NERENZ: Just quickly, on that point --

MR. WINTER: Kate has something to add on your question, Jack.

DR. CROSSON: David, do you want to make a comment?

DR. NERENZ: Well, just a technical question. Since a great deal of E&M is provided by specialists, and actually on the ground it may be provided by nurse practitioners and PAs who are feeding the specialist billing, it just seems to me very messy to look at E&M in a category and get an answer to that question. So -- now, if there's a way to do it, then go for it, but --

DR. HOADLEY: I would accept whatever good, smart definition these guys could do.

MS. BLONIARZ: So I just wanted to provide a couple of answers on NP and PA primary care and a couple of other things.

So, Sue, you asked about whether we see geographic differences in primary care and whether it's covered --

whether it's delivered by APRNs and PAs. In our physician survey, our beneficiary survey, we do. We see it's about -- rural beneficiaries are much more likely to report that they're getting all or some of their primary care delivered by a APRNs and PAs.

The other point I just wanted to make is it's dated, but a couple of years ago when we looked at this, about half of APRNs in the category of nurse practitioner were working in primary care, and about half in specialty. For PAs, the share in specialist settings is higher. It's around 70 percent. Both have become more specialty focused over time, consistent with the trends in the physician workforce, more generally.

DR. CROSSON: Thank you, Kate. Alice.

DR. COOMBS: Yes, thank you, Kate, and one of the other things is this whole notion of the migration of advanced practice nursing and NPAs. Historically, there was this need that, you know, there were rural distribution, but there is this migration of advanced practice nursing and PAs into urban areas, so that that need is met.

We actually did one study, looking at, if we could

actually tell what services were rendered by advanced practice nurses versus PAs, but the problem is that the physicians that are supervising actually will submit, under the code, depending on the practice setup. So it was really a mess in the end, that you couldn't differentiate who was receiving what care under a robust health care delivery system, as far as you could tell. You'd have to actually go back, look at notes, and look at whether there were additional addendums and that kind of thing. And in the ICU, we actually worked with advanced practice nursing as well as PAs. And AACN actually did something, in 2014 -- 143,000 of the number of -- the big number for advanced practice nurses -- and PAs were a little over 100,000.

DR. CROSSON: Okay. We're still on clarifying questions and we have five minutes left on the agenda. So, Bruce.

MR. PYENSON: Very quickly. On page 3 of the slides, I was delighted to see the concept that increased productivity should decrease unit prices for the procedural RVUs. And a question about that -- two questions about that. Is there precedence in the Medicare fee schedule for doing that sort of thing? And the second question is,

presumably productivity increases in the procedures. It has not come to an end, so that will continue in the future, which, in theory, would generate extra funds on a budget-neutral basis for primary care, and have you envisioned that?

MR. WINTER: So the way it works now is if there are -- codes are reviewed on -- once every several years, sometimes not for many years at all, and on a code-by-code basis, and they are examined by the RUC, which is run by the AMA and the specialty societies, and they'll look at whether there have been changes in the physician work involved and the direct cost for practice expense over time. And if -- you know, that's really the primary way that efficiencies, through productivity, are taken into account. There is not an automatic adjustment or an automatic process that, for example, reduces rates by -- reduces the RVUs by 10 percent after five years, based on an expectation of a productivity improvement that would reduce the time and resources involved in delivery the service.

So that's one of our concerns is that because it happens on a code-by-code basis, and codes are often

reviewed infrequently, that these efficiencies are not often taken into account in the RVUs -- not reflected in the RVUs.

Does that help answer your question?

MR. PYENSON: Yes. Thank you.

MR. WINTER: Okay.

DR. CROSSON: Okay. So could we put up Slide 17?

It seems to me we have basically four options here. One would be to do nothing, just allow the -- whatever you want to call it -- the market dynamics, educational dynamics to play out as they are. And then at the bottom of Slide 17, we have three other options. One is to essentially, on a budget-neutral basis, replace the money that sunsetted at the end of 2015. The other would be to increase that by reallocating the $500 million from the MIPS exceptional performance pool of money. And then -- and these are not mutually exclusive, as Ariel said -- to do that in a way that provides up-front money for physicians, as opposed to simply paying the money over a period of time, or on a per-beneficiary basis.

So what I'd like to do -- I think these are fairly discrete enough options -- do nothing, or pick one or two

from these options, as a preferred choice -- that I'd like to see if we can do that relatively expeditiously. In other words, I think we should do nothing or I think we should do this or that.

Is that going to work? Paul, do you have a suggestion?

DR. GINSBURG: I was meaning to say that I think it's very important that we don't couch this as our chapter on dealing with the problems of the fee schedule, because the fee schedule problems are much broader. They affect more than primary care. And Jon had actually brought this up when you were out of the room, but I think we should characterize this as, you know, changing the way we pay primary care, reflecting the different expectations and different roles played by primary care physicians, and our options happen to, you know, not be budget-neutral within primary care because of the recognition that primary care is so underpaid.

I think that it's really important that we don't characterize this as our solution to the problems in the fee schedule.

DR. CROSSON: Okay. Thank you for that. I appreciate

that.

Does that feel all right as a way to proceed?

So I think we'll take hands by acceptions. We'll go Craig, Jack, Kathy, Alice. Okay. So Craig --

DR. SAMITT: Before I share my choice -- and, actually, I'm going to complicate things by adding another option -- but I would underscore, on this Slide 17, that we need to reconcile what problem are we trying to solve here. If we're trying to sort of recruit and retain more primary care clinicians, I think none of the options on this list will do that.

If we want -- one of the other goals that I think, I think these goals are not goals. They're tactics. I think if another goal is to encourage the ongoing transition of value-based care, I think none of these do that either.

I would also even argue that the goal that's listed here, the tactic that's listed here, rebalance fee schedule, is also not something that any of these will do. Just for kicks, I looked at the distinction between the salaries of primary care, on average, and surgeons, which is $234,000 a year. Option 1 narrows that $234,000 to $230,000, Option 2 narrows it from $234,000 to $228,000,

and Option 3 narrows it from $234,000 to $224.000.

So I think we just have to decide, does this fall into the something-is-better-than-nothing category, and I think they do that, but I'm not so sure that it will address the problem that we have to solve.

And part of it is -- and this kind of goes to the funding issue -- is I wonder if we're thinking about this in the wrong way. We're thinking of the funding as PCP versus specialist, and I frankly think we should think about this as funding that rebalances between primary care services and everything else. And the reason I say that is some of the highest-performing delivery networks in the U.S. have narrowed, nearly completely, that salary distinction, and the reason they're able to do that is high-value primary care very much reduces unnecessary hospitalizations, focuses on wellness and prevention, and does all the things that we want to do.

So it's not specialist to primary care rebalancing. It's waste and things that are not effective toward primary care rebalancing that I think we should focus on.

So with that all said, the option that I would suggest we consider is what if we used the $1.2 billion to

essentially serve as a match program for AAPMs, that if AAPMs actually deliver value as the program is derived, this $1.2 billion, which will predominantly go to primary care anyway, rewards progress and additional movement toward value, which, frankly, becomes a self-funding strategy anyway, because then we begin to see the transition that we would like.

If folks don't like that additional option, I certainly would -- again, falling into the something-is-better-than-nothing category, Option 2 and Option 3 certainly make sense, but just, frankly, I don't think that they're enough to solve the problem we're trying to solve.

DR. CROSSON: Thank you. So we'll go this way. Kathy?

MS. BUTO: I would agree with Craig. The only thing I would add, going back to Jon's point, is I think -- and I like the idea of Option 4, the match -- or Option 5. I don't know how many we're up to.

This just didn't feel bold enough to move the dial even on your opening remarks, Jay, of making primary care more attractive. I've wondered whether we should propose primary care be entirely separated from the free schedule

and created as a different kind of benefit that gives primary care physicians more power in the process because I think there are issues around salary. I'm not even sure salary is even the goal, but I think a lot of it is authority, control, and to some extent, if you talk to primary care physicians -- and I've talked to mine -- they'll suggest a whole lot of other things they like to see done that don't involve money -- reducing unnecessary burdens and reporting and yada yada yada. So I think we ought to look in a more holistic way at this.

And back to Jon's point, I really think that once we figured out what our objective is -- or objectives, we ought to find a way of evaluating whether those are -- or we ought to propose that they be evaluated to see if whatever is done actually moves the dial in that direction because I think we have a way of thinking we solved a problem once we've moved some money around but then not really knowing if it's made any difference.

For instance, even on care coordination, if we were to stay with these options, our hope is there would be greater care coordination. Well, will there be? How will we know? Even the payments for care coordination that exist are not

being used, CCM and TCM. So there's not enough money there to even put in the pot because it would become almost meaningless.

So I just have to say whatever we decide, I think we ought to try to assess whether the -- or build in an assessment component, not that we should try to assess, into that.

DR. CROSSON: Thank you.

Jack.

DR. HOADLEY: So I think Craig's arithmetic is very sobering that what we're doing is really just making a small adjustment, and then I certainly agree with the sentiment of trying to look broader.

I do think we're going to get into that issue of are we talking about -- what Kathy phrased as sort of pulling primary care out, would we be talking about primary care providers, primary care services by all providers? We get back into those issues of who fits in which box, and it is distressing to see that the chronic care management and transitional care management codes just haven't gotten much use, because it did seem like that was at least something pointing in the right direction.

Having said all that, I think doing -- one of the reasons we brought up the original recommendation of the pool was to try to avoid the negative signal of actually letting this thing go away, the PCIP go away. That's now happened. The negative signal has been sent. To me, that just makes an even stronger case for doing at least Options 1 and 2, and 2 has got more dollars. And I think Option 3 makes sense and is sort of well-crafted as an experiment in the sense of doing it within those environments, those ACO environments, where physicians are already engaged in some kind of broader thinking about how to do things.

It would be kind of hard to think about how you would do this on a broader scale for just more traditionally practicing physicians and actually have a confidence that you'd get the result, but at least in this setting, there's more reason to think that it would lead to the kind of results that we're looking for.

DR. MILLER: So I just lost you partway through, and I'll do this very quickly. You started off referring to Craig's point, which I take as take the $1.2 billion and put it into the APM world, just for simplicity's sake. And then you made comments where you were sort of saying Option

1 and 2. Where did --

DR. HOADLEY: So I was really using Craig's preamble in a sense to say this is a small piece.

DR. MILLER: Okay. All right.

DR. HOADLEY: I think we can do something like these things. I mean, we can recommend them quickly. We've already recommended No. 1, and so I think we should continue to look, but if it was a matter of making recommendations like these in this year's report and beginning to work towards something more ambitious for another year's report, that might be a sensible route.

DR. MILLER: I see. Okay. I just missed the handoff in there.

DR. CROSSON: Alice. Alice?

DR. COOMBS: Thanks.

So I think about this in terms of short term versus long term, and on the short term, I would say that of the three, I probably -- I don't mind 1, but I probably would favor 2 because of the transition that's happening already with MACRA, and that it could be easily kind of manipulated through the current transition that the workforce is going through.

I do think for the long term, I would declare this not quite a 911 call, but I know we did this many years ago. And I've talked to Glenn in former years about the GME notion and what can we do creatively with GME, because that's where the rubber meets the road in terms of the number of primary care doctors.

Some statistics from the AAMC, 40 percent of the physician workforce is over 55 years of age, 28 percent of which are primary care. If the stock market does very well, they may decide to leave us. That leaves a lot of communities without primary care physicians. So I think this is probably an urgent thing that we need to consider short term doing something that keeps people -- you know, give them a little bit of infrastructure support or whatever is necessary.

Long term, we need to do the GME thing again, and we need to consider the Institute of Medicine's recommendations regarding some of the innovative ways in which we can address primary care through GME, specifically.

DR. CROSSON: Thank you.

Brian.

DR. DeBUSK: I would do 2 and 3 in the short term, and I also really hope we get to explore Kathy's idea of factoring primary care out of the fee schedule and treating it as a separate payment.

And I couldn't agree with Alice more as well on the graduate medical education. That needs to be completely revisited.

DR. REDBERG: I also favor, I guess, Options 2 and 3, but I just want to echo Craig's points as well about remembering to promote high-value care.

Also, where I was going with defining primary care, I honestly think even though we're very committed to choice in the Medicare program that we should seriously consider requiring our beneficiaries to choose a primary care provider, identify them. I mean, primary care, I think "primary" means the first doctor you see, but that's not at all how our Medicare program works, and I think the average beneficiary, the last time I saw data, is seeing five to seven specialists regularly. And nobody is serving as a primary care provider.

I know when we added the chronic care management, the idea was to have someone coordinate, but that's really what

primary care is. If we actually had -- beneficiaries had to choose -- and they could choose their own primary care provider, but having done that, have that person actually serve as the primary care provider and then make the referrals when necessary and coordinate.

I can just tell you, my mother who had some skin cancer issues and saw a dermatologist Weill Cornell, who then had wound care problems, so then she went there, and she has a cardiologist for her heart failure at NYU. And she calls me constantly because she says, "They don't talk to each other. This one doesn't know what the" -- I mean, I don't think that's uncommon. I think the records are separate. Everything is separate, and it's not -- people are on multiple medications that nobody is coordinating. And I think that is really what primary care is supposed to be.

Back when I was in medical school, I spent a year in Britain actually studying health policy but worked a little bit in their system, and they actually -- that is how it functions. You have a GP who knows you and coordinates all of your care, and I think it's a much -- I don't think having the freedom to see multiple doctors for the same

problem is in our beneficiary's best interest, not that they couldn't do it, but I think having someone -- having every beneficiary choose a primary care provider would really strengthen primary care and be much better for the beneficiaries.

The other point I just wanted to echo is what Kathy also said in terms -- and it's not just primary care, but I think part of the reason it's less attractive besides salary differences is the increased burden, well intentioned, but these performance measures feel like you have this long checklist of things you're supposed to do, flu vaccines and all kinds of screening measures. It's very burdensome, and the electronic record is very burdensome.

Again, it was well intentioned, but it takes so much longer to see a patient and do an electronic record than it did before this system, and these are all huge burdens on doctors who are seeing mostly E&M visits.

So those are other issues besides the payment schedule that really affect the attractiveness of primary care and the quality of care for our beneficiaries.

DR. CROSSON: Thank you, Rita.

Coming up here.

DR. NERENZ: Very quickly, amen to all of my colleagues' comments. I want to highlight particularly Craig's comments on needing to do things far more radical than this. These are the right direction, but it's got to be more.

And then the Kathy/Rita comments on burden, that was in my head also going into this. It's a bit deal.

MR. GRADISON: I'd be happy with Option 2. I think it should be embedded within a very strong statement about the weakness of the current system for setting fees and a strong call -- a strong statement about the damage, the actual damage that is over time doing to the beneficiaries that we are concerned about.

DR. CROSSON: Thank you.

Warner.

MR. THOMAS: I agree with all the comments made. I think Option 2 is a great option. I like Craig's comment about trying to do some sort of matching.

I also would just add on to his point that there probably are not enough dollars here, just doing a 10- or a $15,000 adjustment. I think one of the things that ought

to be considered is what would be material enough, whether it's 20-, 30-, 40,000, and then back into the cost in that, just for a true primary care physician, somebody that's doing primary care all the time, and think about redistribution of Part B funds totally. Maybe look at the drug area. Maybe look at other areas to redistribute not just in the physician fees, because there's a lot of dollars in other places that could be redistributed and help build this program.

But I think the idea of looking at what would really make a material enough differences, and if 10 is not enough, looking at some other options and then sizing that and figuring out how we solve for it.

DR. CROSSON: Comments. Paul?

DR. GINSBURG: I can support Option 2, say, without enthusiasm --

[Laughter.]

DR. GINSBURG: -- because it is such a drop in the bucket.

Also, I think anything we can do in the short term to get more money into primary care is a good thing, so that's why I support it.

But I'd much rather take the money and put it into the more organized system than put it out just in the fee schedule and the fragmented system.

I really think that we ought to plan -- perhaps it's too late for this cycle, but something really serious about addressing the fee schedule as a whole.

DR. CROSSON: Thank you, Paul.

I have to reconsider now how we vote. Usually, it's yes, no, abstain. Now I'm going to have yes, no, abstain -- enthusiastic?

[Laughter.]

DR. CROSSON: Sue.

MS. THOMPSON: I'll be quick.

But yesterday, when we were, I think, in one of the drug conversations, Warner asked us to think about ourselves as the board of directors of the Medicare program, and I would put forth that the role of the primary care practitioner is absolutely foundational to our work around population health and transforming this care delivery system. And if we were on a board of directors and we understood the foundation of our organization was crumbling, we would act urgently and quite aggressively.

So all those comments, agree. My comment.

DR. CROSSON: Thank you.

Bruce.

MR. PYENSON: I think there is terrific enthusiasm for taking a look at the fee schedule, and I'd like to support that.

But yesterday I expressed my frustration with transitions, but I think this is a case for transitions when we think of the periodic updates on a crude basis where everybody floats the same. We have an opportunity to for shifting trends and updates to move money in a strategic direction, and if that's towards primary care and away from specialist care, that's a perspective we should take on a prospective basis rather than playing catch-up.

DR. CROSSON: Yes, Pat. Yeah, go ahead.

MS. WANG: I hate making the perfect of the enemy of the good, but I think that I am in favor of trying to put more money into primary care, at least on Option 1. I would just augment the fee schedule.

The per-beneficiary payment is a lot of work for people. I mean, I can tell you that in New York, to implement PCIP, the plans, the Medicaid plans were asked to

gather all the information and all the surveys and qualify people, and it was a huge amount of work for a very little amount of money. If we really think that the fee schedule is undervalued, why don't we just put the money into the fee schedule?

Grabbing $500 million extra that might be in play right now for MIPS is a good idea. Augmenting the fee schedule by 10, 12, 15 percent might be too much. I don't know. But I think that Option 2, unfortunately, it sounds good in concept, but all of the issues that were raised in the paper -- attribution, the dollars get big into a per-beneficiary payment. How do you have any accountability for that? You're just paying out this lump sum to folks who may be referring people to the urgent care center around the corner.

In the private sector, there's accountability that is sort of tracked and demanded, I think, a little bit more closely from health plans when you start to play things out in a lump-sum up-front basis.

So I would be in favor of kind of trying to grab whatever money there is, whether it's through the mechanism of taxing the other non-primary care codes or grabbing MIPS

and just augmenting the fee schedule.

I mean, I am going to state this a different way. If people are upset because, on average, women make 70 cents on the dollar of what men make for equal work, the solution to that is not to say, "I'll give you an extra 23 cents if you do extra work." The solution, right, that people press for is you just equalize it.

So I'm not sure that all of the detail and the complexity around the per-beneficiary payment, while well intentioned, is actually solving -- it might be an easier problem to solve to augment the fee schedule.

MS. BUTO: Jay, just one quick addendum to Pat's point is --

DR. CROSSON: Yeah.

MS. BUTO: -- the problem with the fee schedule approach is that there is no specialty designation in the fee schedule. So enhancing payment for primary care services will go to everybody, and it really doesn't get at the fundamentals. But I know what you're saying.

MS. WANG: But the fundamentals, I should just add, I think that the suggestion that you made to approach this from the other end, which is what is the role and the

importance of primary care in our health care system today and in the future and take it from that perspective, that is a multifactorial, multi-conventional conversation. This is just about money.

MR. THOMAS: One last quick question. I would just like to plug in on Rita's point about choosing a primary care physician because it will help solve that issue. It will help on the coordination of care. It will help with all the APM work that's trying to be done, and frankly, it's critically important to how we try to organize care going forward.

DR. CROSSON: Well, thank you.

I mean, I think this has been a good discussion because it's pointed out a couple of things to me. One is that what I thought was going to be kind of a chip shot here turned out to not be.

I mean, I think what we were trying to do here was, essentially, as I would say to my three-and-a-half-year-old grandson, "Put a Band-Aid on the boo-boo," so we have a payment boo-boo because we've kind of -- not "we," but the additional money that was added to primary care payments disappeared a year ago, and we wanted to try to reverse not

just that from a dollar perspective, but the trend and the negative trend and head that off into a better direction.

Having said that, I think it raised for virtually every Commissioner, appropriately so, the more fundamental questions, which is things like, Is this just a Band-Aid? Yes, it is a Band-Aid. Is it going to fundamentally solve the potential undersupply in the pipeline? No, it's not. How do we do that, as Paul pointed out? Let's not pretend that we're addressing this as part of the problems with the physician fee schedule, because the problems with the physician fee schedule, particularly the changes that have come about over the 30 years since that's been in place are much larger and much more fundamental in many ways than this solution.

We have said here at the Commission that we want to address the physician fee schedule, and we are going to do that. We have not brought that forward at least now and in the next couple of meetings because of the complexity involved with that, and quite frankly, we want to come back to that issue when we think we have a robust, appropriately thought-through response. And we don't have that ready at the moment.

Craig, I think your notion, which is to take this money, but to use it to augment primary care services delivered in a fully accountable system is a good one. That's an option we didn't have on the table.

So I think what I don't want to see happen is for us to essentially not put the Band-Aid on the boo-boo and have that somehow be a message that for primary care physicians that the solution to this is long in the future and have that negatively -- further negatively impact the situation.

So I think, without consulting with Mark here, that we would like to come back. We will further explain why a per-beneficiary payment perhaps works better than changing -- just adding to the fee schedule, so we can argue that out, take Craig's option as another option. But I don't know that we can say to you at this point in time, "And we're going to come back with a solution to the physician fee schedule and have everybody decide which one they'd rather have." We are going to do that.

But in the shorter run, I hope that -- and I don't know whether you want to go back in March or April or what you want to do here with this.

DR. MILLER: Not until I talk to Jim.

DR. CROSSON: Okay. Jim will be dispositive. So everything I say will probably be irrelevant.

[Laughter.]

DR. CROSSON: But we will come back with this at some point. I do hope that we can take this, and I think somebody -- maybe Alice said we've got a short-term issue and a long-term issue. That we can do something with the short-term issue, while we use the discussion to further elaborate, I think, the range of options we want to take with respect to the more substantive issues of how physicians are paid and in what context they're paid, like Craig was suggesting, and whether or not the fee schedule fundamentally needs to be redone, because I do believe that it does as well.

DR. MILLER: A couple things I'll say, and I know we're way over time. In part, we're way over time because we spent a lot of time on Part B. Good, needed to, and all the rest of it, but that's going to play out through the rest of our two meetings.

So Jim and I have a lot of things stacked up for the last couple of meetings, and moving things around is always a big issue. Jim is always living right on the brink, and

so have to be careful, so -- well, think about it. I mean, he has to deal with me on a daily basis.

The one thing I would say here is I don't think it is realistic that we can open the full-blown fee schedule conversation this cycle. Remember, a lot of the same people -- there's not a lot of people. No same people are doing MACRA and they're doing the primary care discussion, and these seem to have higher priorities in your minds. And those are the same people who would do the fee schedule stuff, which is why that got put at the end of that train, so that's one thought.

With this conversation, I might be able to, without committing Jim -- I might be able to come back this cycle and readdress some of the issues as were raised here.

Craig, we did talk internally about your idea of like why don't we put this on the APM side. All through the conversation, David has been eyeballing me saying, "I told you so," that type of thing. Just so you know what's going on behind you, when you made the comment, he was right in there, and it actually was a good idea, even coming out of David. We thought this was closer, although not all of them are, but it was a good idea coming out -- we thought

this was closer to what people were sort of asking for. Now we were there is a bigger pallet here.

And so what we may be able to come back with is a couple explorations of these ideas that you've raised, perhaps with a chapter in the end at June that says -- because we don't have recommendations, because now we don't have the time to structure all of that, but describes how you might be able to do something shorter and long term.

I have a thought. I don't want to say it yet until I've talked it out with folks, but there might be something that we could put on the table, just as an idea that we could frame out for the world in this area that captures the kind of No. 2-ish stuff and the Craig stuff.

MS. BUTO: Putting in the primary care physician designation, for it or we're not for it?

DR. MILLER: The designating a primary care, internally we have talked about this a lot, the notion of choosing and particularly when you're inside an ACO type of environment, whether you should broaden that out. We have talked about that a lot. We are more than willing to have that conversation.

Many of you who have been around the block know what

the reactions are that it's going to provoke. That's a freedom of choice issue, and people will react.

But, seriously, I mean, it may be time to have that conversation.

DR. CROSSON: Thanks, Mark.

So that brings us to the end. Thank you, Commissioners.

It's now time for the public comment period. If there any members of our guests here who wish to make a comment, now is your time to come to the microphone.

[No response.]

DR. CROSSON: Seeing none, we are adjourned until the March meeting. Thanks very much. Safe travels, everybody.

[Whereupon, at 12:14 p.m., the meeting was adjourned.]