MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

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9:20 a.m.

COMMISSIONERS PRESENT:

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AGENDA PAGE

P R O C E E D I N G S

[9:20 a.m.]

DR. CROSSON: Okay. Let's see if we can get together.

Let me welcome our guests to the morning session. Our first order of business is continuing our discussion, which has been going on for well more than a year, on MACRA but specifically on the issue of MIPS payment and more specifically on refining and addressing questions that Commissioners had in the October meeting about a potential alternative to MIPS. And we have Kate and David, and David is going to begin.

MR. GLASS: Yes, thank you. Good morning. We are back again.

[Laughter.]

MR. GLASS: As background to today's discussion, let's first review what MACRA did. It repealed the SGR, something the Commission had been recommending for several years. It set statutory updates for clinicians going forward. It created a 5 percent incentive payment for clinicians with a substantial involvement in advanced alternative payment models, or A-APMs. And it created

MIPS, a new value-based purchasing program for clinicians who are mainly in fee-for-service, and that is the part of MACRA we are going to talk about today.

So SGR stays repealed, the updates are what they are, A-APM incentive payment continue. We are focusing on MIPS.

We are focusing on MIPS because we have some major concerns about MIPS. It will not identify or reward high-value clinicians and presents a significant burden to the program and clinicians -- a burden CMS estimated at more than $1 billion in the first year and $800 million per year in following years. We have raised these concerns over the last several years in public meetings, comment letters, and in our June reports to the Congress. And we are not the only ones who are concerned.

CMS has delayed full implementation in the first two years and allowed reporting one measure for one patient to be sufficient to avoid a penalty. This policy, coupled with very low thresholds, will make any rewards in the first two years very small.

Providers, academics, and others have weighed in as well, pointing out difficulties with measures, the

burden of reporting, and the random nature of any rewards that might eventually transpire. Some have asked that CMS be allowed to continue to delay full implementation. This background is what brought us to last month's discussion.

Last month the Commission discussed the state of MIPS. We reviewed the concerns I just mentioned and pointed out that time is of the essence because payment adjustments under MIPS begin in 2019. There seemed to be general but not unanimous agreement to eliminate MIPS. But there was also some desire to keep a value component for clinicians in Medicare fee-for-service.

To that end, we presented an outline of a potential voluntary value program, or VVP, as an alternative to MIPS, and you raised a series of questions about that alternative and asked for a fuller description. So today Kate will address your questions about the VVP.

First, however, I will take a few minutes to address some questions that arose about how the VVP fits with the advanced alternative payment models, or A-APMs. These models are the other path for clinicians set up by MACRA. Clinicians in A-APMS are exempt from MIPS and get a 5 percent bonus payment on top of their clinician fee

schedule billing to Medicare.

So the basic question Jay raised last month is: Are A-APMs available for clinicians to join? If we eliminate MIPS, is there someplace for clinicians to go in addition to the voluntary groups in the VVP?

CMS has taken a number of actions to make A-APMS more accessible to clinicians, and we have commented on a number of them and agree on many:

For example, prospective attribution of beneficiaries to ACOs; that is, letting ACOs know who their beneficiaries are at the beginning of the year. This is important because it creates certainty for clinicians of who they are responsible for. It also makes it possible to for CMS to give the ACOs more flexibility by waiving certain regulations.

Allowing aggregation of smaller organizations not necessarily contiguous into larger national entities, which has proved useful for several ACOs including some in rural areas.

Making models available to any willing provider as in MSSP and Track 1+. In contrast, most demonstrations require entities to apply. Then there may be a competition

to choose winners adding up to possible delay and uncertainty.

Incorporating asymmetric risk, as we discussed last year, to change the risk equation and make A-APMs more attractive. This is being done in Track 1+ ACOs.

Allowing beneficiaries to be rewarded for using ACO providers as in the Next Generation ACOs. This is something the Commission has supported.

And, finally defining risk as a share of revenue rather than as a percentage of benchmark, which can lower the risk for clinician groups by making it more proportionate to their ability to bear risk.

So the answer is yes, there are many A-APMS for clinicians to join, some such as ACO Track 1+ which are designed for clinician groups.

However, we do want to add that there needs to be a balance between availability and capability. The Commission's principles for A-APMs, which we laid out in the June 2016 report to the Congress, make it clear that A-APMs need to be rigorous and help lead to meaningful delivery system reform. For example, guaranteed payments shouldn't exceed the maximum risk levels in models because

there would no longer be any risk for the providers and less incentive to change.

There is also the question that Craig has raised of: How would the new VVP interact with A-APMS? And would it encourage or discourage clinicians from moving into A-APMs?

We think that on balance the VVP would encourage clinicians to form voluntary groups and start taking responsibility for population-based outcomes. That is true by design. If they don't form voluntary groups big enough to assess population-based outcome measures, they lose their withhold.

This would mean that clinicians would be better positioned to form or join A-APMs because they would be familiar with being in groups and they would be familiar with the type of outcomes-based measures that we propose would also be used in A-APMs.

Finally, clinicians would still want to be in A-APMs because the VVP rewards would be limited, as Kate will discuss, and they would still not be eligible for the 5 percent incentive on their billings.

In sum, there should be A-APMS to join, and the

VVP should function as an on-ramp for clinicians to join them.

Now that I am done with that preamble, let's return to where we left off last month. This was the policy option under discussion.

Eliminate the current Merit-based Incentive Payment System. That is Part 1, which met with general consensus. There was a recognition that the current MIPS program will not accomplish the goal of differentiating among clinicians based on their value, will require a great deal of burden on clinicians to report, and will create the illusion of doing something while actually accomplishing very little if implementation is delayed, or potentially moving money around in essentially random ways if it is fully implemented. Further, there is a sense of urgency because MIPS will start making payment adjustments in 2019.

Under this recommendation we are only talking about MIPS. The other provisions of MACRA would continue. Clinicians would get their regular fee-for-service payments and the updates specified in MACRA. The SGR would not return.

Part 2 was proposed in case the Commission wanted

to create a new value-based program for clinicians remaining in fee-for-service after MIPS was eliminated.

That option was: establish a new voluntary value program in fee-for-service Medicare in which clinicians can elect to be measured as part of a voluntary group; and clinicians in voluntary groups can qualify for a value payment based on their group performance and on a set of population-based outcome measures.

This is the part that raised a lot of questions and required some more elucidation. Kate will now take us through that.

MS. BLONIARZ: The elements of the voluntary value program are as follows: A withhold on all fee schedule services would fund a value pool. Then clinicians could elect to be measured in a voluntary group (and potentially be eligible for a value payment). They could join an advanced alternative payment model and receive their withhold back. Or they could make no election and lose their withhold.

I just want to reiterate something David said. It's generally our goal to illustrate the general parameters of a new voluntary value program, give an

illustrative way of implementing the program, and allow for flexibility in design to incorporate feedback from Congress, CMS, and stakeholders.

So while I will answer some of the policy questions you raised over the next few slides, these would only be described as potential policy tradeoffs in the text surrounding the recommendation.

A key question raised by a number of you was the size of the voluntary groups that would be needed. It will depend on the specific measures, specialties, and attribution methodology.

But one estimate is that a voluntary group of 10 or more clinicians may be sufficient to assess performance on avoidable hospitalizations and emergency department visits if the group has a specialty mix similar to MSSP ACOs. This is based on our work with the MSSP program as well as the experience with the first two years of the physician value-based payment modifier.

Dana, you asked for ballpark estimates of how many clinicians might already be in a formal group of this size. From the work I did last fall, about a third of Medicare-billing physicians work with 10 or more clinicians

in the same practice in their immediate office location; 40 percent of Medicare-billing physicians report a hospital or health system affiliation. Those aren't additive. There is some overlap there.

And, Warner, you asked about MSSP Track 1 ACOs. They could also be a voluntary group, and there are about 190,000 clinicians in those models.

We have generally described a process where there would be no restrictions on the size or makeup of the voluntary group beyond a minimum threshold. CMS could provide technical assistance on referral networks to help clinicians form voluntary groups, and they do something like this currently in the physician quality reporting program.

Jon and others, you asked about whether there would be a voluntary group option for clinicians that wish to join one, but can't find one.

We thought a little bit about a CMS-established voluntary fallback group. The benefits of a policy like that is for isolated or low-volume clinicians to have a guaranteed voluntary group that they could join. But if there's very little barrier to joining a group, then

everyone would almost likely do so, and the value pool would likely be smaller. This means there would be smaller rewards for high-performing voluntary groups.

With respect to measures, our preference is to not identify the measures in detail but, rather, give criteria for Congress and CMS on selection. Those criteria are as follows:

The measures should focus on population-based outcomes, patient experience, and cost. They'd be patient-oriented, encourage coordination across providers and time, and promote change in the delivery system. They should be unduly burdensome for providers to report (either extracted from claims or CMS-administered surveys), and would be risk-adjusted for patient health risks.

David Nerenz, you suggested some additional criteria here. We added that the measures should be reliable and valid using a defined minimum number of cases and that we can distinguish meaningful differences among voluntary groups.

David Grabowski, you raised issues of both risk adjustment and social risk factors and a general concern about making sure that the program doesn't unduly penalize

clinicians treating a high share of vulnerable patients. We do agree that that's a concern, and approaches such as peer grouping might be one way to address it.

Craig and Dana raised the point that this is kind of a miniature A-APM process, and that's by design. The A-APM measures would also be aligned with our quality principles, and so by construction, it would give clinicians an opportunity to get familiar with the measures before joining or forming an A-APM.

Pat, you asked about attribution. CMS currently uses a number of different attribution methods, depending on the purpose of the program. Generally, there's two approaches: single and multiple. Single -- the model generally used in ACOs -- attributes all of a beneficiary's outcome or spending to one provider. Multiple attribution allocates responsibility proportionally across all the providers involved in an episode of care.

In work we did about a decade ago, we found that multiple attribution results in more specialty clinicians being attributed to an episode than single attribution. This may be a reason to use multiple attribution as the default option, with special consideration for certain

measures.

Alice and Dana, you both asked whether specialists would see a connection to their work in the population-based measures that we envision for VVP. I should note as well that we've gotten a lot of concern on this point from the physician community in the last month, and we do understand the concern here.

A point on specialist participation in alternative payment. Although the MSSP attribution process prioritizes primary care, about two-thirds of physicians in MSSP are specialists. Three out of seven of the advanced alternative payment models in 2019 focus on conditions largely managed by specialists: comprehensive care for joint replacement, ESRD ESCOs, and the oncology care model. This isn't to say that all specialists or all clinicians have access to models, so we plan to keep an eye on this.

With respect to VVP, we thought about the relationship between the measures and the specialists. Avoidable emergency department and admissions measures might be most cleanly linked to primary care and some other outpatient medical specialties. With respect to readmissions and Medicare spending per beneficiary, the

linkage is most direct with surgeons or hospital-based clinicians. Patient experience and cost could be relevant for most clinicians.

Sue, Kathy, and Craig all asked about the amount of the withhold. We described an illustrative withhold of 2 percent, and one reference point is that the hospital and SNF VBPs are both also 2 percent.

But this is a policy choice. It's generally small, unlikely to change clinician behavior, and so you could make it bigger or have it grow over time. But, again, this goes to the question of the purpose of the VVP. If it's just to get clinicians comfortable with joining other clinicians in continuing to assume responsibility for population outcomes, then maybe the withhold shouldn't be that big, and clinicians who want more risk or reward could join advanced alternative payment models.

A policy we would emphasize in the text is that the total value payment should be capped to be less attractive than joining an A-APM. This comes from a general sense among Commissioners that clinicians should not be able to receive large bonuses while remaining in Medicare fee-for-service.

Next up is a point that Jack and Craig raised, and that's whether getting rid of clinician-reported quality measures and the attestation process for EHRs would mean that Medicare would result in a loss of meaningful information or backsliding in EHR adoption.

In terms of individual quality performance reporting, other organizations such as ACOs, health systems, or specialty societies could measure and report individual performance to clinicians or the public. With respect to EHR policy around interoperability, this might be a continued role for the Office of the National Coordinator or a condition of participation in Medicare.

I'd like to clarify, too, that a lot of organizations have developed registries, and those could still help with internal quality control and help voluntary groups improve their performance. But Medicare would no longer be involved in certifying them or collecting data through them.

I would again reiterate our concern that MIPS is unlikely to achieve the goal of identifying or rewarding high-value clinicians in Medicare. This has led us to the policy option under discussion, which is printed again on

the slide. Recall that the issues I presented will be discussed in the text as one potential approach. We envision a process that allows for CMS, congressional, and stakeholder input. The question for you all at the end is whether we should move to a draft recommendation in December and the nature and form of that recommendation.

We are happy to answer questions and look forward to your discussion.

DR. CROSSON: Thank you, Kate and David.

We'll now open the floor to clarifying questions. I see Craig and Bruce.

DR. SAMITT: So if we can go to Slide 4, I would love to go a little bit deeper in terms of the availability of A-APMs. Have we done an analysis to specifically understand what percentage of physicians have access to an A-APM? So somewhat distinctly, actually, between primary care and specialty, I'd be interested in that. You know, there have been a lot of levers to expand access, but it's still hard to tell the materiality of availability for each of those groups. Do we have a sense of that?

MR. GLASS: Well, we did note that in MSSP, two-thirds of the clinicians are specialists and one-third are

primary care, so --

DR. SAMITT: Well, but it's the reverse that I'm interested in. For those that are not in MSSP that are still in fee-for-service, what percentage could join an A-APM -- it's available, it's accessible, but the physician chooses not to -- versus it's just simply not available?

MR. GLASS: Right. I don't -- no, we don't have -- I don't think we have a way of particularly knowing. I mean, we can identify what states have them and don't have them, but I think you also might want to wait to see what happens in Track 1+ because I think there could be a lot of entry into that program.

DR. MILLER: Yeah. And the question is kind of a chicken-and-egg because remember the physicians can choose to form them. We might be able to say here is where the existing ones are, and there might be physicians located near these people. But whether that represents access or whether that's what you even want to happen as opposed to people forming new ones, it's a bit of --

DR. SAMITT: So there's always a de novo creation opportunity wherever you are.

DR. MILLER: And I think that's some of the

contemplation of what the legislation is about, is that physicians would come together and say, "I'm going to create one of these things," that type thing.

MS. BLONIARZ: I would just clarify that I think they're generally available for MSSP. I would not say that about the other ones, which are run as demos and only in certain states --

DR. MILLER: That's a good point, right.

MS. BLONIARZ: -- or subject to application processes.

MR. GLASS: So Track 1+ is interesting in that it's a demonstration, yet anyone can join who meets the conditions of participation, basically.

DR. SAMITT: Another way to look at it is physicians that may actually be in commercial ACOs but not in an MSSP. So, in many respects, they're in an A-APM through the commercial environment but perhaps not through Medicare.

DR. CROSSON: Bruce.

MR. PYENSON: Thank you very much.

I am wondering if you could summarize the top one or two differences between MIPS and the VVP. What do you

think are the biggest differences?

MS. BLONIARZ: So I think the two biggest differences are every clinician is measured on the same set of measures, and that the assessment of performance is at a voluntary group level, not the individual level.

MR. GLASS: And the other big difference is the burden. There is no reporting under the VVP as we have outlined it. There is a $1.8 billion worth of reporting under MIPS.

MR. PYENSON: Thank you.

DR. CROSSON: Dana.

DR. SAFRAN: Could you remind us the parameters around earnings available to physicians under MIPS? So, as we understand it, starting 2019, with 2017 that we're in as the measurement period, some physicians will be able to earn. Some may lose. Just remind us of the scope at the physician level.

MS. BLONIARZ: So I'll make a distinction here between what's in the statute and how it's been implemented by CMS because they've used flexibility to set certain performance threshold.

So statute is 2019, up and down 4 percent. There

is also an additional MIPS exceptional performance bonus of $500 million. When I looked at the numbers, I think that could add up to about 5 percentage points on top of that, and that's only on the plus side.

The way that CMS implemented the first share of the program, they kind of did a delayed implementation, pay for reporting year, and they did that by setting a very low threshold to basically not get a penalty.

And so what we think and based on what CMS says, they expect that about 10 percent of physicians, clinicians, most eligible clinicians will get a penalty because they don't report. Everyone else will get either a zero or minimal positive payment adjustment because there's so many more people kind of above the threshold, that clear the threshold.

So I think it will turn out that 10 percent get a minus 4 percent penalty, and then most other people, the basic MIPs adjustments are between zero and 1 percent.

DR. CROSSON: Kate, let me just ask you to expand. So that's in the short run, but if this -- if I understand, the statute, if that plays out, it's not altered by congressional action, then when is it? 2022?

MS. BLONIARZ: Yeah.

DR. CROSSON: You have a potential swing of nine positive and nine negative. So physicians could see an 18 percent difference from one practice to the other based upon what they report and how CMS adjudicates that. Is that correct?

MS. BLONIARZ: That's right. Yeah. It changes -- kind of the expectation changes dramatically from the first two years where CMS is kind of phasing it in, the way they've done that, where we think the adjustments will be very compressed, to later years when we think they could be quite magnified. And there's actually a provision in the law that allows for increases, potential increases that are well above 9 percent because of the exceptional performance bonus and if there's more revenue on the penalty side than on the bonus side. Yeah.

DR. CROSSON: So the potential differential in the end game could be even greater than 18 percent is what you're saying?

MS. BLONIARZ: That's right.

MR. GLASS: Yeah. So kind of the two parameters that affect this are the threshold, that set, which is

what? Three points out of a hundred the first year, 15 points out of a hundred the next year? And then, by law, that goes up to either the median or the mean.

MS. BLONIARZ: That's right.

MR. GLASS: And that's where you'll suddenly get lots of losers, so you'll be able to fund a bigger pool for the winners, and the problem is that once you set it at that higher threshold, it could be very compressed at the top in that if the mean is 80, 90. Everyone is going to be -- a lot of them are going to -- or half of them are going to be compressed up into between 90 and 100, and we don't think that the measure is being reported since everyone gets to report different measures. It will be very meaningful at distinctions between people between 90 and 100, and a lot of money could get swung, essentially, randomly.

DR. SAFRAN: But just to be sure I understand, because that was really helpful, and it feels very important to this discussion, for the '17 and '18 measurement periods, which pay out in '19 and 20, the estimated 10 percent of physicians getting the negative 4 percent and the rest getting somewhere between zero and 1

percent is what's expected, those two measurement years paying out in those two payout years. Do I have you right?

MS. BLONIARZ: Yes. And the only caveat I will make is that that's the basic budget-neutral MIPS adjustment. There is also $500 million available for exceptional performance. When you add that in, I think some people could get up to 4 or 5 percentage points, on the positive side. But the basic adjustments, 90, getting -- or 10 percent, negative 4, 90, zero and 1.

DR. MILLER: And we're just saying that that's roughly what we think the playout is or that's an estimate that CMS or someone --

MS. BLONIARZ: This is in CMS's proposed and final rules.

DR. MILLER: Okay.

DR. CROSSON: Other clarifying questions?

Paul.

DR. GINSBURG: Just to conclude this discussion, it sounds like there is potential under MIPS today to have very large rewards and penalties down the road which would both probably way beyond our confidence and the data that underlie them and could interfere with the A-APMs because

some groups could find that they're going to consistently do better under MIPS than they would do as an A-APM.

DR. CROSSON: Yes. And I agree with that, and I'd also point out the other side of it, which is that since -- and again, this is a projected analysis. Since the measures are different and the comparisons then become very difficult, it would be -- it could be -- turn out to be essentially impossible for a physician or a practice to make a judgment as to whether or not in any given year that physician's reported measure ends up resulting in a significant underpayment, from their perspective, or a significant overpayment.

DR. GINSBURG: Yeah, that's possible.

I actually worry more if it becomes predictable in a sense if a group says, "Well, you know, under MIPS, we can get a consistent 8 percent bonus, and with an A-APM, we're not so sure. And so why should we go to this new world when we're going to do just fine under MIPS?" So I think some of the predictability of MIPS is one of its shortcomings, particularly as it can undermine A-APMs.

DR. CROSSON: Okay. I think we're ready for the full discussion.

I think, Craig, you want to lead off.

DR. SAMITT: Sure.

I want to harken back to our September meeting. I think I made a comment that when we review the Medicare context chapter, it seems depressing every year in that we're not seeing the advancement that we had hoped in either improving quality of care or reducing cost of care, which I think is what we're all about. And what we've discussed in numerous meetings is we need to change incentives to shift more toward value and away from our dependency on fee-for-service fragmented reimbursement.

And so I want to start there because I want to remind us all what this is all about, which is moving forward, not standing still or not preserving the status quo.

And so for all those reasons, I am in favor of what's written in this recommendation. I worry that the existing framework with MIPS without any change allows us -- or even a delay of several years, of three to five years, just sustains the status quo and doesn't advance the value of care for beneficiaries that we're supposed to advocate for.

I also would weigh in -- I don't remember who said it on the other side of the table . In a prior life when we evaluated the various MSSP programs, we did exactly what was suggested. This wasn't about performance. It was about maximizing reimbursement and risk avoidance, and so which of the calculated scenarios would ultimately produce the best net return? I don't think that's what this should be about.

This should be about which of the models will most encourage us to improve the quality of care and total cost of care, and I believe what's written in this recommendation has several key elements that are going to move us forward.

With that being said, I do have a few recommendations. One is less on the MIPS side and more on the APM side. I'd like to see us accelerate the development of specialty APMs. I feel the concern that APMs may not be available on the specialty side really resonates with me, and I think that we need to assure that specialists have a home for A-APMs, and that if there's any encouragement, if we can include that in the chapter, that we must accelerate and advance that opportunity so that

those homes exist for specialists as much as they do for primary care.

The other recommendations that I would make, I do have concerns about the size of the voluntary groups. Ten seems too small to me, and while that may work for ambulatory care-sensitive metrics, I worry for measures like readmission rates that the population size would be too limited, and I would encourage us to think larger numbers and not smaller numbers. And I also worry that if we think about differential numbers, it starts to get very complex. So I think the minimum requirement should be a common number, and it should be higher.

In terms of the quality measures, I think we should consider local benchmarks, not national benchmarks, to reflect regional differences in the voluntary groups, and so if there's an alternative or an option in terms of local versus national, I would suggest local as a measure for these -- for at least the benchmarks for these metrics we pick.

And then the last is I would reconsider the multiple attribution option versus single attribution. I worry that multiple attribution undermines both the

measurement and the accountability and just creates confusion and doesn't drive the accountability that we seek. So I would be more in favor of single attribution, not multiple.

But all that being said, I am in favor of the recommendation. As I've said in the prior meeting, I also worry that 2 percent may not be sufficient to draw the attention to the importance of this transition and encourage organizations to shift to A-APMs, and I would be in favor of larger over smaller numbers in that withhold.

DR. CROSSON: Thank you, Craig.

So let's open this up to discussion. Can I see hands for people?

Let's start with Jack.

DR. HOADLEY: Thank you.

So I thought this was a really very clear update for us, and I really appreciate that. And I am also very encouraged with the direction that we're going. I'm supportive of this overall approach.

I think what I'd like to talk about for a moment is sort of fleshing out a little bit of the notions of what we mean by the potential kinds of things that could be

these voluntary groups, and it seems like in some of the feedback we've gotten, there is a sense that, well, groups won't be available to a lot of physicians. And I want to just sort of go through a few types of groupings and really just make sure that you agree that these are reasonable possibilities for what a group might look like and in one case sort of a notion of where it might go a step too far.

Obviously, you have already talked about the notion that there are the MSSP Track 1 ACOs that are already a clearly formed group. They don't quality as an A-APM. So that one seems easy, and that actually, as you point out, has quite a few clinicians already engaged.

It seems like another possibility are various kinds of group practices, whether it be a single specialty group, whether it be a multispecialty group, whether it be a cluster of single specialty groups. So the local group of endocrinologists might team up with the rheumatologists and the gastroenterologists or whatever and make themselves a group.

It seems like the biggest issue there is risk adjustment and whether some of the measures -- if you're a group of oncologists and you've got a measure about the

total cost of care that isn't adequately risk adjusted, you're not going to fare well next to the primary care practice down in the other side of town. So it seems like, again, these are logical groups but points out the need -- and it's achievable. We know risk adjustment isn't easy, but it can be done -- to get some kind of risk adjustment work or think about what measures so that they're not measures that will overly penalize a group that's formed that tends to be people who are sick.

It seems like another potential group is those affiliated in some loose or not-so-loose way with a hospital, so it might even be a bunch of doctors or other clinicians who have admitting privileges or who are otherwise involved in the work of a hospital, and obviously, in a small community, that might be many of the physicians in the area. In a large metro area, it might be a more selected group. But again, a group that has some affiliation, there's some overlapping sense of patients.

It seems like another potential one -- and this one isn't quite as obvious to me, but would be a regional medical society. Could they create a group or make their membership a group or an option to be a group?

And then sort of the last thing was what about things that go beyond a geographic area, and it seems like maybe that's where it doesn't make as much sense to say a set of practices that are in different parts of the country or a national specialty society, because then you suddenly don't have that sense of a common set of patients. And if this is about population measurement, it seems like that doesn't make sense.

So I don't know if you want to react to any of those sort of types of categories of groups or whether we want to think about -- and again, we don't have to -- we're not necessarily in the game here of spelling out all the rules, but whether we want to make a suggestion that there needs to be some sort of geographic constraint in what should be a group.

MR. GLASS: Well, I think so far, we're pretty agnostic about what group, and I think you could throw win IPAs as well.

But the geographic, there are ACOs that have noncontiguous groups in them, and I think the way they do it is they -- because they are going to start doing geographic-specific benchmarking sort of, I think they are

going to weigh it by the percent of patients in each, you know, proportion to the set of patients. So I think even that would be possible. I mean, it would get away from one feel of local benchmark, local that sort of thing, but in order to bring together enough, it would be possible. And I think in rural areas, maybe it would make sense.

DR. HOADLEY: It seems like those are kinds of points that we could make, talking about, you know, a variety of these kinds of illustrations, a group could look like this, could look like this. We're not necessarily drawing strict boundaries to say it has to look like one of these four, but those are four, and maybe by the time we're done we have eight kinds of examples of ways groups could be formed that make it less intimidating, the idea that you've got to go out and essential re-create something that looks like an ACO.

DR. CROSSON: Rita.

DR. REDBERG: Thanks for this really excellent chapter on a really tough topic, and just to reiterate, I agree with a lot of what Craig has said in terms of I think we're all in agreement that MIPS doesn't really get us to what our goals are to improve quality, improve care, and

improve value. You know, costing $1 billion to put in MIPS, having something like one measure for one patient is clearly meaningless. I don't think anyone is going to go on record defending that and saying that's going to improve value of care.

Clearly, the details are difficult, and you have really, I think, moved us a long ways in this proposal. I'm thinking about, you know, what Craig suggested as changes, and I understand wanting larger groups, and maybe that's right. My only concern is, you know, I think life has gotten so much harder for individual practitioners, and we all, I think, don't want to make it more difficult if we can avoid it.

And I just wonder also, again, just on the local benchmarks, because in general we sort of like national and -- you know, we think variation usually reflects -- you know, perhaps we look at overuse and inappropriate care. So I have some concern, but I don't know what else you were thinking of with local benchmarks. But I really appreciate the work on this, and I think that it's really important to get towards the alternative payment models and have the VVP kind of help as a step to that.

DR. CROSSON: Further comments? Brian.

DR. DeBUSK: First of all, I'd like to congratulate the staff on a very well written chapter. I enjoyed the work that's being done here. It's nice to see that we haven't lost momentum for the -- or it doesn't appear that we've lost momentum for the repeal of MIPS. I just also want to compliment you on continuing to try to develop and refine that compelling alternative. Even if in December it still is somewhat conceptual, it would be nice to see increasing specificity over time.

But having said that, I also have a little bit of concern. I don't know that we want the VVP -- to try to make the VVP do too much, especially when you get into the specialties that are very, very episodic, sort of the classic example would be, say, a joint replacement. But to Craig's point, I could not agree more that I hope to see some specialist APMs developed in parallel, and I think that's going to take some of the pressure off to try to make the VVP be all things to all people, particularly specialties.

And with that said, one final point. As we encourage more of the episodic, specialist-friendly APMs --

and, again, I think we need a lot more of those. I'm excited to or would like to see how advanced BPCI works out, for example. I do think even those should be done with broader population health ideas and -- you know, I don't see them as competing ideas. I see them as complementary. And even then those models need to be subjugated to population health models. I don't think they need to be competitive. I think they need to be complementary.

But, again, I just applaud you, and it's exciting to see this work continue to evolve, and I hope we keep the momentum up.

DR. CROSSON: Pat.

MS. WANG: I think that the issue that a few people have commented on here is what about specialists, whether they're episodic, hospital-based, like they seem to be left out, and there's a struggle. I think there's a general embrace and appreciation for the concept of the VVP and the higher-level population health metrics.

I agree with the comments that were just made by Craig and by Brian around finding a home for specialists, but I would suggest that we try to think about doing that

in the context of something that is a little bit perhaps not full-bore APM but the VVP for specialists with their own metrics that are not the big gigantic, you know, readmissions. I mean, those are very broad population health metrics, and I think they're too big.

I think there's an opportunity, if there could be work done, to, you know, define the appropriate grouping of specialists so you don't have hundreds and hundreds. But those are actually the component parts of a successful A-APM and could actually inform better functioning for an A-APM. A lot of things have to go right to reduce readmission rates, for example, and it's not just how well a surgeon does in the OR. It has to do with all the care that happens, and it has to do with, you know, what happens at discharge. It has to do with follow-up. It has to do with resources in the community and medication reconciliation, the whole thing.

So, you know, I think it's too broad a metric, in fairness, for many specialty groups, and I would encourage us to maybe think about, in addition to building on this really good work and the concepts of VVPs, to try to develop concepts of specialty VVPs with their own simple,

uniform metrics that apply to all of the VVPs in the country that are that specialty as opposed to self-selected, et cetera, et cetera. And maybe the specialty societies have a role that could be constructive there in suggesting what those are.

As far as risk adjustment is concerned and the small number, I am very concerned about just conceptually it sounds good, you risk-adjust all, but for a group of ten and how many patients are we talking about there, I don't know what the validity is, and also just the amount of work that somebody would have to do to be calculating that. I don't know. I mean, to me it sounds very burdensome. And so whether it's, you know, larger numbers or a different way of getting at the importance of not penalizing people for taking sicker populations or populations with socioeconomic status challenges. I don't know what the answer is, but I do have a concern that it might not be practical to think that you could cut it that fine.

DR. CROSSON: Brian, on Pat's point?

DR. DeBUSK: I think Pat makes a great point, but it also moves us into a philosophical question, too, of do you have the VVP as just a core -- sort of, you know, as a

catch-all, almost like MIPS was originally intended? And at what point, if you do a VVP -- which, by the way, is a good idea; I am on board. But if you do a specialist VVP, at what point does it really become an APM? And should it be dealt with through the EAPE payments, not necessarily through MIPS? And I think that may be something that's worth our time to think of do you have core VVP and then a couple of specialist bolt-ons that, again, are specialist-friendly? Or do you try to punt those over into A-APMs and just let MACRA do the heavy lifting there around the QP bonuses and things like that? I hope that's clear, but it's a really interesting point that you brought up, because I could see us approaching it really from either side.

DR. MILLER: Can I just say something about that? Because I think it implicates a couple of philosophical issues, and I'm just going to say it a little bit different than you did.

You made your comment, the preceding one, before we bounced back to Pat, where you said if you created something for the specialist, you made it -- I can't remember the word -- subservient to the overall

organization. And I took that to me that you were -- and, you know, you're here so you'll comment. I took that to mean that you still wanted a population-based incentive even if you built something around the specialist. And so I want you guys to be tracking on that concept, because the other way to take comments that are being made down at -- all over the table, but I'm just going to point at Craig at this moment, of saying I wish there were more homes for specialists, are you talking about homes in which it's just specialists or specialists with other physicians? And, again, you know, so when you're thinking about how to include the specialists, are you thinking ways to get the specialists in with other physicians? Or are you doing this separate thing? And if you're doing a separate thing, how does it relate to your overall population thought process? That's what I'm trying to track from a philosophical point of view.

DR. SAMITT: Yeah, I mean, from my perspective I thought it would be either of those two things. What I think is important is that there are options. If I'm a specialist and I want to become part of an A-APM, whether it's with --

DR. MILLER: I hate to interrupt you, but then I think you enter -- I'm really sorry. But then I think the other metrics or vectors I want you to have in your head is are you talking about the MIPS side of things or the APM side of things? And I think what Brian was saying is, wait a minute, maybe some of that all happens over there on APMs -- I think this is what you were saying -- and, you know, that's a fine conversation, no objection. We're still talking for this session about what do you what to happen on the MIPS side. Ultimately that's our landing point here.

DR. SAMITT: My comments were on the A-APM side.

DR. MILLER: Okay. I just want to make sure people are following, you know, each other's comments. That's all I'm --

DR. DeBUSK: And that's where, again, my mind-set is we know we need to get rid of MIPS; we know that we need a better -- an idea that's really more compelling. You know, we can't just say, well MIPS is bad, it needs to go away. We need a compelling idea.

I think the crossover point for us is when do you say, oh, wait a second, this new model, this specialist-

friendly model that doesn't have a pop health component to it is an A-APM? It isn't just an extension. It isn't a piece of VVP -- which, by the way, again, there is merit in that approach. Do you look at VVP and try to build it out over time to accommodate specialists? Or do you just say, oh, no -- let me go back, say, to interventional cardiology because I wear joints out, so I'm going to change horses here.

Let's say interventional cardiology, interventional radiology, don't we really want those specialists thinking episodes, individual patients? You know, their world really isn't a lot bigger than placing that stent, for example. The concern there and the elephant in the room is serial bundling. You know, what do you do when -- I know, this is plowed ground. And that's where I think that subservient concept, if you had some type of pop health model like an ACO, let's say you're part of -- this APM is running within a next-gen, could you go to those private practice interventional cardiologists and say here is your model, here is your world, but we're not going to just turn you loose to start triggering these episodes. You're part of a population health model that

requires the right referrals, the right steps.

DR. MILLER: But, again, in your comment, they're all about what's happening on the APM side.

DR. DeBUSK: Yes. I'm trying to offload a lot of that into APMs.

DR. MILLER: And that's what I want people to keep track of.

DR. DeBUSK: Because I'm afraid that we're going to pile too much on VVP. Having said that, Pat, I keep -- Pat's comments have merit. I mean, if you really wanted a complete VVP solution, you would build out those --

DR. MILLER: And no dismissal of her comments, and I just want to -- your vocabulary VVP is synonymous with MIPS.

DR. DeBUSK: Yes.

DR. MILLER: Okay. Just so everybody follows that.

DR. DeBUSK: Yes.

DR. MILLER: And, two, I'm not dismissing Pat's comments. I want you guys in this conversation, when you're making your comments, to be clear whether you're talking about the MIPS idea or the APM idea, so that when

we walk away today we know where you're building.

DR. DeBUSK: And even if I lean toward APM for specialists, if it gets us rid of MIPS, I'm okay with either packaging.

DR. CROSSON: Paul.

DR. GINSBURG: I certainly support the elimination of MIPS, and I'm very supportive and intrigued by the VVP proposal. What I like about it is that I believe the future of better delivery of care in Medicare and throughout the system is to have physicians organized into entities, whether it's virtual or otherwise, and they both push in that same direction. So it means that the pressure to come up with more meaningful APMs, particularly for specialists, which I'm really glad Craig brought up, that's not diminished by all this messing around trying to take this unwieldy MIPS structure and trying to get it to work a little better than what is in law. I think a lot of the energy that can go into work along the lines of A-APMs would be very consistent with what would basically support the VVP approach.

One thing that David mentioned, very quickly, was the potential that IPAs could be a virtual group for VVP,

and thinking about IPAs in many areas of the country, certainly California, they're very valuable organizations, I think limited by being able to only function in commercial HMOs and Medicare Advantage. And to give them this additional scope to function in Medicare fee-for-service I think would be a positive all around.

DR. CROSSON: Dana.

DR. SAFRAN: Thank you. So I'll add my thanks for the great work and, in particular, for answering the many questions that we had last time so well.

I also favor the recommendations that are being considered here of moving away from MIPS and moving toward the VVP, though I do have some concerns about how we do that. So, you know, I think there's no question -- others have said it really well -- that we've got too many physicians left outside of the A-APMs to do nothing, which, you know, we were contemplating last time.

I agree that groups need to be local in order to actually have the reality of collaborating around better care, and agree -- and I'll say a little more about, you know, my own knowledge and work on sample size requirements. But I agree that ten is probably going to be

too small, particularly given the recommendation, which I agree with, of the three domains of measures, one of which being cost. We know that for cost measurement you need about 10,000 individuals to get a stable, reliable number. So I think that desire to measure total cost of care at the entity level, whatever that entity is, is going to be the rate limiter on size.

So I think we have a timing issue, and, you know, Kate, you were really helpful in laying out that in the current measurement period of 2017 and '18, I feel better knowing how limited the upside is, quite frankly. And so I'm wondering whether what we want to do is leverage the exceptional bonus as a way to help us bridge getting from the current MIPS set of measures to the VVP structure that we're proposing. And so let me explain what I'm envisioning to add on your ideas of the three domains for VVP, and then maybe that will make clear how that bridge could work.

So I totally agree with your suggestion about, you know, three domains -- population-based outcome measures, patient experience, and cost. So on population out measures, I had two thoughts to share. One is to make

the reporting burden as low as you're trying to in VVP. I wonder about starting to leverage CPT II codes, which are there and could help us -- my understanding is could help us measure some of the clinical outcome measures that specialty societies have endorsed, but that currently we can't measure because we don't have the data in claims because nobody's using CPT II. And we don't have access to the clinical data, so we're stuck.

So if we encourage over this, I will call it, two-year transition period that folks start using CPT II codes, and maybe that's part of what earns you an exceptional bonus, that might help create a bridge toward a new set of measures for specialists.

The other in the outcome space that I have talked about in this group before and that I really want to consider using this period of time to move us along is patient-reported outcome measurement. So starting -- and for specialists, for most specialties, particularly where there's an intervention, where before and after you can see a difference in how the patient feels or functions, we should be encouraging the adoption and use of longitudinal patient-level, patient-reported outcome measurement as a

way to know are we helping people. And so can we, as part of VVP, encourage the adoption of that? We wouldn't, let's be clear, be able to pay based on performance, based on the change scores. But we would be able to pay based on adoption, and we would through that -- and data sharing into CMS, through that begin to have a really significant amount of data to help us with shared decisionmaking for patients, because we'd begin to know for people like you with this starting point, if we intervene by treatment pathway A versus B, what can you expect in terms of functional improvement, pain relief, et cetera.

On the patient experience piece, that's in some ways the easier part because we know how feasible it is to measure that at the physician level with very small sample sizes, 45 patients per doctor have been demonstrated over and over again to be highly reliable, stable, pieces of information. So that wouldn't be hard to do. The question is: Who's implementing the survey? And, you know, in the ACO programs, at least, CMS did it in the early years. So I'd offer that as an idea. And total cost of care, you know, I think I've already shared my thoughts there.

So I just wonder whether we can use this two-year

period where things are already in motion on MIPS to start to bridge and to begin to use that exceptional bonus as a way to reward those who will engage with either CPT II codes or PROMs or both.

DR. CROSSON: Thank you, Dana.

David.

DR. GRABOWSKI: Great. Thanks. Thanks, Kate and David, for a great chapter and presentation.

Like others, I am in favor of repealing MIPS, and I really like the way the VVP is shaping up.

I really appreciate how you went through a lot of our questions in your remarks, and I want to return to kind of the two big questions I asked.

On slide 9, I and others raised the issue. Given the VVP is voluntary, how do we get clinicians to participate, especially in those lower-resource areas?

And I think, first, I really like the call for technical assistance. I think that's going to be really important here.

I wanted to push you a little bit on this fallback, voluntary groups. I do like the concept, but I really worry about, in practice, how those will work.

There's a big literature suggesting when you have a payment incentive, you don't just need the payment incentive up top, but you need delivery-level change on the ground. And you really need to pair those two.

I can see how this voluntary group would have that same payment incentive as any other group, but you can imagine even -- I like Dana's point of making certain these are local. But two docs who are in a local area, who have no other tie, other than being in this voluntary group, are they going to participate in a readmission reduction program? Are they actually going to take actions on the ground to move the needle in terms of quality? I think we will want to be very careful about that. I think we will want to think about how do we pair them.

I like the idea of having a group for everyone, and I do like the idea of having kind of a default group, but thinking about what that actually means and how do we encourage providers that end up in that voluntary group to actually engage.

The second issue I raise -- and you really respond to this on slide 10 -- how do we set up a system that doesn't penalize those physicians in lower-resource

areas? I share other Commissioners' concerns. Ten is too small of a number for a group, I think. I think it really does have to be larger. We've already talked about the importance of risk adjustment.

I think this is the first time I had seen anything about the peer groupings. I really like that idea here. I think that could be really important, so I would just want to put forth my support for that idea.

Thanks.

DR. MILLER: And if I could just make a couple of quick comments.

I want the public to be sure to follow. We weren't saying 10 for every one of these measures. We were acknowledging that depending on which measure you were talking about, you would get a different size, but that for certain measures, it could be as small as 10, just so everybody out there writing news reports doesn't say that it's 10. We acknowledge that depending on the mix of measures and measure by measure, it might be somewhat different.

We also had a lot of internal conversations about the fallback group ourselves and lots of pros and cons,

like it says there, and that's just a summary.

One thing, Kate, am I remembering this, or did I black out? We were saying that if -- because we were getting mixed signals. Some Commissioners wanted them; some Commissioners didn't. You could create them, and then your reward wouldn't be as high. And I think Kate said something along -- or somebody, who shall be unnamed, whose named Kate --

[Laughter.]

DR. MILLER: Maybe you let them get their 2 percent back, but you don't let them get more than that, that type of thing, because of the things that you're saying. So some ideas like that, we're kicking around in the kitchen.

DR. CROSSON: Okay. Bruce.

MR. PYENSON: Thank you very much for a terrific presentation and work.

I am in favor of repealing MIPS, and I am also in favor of developing the VVP. I really like the way this is presented and think it would be very helpful to contrast the micromanagement approach of MIPS to the population health approach that you're using, and that micromanagement

approaches are, of course, very good for the vendors, who would be getting the billion dollars, but are not good for the goal of reducing cost and the goal of improving quality.

I am, in particular, supportive of the potential that VVP has to be a model for the commercial world because when we talk about physicians in the health care system from the standpoint of Medicare, it's big, but it's not the whole story. And to the extent we can create models that are useful and adoptable by the private sector, by the commercial payers especially, I think we've helped make the system move in the right direction, and I think we have that in the structure of VVP. But to the extent we can make that a little bit more explicit on how some of these approaches could be used by commercial payers, I think that would add to the support of the proposal.

I'm particularly intrigued by integrating MSSP Model 1 into VVP, and I think there's potential, to some extent, to think about whether the ACO shares in that. The administrative capability of ACOs and hospital ACOs is significant compared to the administrative capability of most physicians and physician practices. So to the extent

there is a way to leverage the relationship there to move the population health agenda, I think that could be very helpful.

Finally, to add to Craig's list of additions --

DR. CROSSON: You might want to patent that name.

[Laughter.]

MR. PYENSON: This is the last thing.

If we could consider how participation in the Medicare Advantage could somehow be integrated into VVP, I think that would be potentially very helpful, very useful.

Thank you.

DR. CROSSON: Thank you, Bruce.

Kathy.

MS. BUTO: So I support repealing MIPS and moving toward a VVP-type model. I wanted to just re-raise the question of can we consider making the VVP side of the equation between VVP and the A-APMs not budget-neutral; in other words, taking -- let's say a 3 percent withhold and only 2 percent would be available back to the VVP side, 1 percent would go over to help fund or stimulate more interest in the A-APM. I think because -- mainly because I think the VVP side of the equation is going to be huge, and

so it's just another way to create more incentives on the other side.

I think we have to ask the question or answer the question or try to answer the question whether we think all physicians who stay on the VVP side of the equation could eventually be in a VVP group without our fallback option. Do we think that's really necessary?

My own preference is that we don't have a fallback group, but I think we have to realistically face the question of whether we think it's going to be possible to create a group.

I think the specialty group issue that's been raised by Pat and by Craig and others is really important on both sides, and I'm particularly thinking about certain specialties, not so much surgeons or even interventional cardiologists, but really endocrinologists and other specialties focused on more chronic conditions and realizing that they -- we may need to treat them differently to encourage their forming either A-APMs or joining in the VVP approach in a more robust way. So I'm just not sure how to tackle that.

It feels like there would have to be some

population-based measures that are different for those kinds of physicians, and we ought to think about particularly managing chronic disease patients, whether we need to look at different kinds of population-based measures.

DR. CROSSON: Thank you, Kathy.

David.

DR. NERENZ: Thanks.

DR. CROSSON: Excuse me. Did you have a comment on Kathy?

MR. THOMAS: No. I wanted to make a comment.

DR. CROSSON: Oh, okay. Then David. Sorry.

DR. NERENZ: Thanks.

I will try to be brief here. I don't think it will surprise anybody that I have very serious concerns about the VVP part of this proposal, and I also want to make it very clear that they are such that if it comes to us as a recommendation in, more or less, its current form, I will not support it. So I'll just try to list the concerns.

At the top, I think we're talking about some pretty significant social engineering in the structured

medical practice, and I think we're doing it in the absence of what to me would be compelling evidence that this large group structure we're talking about is good. A lot of us believe it. I work in an organization that's been built on that model for a hundred years, but that's not the same as saying there's evidence.

And I have looked for it on many occasions. I haven't found it. So I would think that would be an important part of any fundamental foundation for something like this.

I also don't see any evidence that beneficiaries find value in the set of measures we're talking about, particularly at this level of analysis. We talk about measures that are meaningful to beneficiaries, but I know of no such evidence, and I'm happy to see it if it's out there.

I don't know that these measures have been shown to be able to differentiate meaningful levels of performance. Again, at the level of analysis we're talking about, maybe that's out there, but I'd like to see it if it's there. We may end up with compressed distributions on these scores, just the way we're talking about being

concerned about that in MIPS.

We use the word "voluntary," but I don't think it's very voluntary if there's a financial penalty for nonparticipation, and if the penalty gets bigger, it's less voluntary. So maybe if we really mean voluntary, we should take the 2 percent penalty completely away and let people do it if they want to, but don't penalize them if they don't.

We talk about all of ways groups conform. We talk about fallback groups, but there's no discussion of what it takes to make a group really function and to do the necessary work to improve these measures.

Now, Dana and David have both hinted on this, but I want to make it clear. Good performance doesn't just fall out of the sky. You have to do things, and just putting people together and saying they're a group doesn't accomplish that. So I think there's got to be a lot more attention to that.

And related to that is the cost of doing the work. I brought this up many times in our discussions of ACOs. There is a cost -- data, data analysts, care coordinators, care managers. Whatever is built in as a

reward has to acknowledge and potentially cover the cost of doing it, and I don't see any discussion of that.

I feel that there really, as currently configured, is no meaningful role for specialists in this. I'm not convinced by numbers; for example, the number of specialists in the current MSSP. I'd want to understand how many of them are meaningfully involved, not just listed, but how many of them actually in their day-to-day practice thinks about the population measures that underlie these programs? I don't think that program or this program, as proposed, engage a specialist in any meaningful way.

We talk about applying a uniform set of measures or the same measures to all physicians. It means we measure a primary care physician in the same way we measure a trauma surgeon. Really? Why? It doesn't make sense to me.

In my interactions, friends, neighbors, others, individuals, who want information about quality, they want quality at the much more micro level. Who is a good surgeon? Who is a good cardiologist? Who's good this? Who's good that? This approach will completely mask and

make it impossible, at least through Medicare, to get that information. Yelp will do it, but CMS won't.

This looks a lot like an ACO. We don't use that name, but that's kind of fundamentally what it's about. So maybe the thing is just make the MSSP program more attractive and easier to get into and let that be the pathway.

And two things on size. There's no mention that we talk about maximum size. I want -- looking at numbers, and it seems to me that if this actually went forward in this way, if all the physicians in Idaho made a group and all the physicians in Montana made a group, they do really well, and they'd get rewarded for essentially doing nothing beyond just practicing where they are, doing what they do. Now, maybe that's good. Maybe you say, well, we should reward them for their past excellent performance, but there will be groups that form simply to capitalize on where they are, who they serve. They won't do anything different.

And then minimize size, I wasn't going to say this, but we keep saying, well, 10 might do it for some measures. But I asked in our last meeting. We're not talking about forming a group for this measure and then

forming a different group for that measure. We're talking about forming a group for the whole package. It means you have to have a group big enough to be meaningful on the least sensitive measure in the package, not just the most sensitive measure. So 10 is never going to work.

DR. CROSSON: Thank you, David.

We have got Alice and Warner, and then I think we -- sorry?

DR. MILLER: Let me just get one other thing. You have gone through those before, and we tried to address some of them. But also, before you said -- but you do support repeal.

DR. NERENZ: Yeah, except that if -- I did say last time and I'll say it this time. I don't think this is a better alternative.

DR. MILLER: No. But you do -- I just want it on the record.

DR. NERENZ: I said it last time. I agree.

DR. MILLER: Yeah.

DR. CROSSON: Alice and Warner, and then I think we need to conclude the discussion. Alice.

DR. COOMBS: Yes. I'm not on Craig's list.

[Laughter.]

DR. CROSSON: How about Yelp?

DR. COOMBS: But I like Craig.

So I want to go on record as voting against repealing MIPS, and I think MIPS has a lot of problems.

But that being said, I think that right now where we are, there are some measures that are in MIPS, and you talk to the various -- my various colleagues that actually speak about not necessarily being completely ready to do all of this required with MIPS, but there are some things that are coming out of MIPS that are actually good. And if Medicare abandons that without something for adequate replacement, the VVP program, I am totally not in support of. I think it's a problem at this time, and so I'm giving you a temporal kind of "not support." And that's basically because I think the replacement for it is inadequate, and without some of the process measures that we do -- same-side infection, wrong-side surgery -- you're not going to die from it, but you sure are concerned about it. Beneficiaries should be concerned about that.

I'll give you an example of a patient who's taken care of by a primary care doctor, comes in, gets screened.

He actually has a colonoscopy and gets screened and has colon cancer, and he seems the gastroenterologist. He sees -- all of the next group of people that he sees and gets his definitive care are actually specialists.

So with this proposal, you might be in a community setting where you're not necessarily under lead institutions. All of the people that we talk about, past the primary care doctor now, may or may not be a part of this fallback voluntary group.

And I am concerned about the specialists. I voiced that the last time. The answer was not really appeasing right now for me, and I'll be honest with you. Because there's nothing to address that concern in terms of population measures, but there's so many other things I see as a practicing physician, day in and day out. They're not death. They're not readmission. But they sure as heck count, and those are the things that really kind of compel me to say we should be measuring some of the things.

Yes, MIPS has a lot of problems, but there are some good things with MIPS. Giving an antibiotic within an hour of incision, that cuts down on perioperative infection. There's so many of those kind of things that

are really important.

Now, I'm not going to argue statins. I'm not going to argue PSAs, but inside of my world, it makes a difference, and you can see a difference in terms of postoperative outcomes that are not necessarily readmission rate back to the hospital and not necessarily mortality.

So for me, what I see on a day-to-day basis, working in the hospital at night and during the day, it matters to us to move the pendulum, and it matters to the beneficiary if they know that this hospital has a low nosocomial infection rate. Guess what? They don't have much C. diff here because they use a good handwashing technique. All of those things are process measures, and so unless you do some of these measures, you wouldn't want to wait until the ninth hour to find out are our mortalities increased from toxic megacolons from C. diff because we had so many cases. You would want to intervene long before that. So in terms of making an intervention within the landscape of health care, I think that something is needed.

This VVP program, I am in total disagreement because you are eliminating somewhere between 60 and 65

percent of the providers. They're not going to be addressing population measures. Under an umbrella of an APM, yes, if that were to happen.

And so the other thing that I would tell you is that from colleagues who are like in the trenches, there's some doctors who may not be a part of an APM, and then if you were to put them in the fallback group, you get all the doctors with high-risk patients, and their risk profile looks different. Their performance looks different. You know, the patient's adherence to medication is in compliance. All of that looks very different.

I think you have to consider those things. Those are things that for a practicing physician -- and it doesn't mean you're in an academic setting. It could be that you're just a group practice trying to make things happen for your community.

So for me, I think those are some of the things that I'm concerned about, and then the whole notion of how you base performance and reliability and this cross-section of having multiple specialists being evaluated, and you throw, as mentioned already, an oncologists and a rheumatologist and an endocrinologist all together versus

what other kind of specialties might be in there, that's going to skew those population measures tremendously, and how do you compare group with group and apples with apples?

And so I am very concerned -- I don't want to belabor the point -- about the 60 percent or so of doctors that are not included in the whole thing, that may be left out.

And one last thing, and that is the LAN report actually showed that there was a 6 percent progression to APMs, just between 2015 and 2016. So maybe getting rid of MIPS may not be the thing that moves people towards APM because it's already happening while we're sitting here discussing it.

DR. CROSSON: Thank you, Alice, and thank you. I understand your concerns.

I just want to make one point sort of for the record, particularly as an infectious disease physician myself.

I don't want it to read our proposal as MedPAC retreating from the importance of measuring things like surgical infection outcomes and the like. I think the thrust of what we're saying, though, is that doing that at

the individual doctor level for the purpose of Medicare payment is probably not the appropriate direction to go in -- and for a lot of reasons, including simply the problem of small numbers.

But in terms of other entities -- and I'm talking about hospitals, I'm talking about ACOs, I'm talking about entities who are accountable for the health of their population -- aggressively pursuing those measures and particularly processes improvement, we're all for it.

DR. COOMBS: And the other piece I was saying is that even at -- even measuring that at the individual level influences the masses, so that I think you might have the specialists come forward with protocols that will actually change the paradigm for larger landscapes, and that's -- and I've seen that happen.

DR. CROSSON: Thanks. Warner, last comment.

MR. THOMAS: I'll be brief. I actually agree with -- number one, I agree with, essentially, eliminating MIPS and I agree with Kathy's comment of not necessarily having us be budget neutral but taking a withhold that is slightly larger than the dollars that are being reinvested and reinvest more dollars into APM to get folks to continue

to transition more into advanced APMs.

I hear David's point around individual measures versus group measures, but I just think that getting groups working in a more collaborative way around the entire patient's need and moving from a reactive to a proactive model, which I believe the APMs do, is a much better direction. I think essentially the fallback voluntary group, I don't agree with that. I think the idea that David actually brought up, around having people go into MSSP and having people organizing within MSSP is the fallback group, and those options are there today.

I frankly think we have people that are not organizing because they don't want to, not that they don't have the opportunity to and that they just don't want to, and they want to go it alone and go on their own. And I think changing this methodology will certainly create the right incentive for people to organize and to move in the direction of being proactive and working together as a group and not reactive and working individually.

I hear Alice's point around MIPS, but, you know, there's such ability, I think, to gain MIPS and to, you know, this idea of one patient, one measure. We need

people thinking bigger and we need our physicians, you know, being creative and working towards a proactive model. So I would like to see us do it in a non-budget-neutral fashion, use MSSP has a backdrop, and really try to get people to move further down the road of advanced APMs and in that direction.

I know that people would say that there are still mixed results there, but I think the incentives are in the right direction and the creativity will be there to be -- to generate, I think, better results down the road.

DR. CROSSON: Okay, thank you. Jack.

DR. HOADLEY: I just want to make a process point. I mean, it seems like we've had two very interesting perspectives that by the chance of the draw ended up at the end of the discussion, and so I hope maybe when we queue this up next month we make sure we've built in some chance to really engage these issues that Alice and David have raised, so that we can fully sort them through before we are at the point of making a decision.

DR. CROSSON: Well, a point well taken. So I just want to take the opportunity to thank Kate and David for the presentation, and the content of that, in

addressing, very ably, questions that have been brought up in the October discussion. It was very helpful. A number of Commissioners commented on that.

So as we have mentioned before, we will proceed and present a draft recommendation for consideration by the Commission at the December meeting, re-presenting it again, as we customarily do, in January. It will take into consideration the points that have been made here today as well.

Thank you very much and we will proceed with the next item.

[Pause.]

DR. CROSSON: Okay. We can proceed with the next discussion, presentation and discussion. So here we are talking about issues with respect to freestanding emergency departments, and there are really two pieces to it. I won't give your presentation for you but we've got Jeff, Sydney, and Zach, and I guess Brian in the bullpen. And who is going to start out? Sydney?

MS. McCLENDON: Good morning. Today we revisit our discussion on ways to improve efficiency and preserve access to emergency care in both small rural communities

and urban areas. Before we begin, I would like to thank Brian O'Donnell for his work on this project.

For this presentation we will be focusing on a growing phenomenon, stand-alone emergency departments. We have discussed stand-alone EDs on multiple occasions over the course of the last few cycles, including in our June 2016 and 2017 Reports to the Congress. While those reports discussed stand-alone EDs in separate contexts, such as in urban and rural environments, today we would like to bring together those discussions and also consider how stand-alone EDs interact with our site-neutral principles.

To begin, I'll review the current ED payment system, and then provide some background information regarding stand-alone EDs. From there, we will review the growth we've seen in stand-alone EDs in urban markets, and then discuss some concerns regarding site neutrality and urban stand-alone ED payments. We'll then consider rural emergency department payment concerns, and finish with potential policy options for each of these issues.

Currently, ED visits that do not result in an inpatient admission generate two claims: one for physician services and one for the facility. Physicians' claims are

paid through the physician fee schedule, and facility claims are paid through the outpatient prospective payment system, or OPPS.

On the slide is an example of the physician fee schedule and OPPS payment amounts for a patient that presents with a similar, mid-level non-life threatening medical condition at different facilities.

Type A hospital EDs, displayed on the far left, are EDs that are open 24 hours a day, 7 days a week and they receive the highest total payment of $264. This number includes both the physician and the facility payment. Type A hospital EDs can be both on and off of the main hospital campus, and they generally account for about 99% of all Medicare emergency department claims.

The less common Type B hospital ED, which is an ED that is open less than 24/7, would receive a total payment of $188, as seen by the middle bar in the chart. We will be discussing Type B rates later in the presentation, but it is worth noting now that the Type B ED rate is typically lower due to lower standby capacity needed for fewer hours.

Finally, on the far right, we have included the

payment amount for a similar visit at an urgent care center or physician office, which would be $109. We included the urgent care center payment amount for additional comparison, as urgent care centers' patient mix often overlaps with lower severity patients seen in EDs.

I will now provide some background information on stand-alone EDs. As a quick review from our previous discussions, not all emergency departments are located on the main hospital campus. These facilities, which I have been referring to as stand-alone EDs, come in two forms: hospital-owned off-campus EDs, or OCEDs, and independent freestanding emergency centers, which are independent facilities and not affiliated with a hospital.

As of 2017, we have identified 580 EDs operating apart from a hospital campus, and about two-thirds of these facilities are affiliated with a hospital and therefore considered off-campus EDs.

Currently, only OCEDs, if deemed off-campus provider-based departments, are allowed to bill Medicare. The facilities receive the same payment rates as on-campus EDs, and many independent freestanding centers are now converting to off-campus EDs in order to receive payment

from Medicare. Stand-alone EDs are still a fairly new phenomenon, and last year we raised concern that these facilities, especially the independent centers working to gain payment from Medicare, might be creating excess emergency capacity and unnecessarily increasing program spending.

On this slide, we've included an example of how Medicare pays different facilities based on their geography.

There are three types of facilities presented on the slide: on-campus hospital EDs, represented by the middle, purple circle, off-campus hospital EDs, represented by a white circle, and urgent care centers, represented by the dashed, yellow circles. Each facility's Medicare payment amount for either a level 3 ED visit or level 3 office visit is included within the respective circle.

The slide also includes a 35-mile radius surrounding the main hospital campus, which is indicated by the large, red dashed circle on the slide.

As you can see, the yellow urgent care centers are paid the same amount, regardless of whether they are inside or outside of the 35-mile range of the hospital.

Off-campus EDs, however, are paid different amounts based on their proximity to the main hospital campus. Off-campus EDs within the 35-mile radius of the main hospital campus are paid the full on-campus hospital ED amount, $264, while an off-campus ED more than 35 miles from the main hospital campus cannot currently receive payment as an ED, and would instead have to bill as an urgent care center.

The number of stand-alone EDs in several urban markets has grown rapidly in the past few years, and multiple studies, in addition to our own analyses, indicate that these facilities tend to locate in higher-income areas. The growth of these facilities in Texas is well-documented, but in the last few years the literature shows increases in the number of OCEDs in places like Florida, North Carolina, and Ohio.

Studies examining the stand-alone ED phenomenon in states like Texas, Maryland, and Colorado show that they also tend to see lower-severity patients than on-campus EDs. Although the data is somewhat limited, we believe the severity of patients treated at stand-alone EDs falls somewhere between on-campus hospital EDs and urgent care centers.

We also believe these facilities have lower standby costs than on-campus hospital EDs, due to not having to maintain an operating room or full trauma capabilities. Some stand-alone EDs assert that they can treat stroke and cardiac cases, but most stand-alone EDs do not have operating rooms, trauma teams, or specialists on call. In addition, representatives of the ambulance industry and researchers in Maryland have found that when patients require trauma services, ambulance drivers often bypass stand-alone EDs in favor of the on-campus hospital ED.

Despite seeing less severe patients and having lower standby costs, hospital-affiliated OCEDs that are located within 35 miles of the main hospital campus receive equal Medicare payment to on-campus EDs, making them a profitable expansion option for hospitals.

Related to the topic of stand-alone EDs is an additional concern that we have regarding site neutrality under Section 603 of the Bipartisan Budget Act of 2015.

Section 603, which established site neutral payment rates for some facilities, prevents off-campus hospital departments from receiving higher OPPS payment

rates and instead pays them the lower physician fee schedule rates.

Emergency departments were exempted from these site-neutral payment changes, however, which means that hospital-affiliated EDs -– including off-campus EDs -- can receive higher hospital OPPS rates for both emergency and non-emergency services, which could include services like imaging and scheduled physician office visits that are not related to emergency care. While we understand the logic of providing emergency services this exemption, the logic seems to make less sense for non-emergency services.

The concern here is that this non-emergency exemption creates an incentive to build OCEDs and then co-locate physician offices, because in doing so the physician office receives higher hospital OPPS payment rates than if they were a separate off-campus physician office. We will next discuss a potential policy option to address this issue.

As I just mentioned, current law exempts emergency departments from Section 603’s site neutrality and allows OCEDs to bill facility fees for scheduled visits to co-located physician offices.

An alternative policy could be to pay the co-located physician office the same rate that they would get if they were in a free-standing physician office.

The net effect of this new site neutral policy would be lower rates for physician practices co-located with OCEDs, lower cost-sharing for beneficiaries, and less incentive to build an off-campus ED in areas where an urgent care center would sufficiently serve community needs.

I will now turn it over to Jeff to discuss a new policy option for urban stand-alone EDs.

MR. STENSLAND: All right. Now we will shift gears to talking about setting off-campus ED rates in Medicare.

As Sydney explained, resource needs of off-campus ED patients appear to be between those of an urgent care center and the on-campus ED. And as we explained in your mailing materials, off-campus EDs tend to get fewer patients arriving via ambulance and tend to get more walk-ins. In our interviews with hospitals, ED operators, and ambulance companies we heard that off-campus EDs near an on-campus ED will often be bypassed by patients with more

complex needs.

So how would we set payments to better reflect the resource needs? We could set up a whole new rate for off-campus EDs. However, that may be unnecessary. Medicare already has Type B rates for EDs that are not open a full 24 hours and thus have lower stand-by costs. We could pay off-campus EDs this lower Type B rate. For example, The lower Type B rates could apply to all off-campus EDs that are within 25 miles of an on-campus ED, the rationale being that the most difficult cases will often end up bypassing the off-campus ED for that on-campus ED that is nearby.

If the Type B rates were adopted, it would modestly lower rates for off campus EDs. The rate would drop from $264 to $188 for a level 3 ED visit. Payments would more closely align with patient resource needs. Second, the lower payment rate would mean lower cost-sharing for beneficiaries.

The key change is it would reduce the difference between payment rates to urgent care centers and off-campus EDs. This would reduce the incentive to build an ER when the communities' needs could be met adequately with an

urgent care center.

Now we will shift to discussing rural issues. You may recall that we discussed rural ED issues over past years and published a chapter on preserving access to rural ED services in our June 2016 report.

The key concern we discussed in that chapter was preserving access to emergency care in areas with low population density. Historically, the Medicare payment system has supported small rural hospitals by paying higher inpatient rates. When the sole community hospital program was started in 1983, inpatient services dominated hospital finances and this model of inpatient subsidies may have made sense at that time. However, 35 years later, rural hospitals are now much less inpatient focused, and trying to indirectly support emergency services by paying higher inpatient rates has become problematic.

There are now two key problems with inpatient-centric rural payment policies. First, using inpatient subsidies to assure emergency department access is increasingly inefficient. The volume of inpatient services declined markedly at many small rural hospitals. Given the fixed costs of running an inpatient department, as volumes

decline the cost per discharge goes up. The result is an inefficient provision of inpatient care. Second, higher inpatient rates have not always resulted in financially viable hospitals, and let's look at the data to illustrate these problems.

The decline in inpatient volume is illustrated in this graphic. The top yellow line shows that the median CAH saw its volume of admissions fall from 624 per year in 2003, to 365 in 2016. This is more than a 40 percent decline.

The lower red line shows admissions for the CAH at the 10th percentile of inpatient volume. This tells us that in 2003, 10 percent of CAHs had fewer than 170 admissions. By 2015, 10 percent of CAHs had 81 or fewer admissions per year. This is more than a 50 percent decline.

Having 80 admissions a year, or less than 2 per week, creates a cost per inpatient day problem. It can also create quality concerns if clinicians in these hospitals do not have the advantage of gaining experience with a large number of inpatient cases.

You may ask why the community just doesn't close

the inpatient units. The problem is if they closed this low-volume inpatient units they could no longer bill as an emergency department under the current payment policy. They would also lose some particularly high rates they receive for providing post-acute care in hospital beds.

The second problem is that the current programs do not always preserve access. Twenty-one Critical Access Hospitals closed between 2013 and 2017. Some of these hospitals closed due to excess capacity, and in these cases, volume could be consolidated at neighboring hospitals. But two of the closures were more than 35 miles from the nearest hospital, creating access concerns.

Among the CAHs that closed in 2014, the average CAH received cost-based payments in the year prior to closure that were about $500,000 above PPS rates. But the supplemental payments provided little in the way of subsidies to cover uncompensated care in the emergency room. The high Medicare payments received for post-acute care at these hospitals, in large part, were spent covering the high inpatient costs per day at these low volume hospitals.

So this raises the question: If a hospital closed

its expensive inpatient units, would there be a way for existing rural hospitals to convert to financially viable outpatient-only facilities? And rural health researchers and hospital associations have shown interest in this type of outpatient-only model. However, what is missing at this point is a new payment model to match the new organizational structure.

Next we will outline a Medicare payment model to support outpatient-only hospitals.

The idea is to set up a 24/7 outpatient-only facility with an emergency department. The policy change is focused on isolated providers, and the reason is that under current policy, hospitals that close and are more than 35 miles from another hospital do not have the option of becoming an off-campus free-standing ED. Recall from Sydney's graphic that the picture showed that EDs located more than 35 miles from the main campus cannot receive ED rates from Medicare. They would have to bill like an urgent care center. This new payment policy could be targeted at these isolated hospitals that currently lack another option.

To help fund the new program, Medicare would do

the following. First, outpatient-only hospital would get full Type A PPS rates for ED services. Second, there could be an annual fixed payment amount to help cover the facility's fixed costs. To receive the fixed payment and assure that the community is buying into the new model, the local government or hospital district could be required to contribute some type of matching grant to the new outpatient-only hospital.

The goals of an outpatient-only model could be as follows. First, the model should preserve access to emergency services. Second, the cost of the program could be offset with savings from efficiency gains. The efficiency gains I've talked about come from closing low-volume inpatient operations. As low-volume inpatient units are closed, acute inpatients would be shifted to other low-volume hospitals in the area. This may help neighboring hospitals that are also struggling.

The main savings will come from shifting patients receiving post-acute care in critical access hospitals. Currently, CAHs receive an average payment rate that is about $1,400 per day more than the rates received by skilled nursing facilities for the same care. By closing

the expensive post-acute care provided at CAHs inpatient beds and shifting those patients to SNFs, significant funds could be freed up that could be used to subsidize emergency care in these communities. Now the idea is not to reduce overall spending but to redirect dollars away from inpatient subsidies and toward funding emergency services that are needed in isolated communities.

For providers there would be three key effects. The first thing to remember is that this is an optional program, so if they want to continue as a critical access hospital they can do just that. Second, this could serve as a way to preserve the rural ED when inpatient volumes are so low that a traditional inpatient focused hospital is no longer practical.

Third, hospitals often play a key role in the recruitment of physicians to small communities. If a hospital converted to an outpatient-only facility, some rural hospital boards may be concerned about who would recruit the physicians. Under this model, the outpatient facility would still be there to recruit physicians into the community, and that work may be seen as a more desirable, given the financial stability provided by the

annual funds to the hospital and the more limited duties the physician would have.

There would be three potential effects on beneficiaries. First, it would preserve access to emergency services. Second, patients would need to travel for inpatient care, but many are already bypassing their rural hospitals for inpatient care. Recall, that we have 130 CAHs have fewer than two admissions per week. Finally, as we showed in your mailing materials, coinsurance will be substantially lower than at critical access hospitals. Shifting from CAH level coinsurance to PPS level coinsurance would often reduce the coinsurance owed by a rural Medicare beneficiary by over 50 percent.

So this brings us to the discussion topics.

First, the issue is the technical fix to the site-neutral policy outlined in Section 603 of the Balanced Budget Act of 2015. The fix would set payments rates for scheduled physician office visits at clinics that are co-located with EDs to an amount that is equal to independent physician offices.

Second is moving toward paying Type B rates to urban off-campus EDs within 20 minutes of an on-campus ED.

The third policy option is to retarget existing rural subsidies that are currently used to prop up hospitals' inpatient services. Those subsidies could be redirected to support emergency services at stand-alone rural EDs.

Depending on the outcome of your discussion, these three policy options may be refined further and presented as draft recommendations at a future meeting in the spring of 2018.

Now I will turn it over to Jay, or Jon.

DR. CHRISTIANSON: In this case it would be Jon. So questions? Clarifications? Round 1.

DR. SAMITT: So a quick one. In terms of the second topic, the rural stand-alone EDs, would this only pertain to critical access hospital conversions and this would not be available for organizations that want to create a new freestanding ED in a rural environment?

DR. STENSLAND: The way it's structured, the way we talked about it, it would just be available to critical access hospitals or isolated PPS hospitals that want to convert into a freestanding ED or maybe a location that recently closed. So you wouldn't be creating new

operations.

DR. COOMBS: So what wasn't clear is that if a for-profit wanted to move in the area and set up a hospital, is there a grandfather, a cutoff for when this program would be implemented? In other words, new hospitals to the scene, would they be able to do the same thing going forward?

And, secondly, how much of the post-acute care in the rural setting, just thinking about what has happened in the past, so it's a 10 percent closure, you say, per year? Or is it 5 percent closure for rural hospitals? That graph looked like it was...

DR. STENSLAND: Well, the graphic was the volume of the --

DR. COOMBS: Oh, admission.

DR. STENSLAND: Admission.

DR. COOMBS: So how much would be generated by -- what percentage of revenue would change based on the number of closures with post-acute care?

DR. STENSLAND: For every closure -- I wouldn't call them a "closure," but every conversion of a hospital to an outpatient-only facility, on average they would cease

getting paid their current cost-based rates for their post-acute care because those current rates are very high, often about $2,000 a day. And eliminating that and paying PPS rates to a SNF for those same patients would save about $500,000 per closure. So that's where all the savings come from, and you just take that amount and give it to the ED.

DR. COOMBS: And so we could project from past -- the curve of closures in the past what roughly the number of hospitals closing going forward? How many of these small critical access hospitals can we project that this is going to impact?

DR. STENSLAND: Well, I think that is hard to project because that's really a community decision. But I think we had, what, 130 of these small isolated places that have fewer than two admissions per week. So they could all be potential candidates for doing this. You know, they have the option of doing it. Whether they would actually do that or not would probably depend in part on, you know, local community perceptions of their hospital and also partially probably from a practical standpoint on what the physicians in the community wanted.

DR. CHRISTIANSON: David, did you have any

clarifying questions? Okay. Kathy.

MS. BUTO: So I'm wondering whether we've gotten any indication of interest on the part of some of these small, rural, isolated hospitals in this option. In other words, it sounds good, but I'm wondering if any of them would take -- it would be voluntary. Would they take it up or would they only take it up if they were really truly not getting enough revenue from post-acute care and other sources? In a sense, would it be -- is it really the most efficient approach? And does it appeal?

DR. STENSLAND: We did go out and do some site visits, and we do see some places -- usually, it's when the hospital is in financial trouble, so it's basically, you know, we're losing our patients, we don't have customers, now we don't have money, now we need to do something else. And in some of those cases, we've seen some of those convert to off-campus emergency departments of a neighboring hospital, like they'll approach their neighboring hospital 15 miles away and say, you know, "Can we become your outpatient department and be part of you so we can still have an emergency room? Because, otherwise, we're just going to have nothing."

In some cases, people that we've talked to said they've also been contacted by places that are more than 35 miles away, and they said, "Would you do this?" And they said, "From a practical standpoint, it doesn't work because then we're not getting any emergency department facility fees for having this emergency department that is way out there." And the secondary effect was and these places that are really far away from us, they're actually less likely to be bypassed by the difficult cases because they need to give them somewhere than the place that's, you know, 10 miles away from the main hospital.

DR. MILLER: The only thing I would also add to that, Jeff, just to make sure I get this right, there was some discussion about this in the rural community like the Kansas Hospital --

DR. STENSLAND: Sure, there's discussion of this. If the Kansas Hospital Association, the Washington Hospital Association, Kansas has gone through and done some financial modeling of saying who could become outpatient-only facilities. So the model of being an outpatient facility is very in the forefront of a lot of the hospital associations' mind and certainly the systems seeing some of

this. I think the step that's missing is, well, we don't have a payment model yet to match the organizational model.

DR. MILLER: And one other thing I really don't like to do with Sue not being here, but I also thought Sue was saying, "I really want us to pay attention and talk about this model." I don't want to express her opinion, but she has encouraged us to bring this forward.

DR. CHRISTIANSON: Yeah, go ahead.

MS. BRICKER: This is an interesting chapter, so thanks for that. What's going on in Texas?

[Laughter.]

MR. GAUMER: There's a lot. Actually --

MS. BRICKER: With respect to this issue.

MR. GAUMER: -- the Astros just won the championship last night.

[Laughter.]

DR. MILLER: [off microphone] really god.

MR. GAUMER: Was that good? All right.

So there's been a huge surge in stand-alone EDs, and what's happening there is in 2010 the state decided to start registering or licensing these facilities for payment. And so there was a bit of a boom, an

entrepreneurial boom, and we've got I think something like 190 or 200 of these independent freestandings out there. And as a reaction, the hospitals have opened their own off campus, the OCEDs, so you've got even more of those popping up. And I would say that it seems to be that it's reached a saturation point in markets like Houston and Dallas where we're starting to see a lot of the independents that cannot bill Medicare because they're not provider-based as Medicare defines it starting to partner with the hospitals so that they can become an OCED and start billing Medicare.

In Dallas and in Houston in particular, there's been a lot of that converting going on. In fact, I think there was one organization where 40 IFECs now became OCEDs and started billing Medicare. And just to jump back up on the soapbox again, Medicare can't really determine who these entities are when they're billing because they're billing as part of a hospital. So we're kind of flying blind, but we know that they're billing somehow.

MS. BRICKER: That's interesting. This reference to 20 minutes or 20 miles, in an urban setting 20 minutes could be 5 miles. So what -- why --

DR. STENSLAND: I think that was probably a

result of me misspeaking, but I think in the urban areas, we were thinking 20 minutes or some minutes as opposed to miles. I think in the rural areas, the 35 miles is pretty straightforward because that's usually pretty close to your travel time. But in urban areas, it would make sense to be minutes.

MS. BRICKER: Okay.

DR. MILLER: Amy, did you get your answer there [off microphone]?

MS. BRICKER: Yeah, I didn't know if he meant that, but I think he did mean that, and I'm just wondering what incentive that gives entities in New York or L.A. to -- 20 minutes isn't -- you know, you could be -- you could count the miles on one hand in those communities. And is that what we intend to do?

DR. MILLER: Yeah, I mean, as I think about it, Jeff and Zach and Sydney, what we're saying is you want -- these freestanding EDs seem to be behaving not quite like an on-campus ED. And so then you draw a circle, and we're saying for the purposes of discussion, let's call it within 20 minutes of an on-campus, then they're going to get the lower rates because they're not acting as a full-fledged

emergency room. Perhaps if they were further out and really addressing an access issue, maybe they would. The 20 minutes is the proxy for us to have this conversation, and there is this difference between miles in a rural area and minutes within urban, because miles don't really matter as much in an urban.

MS. BRICKER: I see. Thank you.

MS. McCLENDON: I will say one more point on that, that we did do a little bit of analysis looking at a couple of markets where these freestanding EDs are popping up, and in a lot of the urban markets that we did look at, this 20-minute marker really encompassed a lot of them. There were very few that were more than 20 minutes away from an on-campus ED. So in that case, it's are they really bridging an access need or are they just there for the profitability?

MS. BRICKER: That is helpful. Thanks.

There's a reference throughout, when you then switch to the rural critical access hospitals and a policy recommendation to have this community funding. Is there precedent for that?

DR. STENSLAND: I can't think of any precedent

off the top of my head, but the rationale there is to make sure that the community actually sees this as a need, and so they're actually willing to put some of their own money into the ED as opposed to saying that they just want this for economic reasons for the community as one more business or one more source of Federal funding coming in. That's the rationale with the matching --

MS. BRICKER: I just think --

DR. GINSBURG: In some sense, when you say the community, perhaps you're referring to the town government or something like that.

DR. STENSLAND: It would be, I'm guessing, the county government, maybe the -- a lot of these places now currently have funding for the hospital under a hospital district, and they could just take that same tax funding they have for the hospital district and have it go to this outpatient-only hospital.

MS. BRICKER: That sounds good in theory; I just fear that in a lot of these rural communities, you know, they're pretty poor and is there infrastructure there to put an additional burden on them as part of this policy? That's my concern. I'm just thinking about towns, you

know, where I grew up. I don't even know how much from a tax perspective they're even getting, you know, socioeconomic status of much of these towns, I just don't know if they would be able to support that. So just a question. I don't have any data.

And, lastly, you referenced that there are quality concern because of the hospitals that are seeing very low admission. Is that based on data that we have or is it assuming that?

DR. STENSLAND: So a few years ago, we did a report on rural hospitals, and so we looked at our own data, and it does tend to be a risk-adjusted mortality and volume outcome relationship. And this is not only us, but the literature is pretty strong on the history of that relationship. There is also some weaker relationship with respect to the process of care and the outcomes.

MS. BRICKER: Thanks.

DR. GRABOWSKI: Thanks. Amy actually asked my question, but I just wanted to push as well on this community funding and matching funds. I find that also problematic, this idea of -- I was just curious if you had any sort of background on the willingness and ability of

these communities to actually sort of come up with those matching funds. Thanks.

DR. CROSSON: Paul.

DR. GINSBURG: Yeah, on page 25 of what you sent us, I was very alarmed by the data because, you know, first you made the point that it looks like there's been some movement out of urgent care centers into EDs. And you would think that that would make the mix of visit levels less intense, but in a sense the data showed a striking increase in intensity, which I suspect is due to something else that is happening at the same time.

I know that there has been some significant change in the employment relationships with ED physicians. They're increasingly employed by national companies and presumably who can counsel the physicians about how to code differently. So I'm just concerned about this issue and whether this should be something on our agenda at some point.

DR. CROSSON: Questions? Pat.

MS. WANG: For the urban situation of an OCED, do you think it would be feasible or have you considered there are situations, I think, even in urban areas where an

inpatient facility that may be underutilized or in trouble, the idea of closing it meets with tremendous community opposition, and sometimes the solution is we'll replace it with an OCED with a new operator so that the community will still have access to robust, et cetera, et cetera. That sort of OCED would fall within the definition of the within 20 miles and be subject to the proposal here for Type B rates. Do you think that it would be feasible to kind of nuance that a little bit and say "except if the OCED was created as a result of the closure of an inpatient facility"? You know, you don't want to create countervailing incentives of a new operator saying, "I can't do it," and so instead you wind up leaving a failing inpatient facility open that costs everybody a lot more money. Do you think that would be feasible?

MR. GAUMER: So one thing I'd say is the 20-minute thing was put in there with the idea that there are probably isolated urban facilities that are serving a purpose out there. And we've found our way across a couple of them around the country, and we've seen that they do exist. And so that's why that's there.

But in terms of what the urban -- you know,

whether the urbans could be a part of kind of the rural idea, I'll let Jeff speak to that.

DR. STENSLAND: You know, I think it would be hard to actually do that regulatorily. But the way it's structured now is they would still get more than an urgent care center. So, you know, they could go ahead and say we're going to convert this into an emergency department, and they would still get more than they would if it was just an urgent care center there. They would get whatever, the 188 rather than the 90 per visit. And I think that might -- the rationale being that that might be appropriate, because even if they are close to another hospital, the ambulances are going to know now that this is just an independent emergency department, and they probably aren't going to take their heart attacks there. They'll probably bypass it and go to someplace that has reperfusion capabilities. That place will no longer have to have an operating room standing by to do trauma surgeries, because those will also probably be bypassed there.

And so we're trying to kind of become more equitable between the off-campus ED that's getting the difficult cases bypassed and the on-campus ED that has to

have these standby capacities such as getting their OR bumped when an emergency comes in or, you know, they have their own stroke team available, those kind of things.

So I think in the end, we're not saying that it's just going to be like an urgent care facility, they're not getting any extra money. They would still get extra money, but just not as much as if they maintain that on-campus capability.

MS. WANG: It's hard to cut it so fine. I get it. On the rural proposal, can you just go through, is the idea of sort of, you know, convert, you get a higher bump, there's money saved from avoided -- you know, inefficient inpatient care, et cetera, et cetera. Is this a budget-neutral proposal in your mind? Or how do the offsets -- there's a statement in here that higher ED rates would be offset by lower inpatient subsidies or what have you. Just in general, is this -- are you thinking it's budget-neutral, you know, budget-negative, budget-positive?

DR. STENSLAND: I think end score -- you know, CBO would do the end scoring, so we're not going to actually score it. But the cost of this I think would be quite small, because you'll have the -- the majority of

these things are operating as critical access hospitals now, and so if you have an existing critical access hospital that converted to an outpatient-only hospital, that would be about a wash. Okay?

Now, there may be some that otherwise would close, and there would be no access, and it's going to be cost here because we're going to prevent this closure, so there will be a little bit of cost there. Then there might be a few PPS hospitals that are isolated out there that aren't critical access hospitals that would take advantage of this. There would be a little bit of cost there. But the costs, you know, are going to be low costs per year, maybe in the single millions of dollars type net cost.

MS. WANG: Thank you.

DR. MILLER: And just to answer it just a little bit differently, it's not designed to save money. It's not designed to cost money per se. It just works out that it looks like it's a little bit on the positive side.

MS. WANG: [Comment off microphone.]

DR. MILLER: Right, no. I got your question.

DR. CROSSON: Warner.

MR. THOMAS: On the physician offices collocated,

how prevalent is that situation?

MR. GAUMER: So we don't have a good read on that, actually. We know that, you know, this is a flaw in Section 603 and that it could be done, and it would be logical that this could develop. We haven't seen a lot of examples of this, but we don't have a great idea of how common it is.

MR. THOMAS: And I guess how different is this from, essentially, if you're a hospital-based clinic? I mean, is that the same thing if you're a hospital-based clinic and you're within the 35 miles or whatever? Is that the same phenomena, or is it different?

MR. GAUMER: No. This is the same as the off-campus physician office issue, and really, the subtle difference here is that the exemption in Section 603 said for emergency department services, they can get the higher hospital outpatient department rates. But also, those non-emergency services can get that higher rate, and we think that that extra incentive or extra exception provides the incentive for these things to proliferate a little bit.

MR. THOMAS: And on the rural situation, as you talk to constituents, are you hearing pushback around this,

this idea of being able to have the conversion? Do they like the idea? Do you have any feedback on that?

DR. STENSLAND: I think in general, they like the option because this is just an option. They don't have to do anything. They don't lose anything whatsoever.

I think there's going to be -- still, it's kind of a -- these are places that have had this inpatient facility for years and years, and it's going to be a difficult transition for them. Even if the medical community and the community knows this, it will still be difficult for the community to say, "Okay. We're not going to have post-acute care in our town. We're going to have to go 20 miles away to visit our people in the snow."

DR. CROSSON: Rita.

DR. REDBERG: Thanks.

On table 3 in the mailing materials, I noted level 5 visits were the ones that had the biggest increase in the last 5 years, and I'm wondering if you could tell us what makes a level 5.

MR. GAUMER: So the levels of ED visits, the definitions are somewhat vague, and I think that that might be part of the issue here.

It's not based on time like other services are in the CPT codes, but it's more other -- this is more kind of a -- generally how much time did you spend with this patient and how much information did you have to extract from them and what was -- yes. I'm sure Alice can talk to this a lot better than I can.

So it's kind of a vague concept, and the hospital as well as the physician is left to kind of determine where this falls, and so there is kind of risk of coding creep in there, and I think that that might be one of the reasons why we're seeing this creep. There could be other reasons in there like ICD-10 or other things.

And to Paul's point, this is something that we haven't had as much time to drill down in yet.

DR. REDBERG: Right. Okay. Well, that would be an interesting area to look at.

I'm also wondering, in the introduction in the mailing materials, you mentioned that some private insurers are not paying for care deemed non-emergent, and I'm wondering, do you have any info on how that is going, that program?

DR. STENSLAND: We don't have much information on

how it's going. These are just the initial news reports.

DR. CROSSON: Jack.

DR. HOADLEY: So just two questions. We talked about the rural option back in the 2016 report, and I guess I'm wondering, is there anything substantively different in the way you're presenting it now from what we talked about back then?

DR. STENSLAND: I think the fundamental idea is the same.

DR. HOADLEY: Okay. And in 2017, you referenced in the mailing materials, the recommendation about tracking, the recommendation to the Secretary for tracking OCED visits separately. I got the implication was nothing has happened on that. Any feedback? Any possibility? Any negative reaction to it?

MR. GAUMER: Actually, we have seen nothing on it in the final rules that have come out since. I think the outpatient rule just hit yesterday. The final hit yesterday, but we didn't expect to see anything in there.

DR. HOADLEY: So it might be something where if we end up with a recommendation on this to kind of reference, re-print that one, we still believe that's

important.

DR. CROSSON: Okay. I've got Alice and Dana, and then we'll proceed with the discussion.

DR. COOMBS: Thanks.

So Paul nudged me in that area, something, and I wanted to ask the question, and that was to follow up with the -- one of the things that Rita just mentioned is a level 4 and 5 increase. One of the proxies for that is how many of those level 4 and 5's got admitted to the hospital, and that's something that's easily trackable, because if you saw the number of level 4 and 5's increase suddenly and all of them went home, then you say, "Okay. Something is at work here, other than the severity of illness."

And just to answer a question earlier that you will be down-coded, if I up-code in the ICU to a 99292, I will be down-coded if that patient is going to a LTCH that day. It indicates that that patient is not critical ill, doesn't have any pending deterioration of cardiac status or life-threatening. So that they can read from the note to down-code, probably something like that might happen here as well.

DR. CROSSON: Thank you, Alice. That's a good

point.

Dana.

DR. SAFRAN: Yeah. Just a quick question. So I understand that Medicare is not dealing with OB care, but on the rural proposal, I'm wondering, do we imagine that these hospitals that become just an emergency room would also be able to handle OB care, and does that affect our proposal in any way?

DR. STENSLAND: I think they generally wouldn't be doing OB care, and I would guess that the majority of these are not doing OB care already.

If you look at the share of rural, isolated small hospitals that are doing OB care, it's gone down pretty dramatically, just with the number of fewer and fewer family practitioners out there delivering babies.

DR. CROSSON: Okay. Thanks for the presentation. Good questions.

Let's put up the last slide 18, if we have. You've got it.

So there really are two somewhat connected but distinct problems here that we're trying to address. In the last bullet point, as Jack pointed out, we're coming

back to an issue that we have discussed before and as a matter of fact have written on, and that has to do with providing an option for rural communities to have the financial resources redirected to create a level of services there, which they would not have if they just closed the hospital and walked away from services.

Second issue is the first two bullet points, and it kind of relates to the fact that we have a concern that off-campus emergency departments may be costing the Medicare program more than is reasonable, either as a consequence of the rates that they're paid or as a consequence of the collocation of physician offices. So they're both connected because they're related to emergency departments, but they're kind of distinct in some way.

So what I'd like to do if we could in the discussion, again, is provide direction to staff. The kind of notion here is that we would be heading towards recommendations in the spring, and as Jack pointed out, depending on what we say and want to do, it's that the discussion -- or the recommendation with respect to the option 4 rural hospitals converting to emergency departments may be the same as the one in the set of

discussions that we've had before.

So to the extent that people are concerned with that direction, I'd ask you to say "I kind of like this" or "I don't like it, but I have concerns about the rural piece."

And with respect to the first two bullet points, do you have a preference? Do you feel we should move in one direction or the other? Do you feel we should move in neither direction, so that we can further elaborate that set of issues with respect to Medicare costs later in this cycle? Is that at all helpful?

So let me see hands for comments. Okay. Let's start with Craig this time.

DR. SAMITT: So in terms of the overall recommendations, I would say that I am in support of the first and the third, and I have some concerns about the second.

I'd start with the notion that when we've looked at the utilization of freestanding EDs, we see a significant amount of inappropriate use of emergency departments for non-emergency services. It may have been included in the materials that the Center for Improving

Value in Health Care did a study in Colorado and found that 7 of 10 visits in freestanding EDs were for non-life-threatening conditions versus 3 of 10 visits in traditional EDs.

So I would imagine that our recommendations would seek to temper some of the profit-seeking in this space and address some of the inappropriate use of freestanding EDs for urgent care-related services.

So I worry that the middle bullet doesn't quite capture the disincentive that we would want to put in place for the creation of these freestanding EDs. I may make a somewhat unorthodox recommendation here, but I wonder whether what we should say for these OCEDs is if it's a level 1, 2, or 3 visit, it is a site-neutral payment equal to urgent care. If it's level 4 or level 5, then it actually could be type A.

Now, I recognize this would encourage even further up-coding scenarios, and so I'm offering an unorthodox and probably inappropriate recommendation, but I wonder whether we want to think about some other alternative that essentially says if your freestanding ED is being used predominantly for non-emergency services that

you shouldn't even get type B rates for these types of visits, that there should be another option.

DR. MILLER: So just to clarify, the coding shift you're worried about just happened, I'm sure in response to your comments.

[Laughter.]

DR. MILLER: But what I do hear you saying is you don't like -- or you may not be on board with No. 2 because you don't think it goes far enough. You need it to be more aggressive.

DR. SAMITT: Yeah. I worry when I hear the Texas story --

DR. MILLER: Yeah, I hear you.

DR. SAMITT: -- about ongoing proliferation of these facilities. I would rather we create incentives for the proliferation of urgent care centers, not freestanding EDs, where the demand truly is, the rural issues aside. I just worry that even with type B rates, we're going to see proliferation of EDs that we don't need.

DR. CROSSON: Rita, on that point?

DR. REDBERG: Yes. I was thinking maybe we should add incentives to sort of primary care or ACOs on

not refer -- or triaging. There's a lot of people who call their primary care doctor for atypical chest pain, and they say, "Go to the ED." And it's not really appropriate to go to the ED for that, but there's every incentive to say that and no incentive not to say that in our current system because who wants to miss a heart attack. But now we're talking about your chances are greater getting probably hit by a car crossing the street going there than actually having a heart attack, with a lot of the things that get referred.

And so I was thinking we should put incentives to sort of accomplish the same thing, but on the ACO or primary care side, it's not to discourage that, what I think is a lot of inappropriate triage, because so many times when I see people that I don't think should have ever come to the ED with -- a lot of times, chest pain is what I see. They were referred by their primary care practice. Usually, it's not their own doctor. They reach someone, you know, a mid-level who was covering, and it's a complicated issue, but I think there is a lot of potential to do a lot better if we discouraged triage to EDs and encouraged primary care, sort of accessibility and

availability for these kind of low-risk issues.

DR. SAMITT: Yeah, I'd support that. I just wonder whether those incentives already, to some degree, exist as being part of an ACO. It's something that ACOs would already be paying attention to. The question is, Is the incentive adequate?

DR. CROSSON: Okay. Coming up this way, Alice.

DR. COOMBS: So I support the three, but the first one, it's analogous to an HOPD? Really? Jeff, I think they're the same thing as a physician and a hospital-associated PD--outpatient department, right? Would you say it was the same?

DR. STENSLAND: Well, that is the idea, is that, you know, we had --

DR. COOMBS: Okay.

DR. STENSLAND: The whole site-neutral thing we talked about was saying --

DR. COOMBS: Right.

DR. STENSLAND: -- well, if you buy a physician practice out here and you convert that physician practice to part of your hospital HOPD over here, well, then you start to get to build facility fees for your office visits

for your physicians out there. Your payments double.

So then there with the law that was passing --

DR. COOMBS: Right.

DR. STENSLAND: -- no, we're not going to do this anymore.

DR. COOMBS: So they're the same category?

DR. STENSLAND: Yeah, it's the same category, but they were saying, "We're not going to do it anymore," but there is this exception. If you happen to locate it with the ED, then you get around it. It's kind of like a loophole, and we're basically saying close the loophole.

DR. COOMBS: Right. So I agree with that.

In terms of the second bullet, I was thinking, well, it's possible that an ambulance took a person to an off-campus ED that's within 20 minutes or, as Amy said, maybe four miles from the primary. But I would link that capacity with whether or not they were later transferred to a hospital with inpatient capacity, and that would be the real -- because there is a deterrent in that because it is a $500 ambulance ride, and many of the patients -- just the ambulance in itself may not transfer the patient if they didn't really need to be transferred.

So I would link it to whether or not they actually got transferred to the mother ship hospital or the mother ship facility.

DR. CROSSON: Okay. Comments? Amy.

MS. BRICKER: I concur with what Craig said and pick up on the thread that Rita just mentioned around No. 2.

So if there's a way to tie actual admission -- so it's either an issue with the levels. I think that's been addressed already, and then tying, as Rita suggested, maybe the 4 and 5's to admissions, or, okay, leave the levels, but for this discussion, more urgent care like reimbursement for lower acuity and maybe type A, reimbursement for those that actually end up getting admitted or something then that allows the correlation between the type of folks that you're treating in those facilities to actual inpatient visit.

I still want to protect the rural communities. As part of the question-and-answer session, I'm concerned about the burden on those communities and would not endorse a policy that would require a community to come up with funds. I think that's counter to the realities in many of

those communities.

So other than that, in support of the recommendation.

DR. CROSSON: Okay. Paul. Oh, sorry. I missed -- oh, I didn't? Dana. Sorry.

DR. SAFRAN: Sorry.

So agree with the recommendation No. 3 for sure, but really appreciate Amy's point about expecting communities to contribute and would ask us to take another look at that.

All three, actually, I was agreeing with until this discussion, and I think some of the unintended consequences that have been brought up are worth another look.

The one point, additional point, I was going to make that I don't think has been talked about is I was thinking about this issue of the physician payment at the off-campus versus the on-campus and sort of in my mind tying it to the discussion we're going to have tomorrow about telehealth, because this question comes up all the time about, gee, are we going to create access problems if we pay physicians differently in different settings, and

really, what we want to be doing is promoting the use of services that are most convenient and still in a site of care that has what the patient will need for care to be appropriate, which to me almost says that you want to motivate by giving higher payment rates for the care that's more accessible and not tied to a facility.

The downside of that, of course, is we move even farther than we are today from a real cost-based approach to what folks get charged.

So I wanted to put on the table that tie it to telehealth and that we should be thinking of these as a continuum as we think about what providers are being paid for the services they deliver and really keeping access in our mind as we do that.

DR. CROSSON: Paul.

DR. GINSBURG: Yeah. I'm very much in accord with supporting the first one and trying to make the second one more stringent. I don't know the exact best way to do it, but we've got the time to work on it.

I want to share my enthusiasm for the rural approach, and part of that is influenced by some work I did in a situation where there was a hospital in a rural part

of a metropolitan area that had been acquired by a system. And they had this convert. They closed the inpatients and expanded their outpatients and kept their emergency department open, and what was striking is how the quality of care before the inpatient was closed had become so problematic and how data showed that the community was bypassing the hospital beforehand. They were going to other hospitals, and that it just seems to be such a good solution that I'm just very enthusiastic.

As far as whether the community should be called on to support, to the degree that there are hospital districts in counties that can do that, I think it's fairly feasible to do that, but it may be that the idea is so compelling we want to do it everywhere where there's a hospital that can close.

DR. CROSSON: Pat.

MS. WANG: I agree with the rural proposal. I think it's great. I also agree with the first one for physician fees.

For the second one, I would encourage us to stay away from any approach that seeks to differentiate payment types within one facility, because I think it encourages

upcoding, and it's already happening, and I think, you know, we shouldn't go down that path.

I would like to ask whether there could be further exploration on the second bullet, for urban situations where an OCED is stood up as part of a closure of an inpatient facility, similar to the rural treatment. You know, to me -- because, you know, there's an example of that that's fairly fresh in my mind, from New York City, and, you know, 20 minutes, if you told the residents of that community which is densely populated, like there's an emergency room 20 minutes away. You know, like that hospital would never have closed, and the only reason that it did, which was a good thing, was that another operator came in and stood up a freestanding emergency department. Did have to meet, you know, state licensure requirements for ED.

So the overhead costs actually are higher than an urgent care center. I really respect the research that you did and it's not right to pay ED rates for urgent care, but there may be a particular situation that is worth paying a little bit more if, in the process, you can get a community to let go of their local hospital. That is a better

outcome all the way around.

And given the trend right now for the way that, you know, health care is going and medicine is being practices, I do think that it's going to be an issue that comes up more frequently, of people needing to sort of say, okay, I'm going to let my local hospital go, because it's just not needed anymore. The beds aren't needed, they're not getting filled, and you have all of this capital infrastructure that is just sucking up money and not providing the highest quality of care.

So if part of that can be to persuade operators to go and stand up a freestanding ED, with higher overhead costs, albeit not handling the, you know, serious trauma, I think if we can kind of take a closer look at that in urban areas it would be a good thing to do.

DR. CROSSON: Warner.

MR. THOMAS: So I would agree with the third recommendation. I think the one comment I would make is you may want to think about -- and this may help get better acceptance -- creating some sort of period, three- or five-year period where they could revert back. I think the likelihood of reverting back is very low, but it may give

comfort to the community that, hey, if we make this decision and it ends up being the wrong decision we've got a chance to revert back.

On the second bullet on the freestanding EDs -- and I think there are examples which you have gone through where there's been a proliferation of EDs, which is unnecessary -- we also have to understand that there's a lot of our EDs, especially in urban areas, that have, you know, 10-, 12-, 14-hour waits, frankly, which isn't great either. Now you could argue that that's, you know -- they need to have better service, but there's also just -- and maybe a bunch of the folks that are there shouldn't be there, but there is a level of care that is not appropriate for an urgent care but probably doesn't need to be in a trauma center, and there's something in the middle. And perhaps your reimbursement or Type B rates, you know, kind of get there.

I mean, for example, we were going to open up an ED, a freestanding ED. It was going to be two, three miles away from one of the -- from the trauma center. We ended up not opening it because the Department of Health and Hospitals asked us not to. But the wait at the trauma

center is 10 and 12 hours. So I don't think that's a great solution either.

So I'm not -- you know, so I don't think having, you know, 50, 60, 70 EDs in an urban area, close to each other, makes sense, but I think maybe something in the middle is a good alternative, understanding that if you look at the ratings of access to many of the large urban EDs, they are not very good.

So I don't know if that's helpful to you, but I do think having an alternative between urgent care and between a trauma center or even a level 2 is an important alternative, even though you don't need to have a freestanding ED on every corner, like a drugstore. We can talk about that later, but anyway.

[Laughter.]

DR. CROSSON: Rita.

DR. REDBERG: So I support the recommendations. I think you did a great job of identifying a lot of the issues, and, you know, addressing sort of the ED needs but not the inappropriate payments and certainly trying to stem the growth of off-campus EDs.

I just wanted to add a comment. You know, I also

have a lot of concerns and it was addressed, I guess, with some of the imaging being paid so high. But there's also just been -- I'm sure you know -- a huge proliferation of use of imaging in EDs. You know, multiple CT scanners, and everyone getting multiple CT scans that are often not appropriate and not good, because it's a lot of radiation risk and a lot of increased cancer. And often even before they are seen now. You know, I know that it's routine. They'll say, oh, you know, abdominal pain, they need a CT, which is not -- you know, it's nice to see the patient first and then decide what you're going to need and what you're going to evaluate.

And so if we could address those inappropriate -- the incentives for inappropriate CT imaging, I think it would be good for the program and good for the beneficiaries.

DR. HOADLEY: So I support these recommendations, broadly speaking. The first one, I think, you know, fixing the loophole makes a whole lot of sense. You know, we're obviously on record with a stronger call for site-neutral rates than what Congress did, even, so, you know, I think that's important context here.

For the urban, you know, I'm finding some of what Craig said and some other have said to be sensible, thinking that maybe this even needs to go further. I do like some of what Pat was talking about in terms of maybe their circumstances but circumstances where a sort of rural style situation could be appropriate. I think it would be interesting to at least think about whether either those elements could be modified from what we have on this bullet two.

And bullet three, I'm really strongly in favor of. You know, I've probably made these comments before but I've seen, you know, both in much earlier settings, site visits that I once went on with some of you, you know, some of these kinds of settings. I think that the notion that communities, if they had an option, could really benefit from them, it really makes a lot of sense.

I think the question of whether there needs to be a community involvement, I think it's a good concept and maybe we need to think about whether some basis to create an exception to that, if we want to go with that route. I mean, as people have pointed out, there are a number of places where these hospital taxing districts have already

done that, and this is a natural extension and it does show that sort of community commitment. But I think Amy's and others' points, you know, make a lot of sense. There are clearly going to be some communities where financial situations just aren't -- you know, it's not taxable in the same way. So we may want to think about putting some language in there that says there could be an exception to this.

Thank you.

DR. CROSSON: Okay. Thank you, Jack. Thank you, everybody. This is a good discussion. I think it's going to be helpful. Jeff, Sydney, Zach, thank you for the presentation. We look forward to hearing more from you later this year.

We now have an opportunity for public comment period. If there are any members of the audience who would like to make a comment, please come up to the microphone and line up so we can see who you are.

MS. McDERMOTT: Hi. Mara McDermott, CAPG.

DR. CROSSON: Mara, just let me -- I have a little prologue I go through.

MS. McDERMOTT: Okay. Prologue away.

DR. CROSSON: This is an opportunity, Mara, I think as you know very well, there are other opportunities to provide input to MedPAC, and sometimes those are more effective, and I know you take advantage of that so I'm not telling you anything you don't know. But I do want to point that out to others in the audience who might think this is the only way to have input to MedPAC and the staff, which can be done through meetings and through e-mail, and through correspondence.

That said, we are delighted to hear from you. We will ask you to keep your comments to two minutes, and when this little red light here goes back on, that's 2 minutes.

MS. McDERMOTT: Okay. Thank you. Mara McDermott with CAPG. I just wanted to share a couple of comments on the MIPS portion of the discussion.

First, our members are very concerned that it's a little bit premature to declare defeat on MIPS. We've seen -- anecdotally, I'll share -- many of our members, about two years ago, looked at MIPS and saw a great opportunity to make a lot of money, scaling factors and exceptional performers and other bonuses. And I think as MIPS has evolved, many of them have sized it up and have said, you

know, that's not certain enough, and that's not an opportunity, and as a result they've moved into next-generation ACOs and Track 1+ and other things, and I think that's exactly what we, as stakeholders, have wanted to see out of MIPS.

So to some degree we think it is working, maybe not perfectly and there is certainly room for improvement, but we have concerns about throwing it out at the moment.

We also wanted to just offer a couple of comments on the VVP proposal. One is that we think that there is great value in having some reporting. So what we've seen with our membership is that there are organizational skills that come into play when you're doing some amount of quality reporting, and we would encourage you to consider that as you make a recommendation that would have no reporting at all.

We had a question about the MIPS APMs, so if you're in a Track 1 ACO in MIPS now, in VVP would that mean that you are reporting the 32 measures and earning back the same 2 percent withhold as a group that's reporting nothing? Sort of how would that work? So I guess that's just a question for the record.

And then the final thing that I'll say is our members have been reporting on quality for a long time, some of them back to when PQRS was voluntary over 10 years ago. They've made investments to be successful PQRS reporters, value-based payment modifier reporters. Some of them are receiving substantial bonuses in that program. And we worry a little bit that that investment that they've made, to be successful in MIPS, hasn't come up at all today. We've focused a lot on people who can't do it but not at all on people who can, and have, and have made substantial organizational and time investments to bring their organizations up to speed with what CMS has announced as existing rules.

So I offer those comments and I see my time is up.

DR. CROSSON: Thank you very much. Okay.

So we have come to the end of the morning session. We are adjourned until 1:00. 1:00 we will be back. Thanks.

[Whereupon, at 12:06 p.m., the meeting was recessed, to reconvene at 1:00 p.m. this same day.]

AFTERNOON SESSION

[1:01 p.m.]

DR. CROSSON: Okay. Welcome, everybody, back after lunch and welcome to the guests we have. We're going to start the afternoon session with a discussion again -- and I'm not sure I can remember how many years we've been talking about this issue -- of potentially rebalancing the physician fee schedule to deal with what may be a looming shortage of primary care physicians or physicians practicing and delivering primary care services to Medicare beneficiaries.

We welcome Kevin Hayes back and Ariel. It looks like, Ariel, you're going to start.

MR. WINTER: Yes. Thank you.

Good afternoon. Today, as Jay said, I'll be talking about rebalancing Medicare's physician fee schedule towards primary care services. And before we begin, we want to thank Kate for her help with this presentation.

Here's the outline for today. I'll start with talking about the context and some background information. Next I'll discuss problems with how the fee schedule pays for primary care services. And then I'll describe two

approaches to rebalance the fee schedule towards primary care.

Our work on primary care is part of a broader agenda on clinician payment policy. This morning, and at prior meetings, we've talked about MIPS. Beginning next month, we'll start presenting information for our annual assessment of payment adequacy for physician and other health professional services. And next spring, we'll provide an update on advanced alternative payment models and ACOs.

The Commission has been working on this issue for several years, as Jay pointed out, and this slide lists several of our key recommendations in this area. In 2008, for example, we recommended that Congress create a budget-neutral bonus for primary care services, which eventually became the Primary Care Incentive Payment program, or the PCIP. In 2015, we recommended that Congress establish a per beneficiary payment for primary care clinicians to replace the expiring PCIP.

We've also made recommendations to improve the accuracy of fee schedule payment rates for all services. We recommended that Congress set an annual numeric goal for

CMS to reduce the prices of overpriced services for each of five years. And we recommended that CMS regularly collect data on clinician volume and work time to set more accurate relative values for clinician work and practice expense.

High-quality primary care is essential for a well-functioning health care system, and primary care has five core elements: accessibility, which includes the ease of getting an appointment and after-hours care; continuity with the same practitioner or practice over time; comprehensiveness, which involves meeting the majority of each patient's physical and mental health care needs; coordination of care for a patient among multiple providers and settings; and accountability for the whole person, meaning that the clinician is knowledgeable about the patient's medical history and preferences.

According to the literature, primary care that includes at least one of these five core elements is associated with fewer emergency room visits, lower rates of hospitalization for ambulatory care-sensitive conditions, lower costs per capita, and higher patient satisfaction.

Physicians who focus on primary care are generally trained in family medicine, internal medicine,

geriatric medicine, and pediatrics. About 185,000 primary care physicians billed Medicare in 2016, accounting for 19 percent of all health professionals who billed the program.

Other primary care practitioners include advanced practice registered nurses -- such as nurse practitioners -- and physician assistants. About 203,000 APRNs and physician assistants billed Medicare in 2016, accounting for 21 percent of all health professionals.

This slide summarizes the key problems with how the fee schedule pays for primary care, and there is more detail about this in your paper.

The first issue is that the fee schedule underprices primary care relative to other services. Payment rates are based on relative value units, or RVUs, and the RVUs for clinician work are based on estimates of the relative amount of time and intensity required for each service.

Eventually, the time needed to perform procedures often declines due to productivity gains and changes in clinical practice, technology, and technique. But the payment rates are not updated frequently enough to reflect these reductions in time.

On the other hand, primary care services, which include office visits, tend to be labor-intensive and so do not lend themselves to similar reductions in time. Therefore, over time, procedures tend to become overpriced relative to primary care services.

The second issue is that the nature of fee-for-service allows specialties that focus on procedures to more easily increase the volume of services they provide than primary care clinicians. This is because it's easier to achieve productivity improvements for procedures than for primary care services.

The third issue is that the fee schedule is not well designed to support primary care because it is oriented towards discrete services with a clear beginning and end. A major component of primary care, however, is ongoing, non-face-to-face care coordination.

Since 2009, CMS has reviewed many potentially mispriced codes, but the fee schedule is still unbalanced. Although the review process has been going on for eight years, many services have not yet been reviewed. These unreviewed services account for 29 percent of fee schedule spending.

Even among the services that were reviewed and received lower RVUs for clinician work, the RVUs did not decline as much as the estimated amount of time that it takes to provide a services.

Recall that work RVUs are based on the relative amount of time spent providing a service and the intensity, or effort, involved in the service. From 2008 to 2016, CMS decreased the work RVUs, the time estimates, or both for about 600 services. The time estimates for these services decreased by an average of 18 percent, but the work RVUs decreased by an average of 9 percent. A potential explanation for this disparity is that decreases in time were partially offset by increases in intensity.

Another indicator that the fee schedule is unbalanced is the substantial disparities in compensation between primary care clinicians and several other specialties, as shown on this slide.

Average annual compensation for primary care -- the second bar from the left -- was about $264,000 in 2015. By contrast, average compensation for radiology was more than twice as high -- $560,000 -- and for nonsurgical procedural specialties it was $545,000. There are concerns

that these compensation disparities could discourage medical school graduates and residents from choosing to practice primary care.

Prior incremental efforts to address the underpricing of primary care services have not succeeded in rebalancing the fee schedule towards primary care. Therefore, the Commission may wish to consider more significant changes. In doing so, there are some important policy questions to think about.

First, should Medicare increase payment rates for primary care services provided by all specialties or just primary care clinicians?

Should payments also be increased for psychiatric services? Many of the issues that affect primary care clinicians also affect psychiatrists. A large share of psychiatrists' fee schedule revenue for ambulatory services comes from E&M office visits, psychiatrists' average compensation is much lower than many other specialties, and psychiatrists are more likely than other specialties to opt out of Medicare.

Third, by how much should payments be increased?

And, fourth, should higher payments be

distributed on a per service basis or a per beneficiary basis?

We have developed two approaches that illustrate different ways to answer these questions.

The first approach would increase fee schedule payments for primary care and psychiatric services provided by all specialties and clinicians. This would be a budget-neutral change. Higher payments for primary care and psychiatric services would be offset by lower payments for other services.

The payment increase would be distributed on a per service basis because the goal of this approach is to spread the increased dollars among many clinicians.

The list of eligible primary care services includes: evaluation and management codes for office visits, home visits, and visits to patients in long-term-care settings; chronic care management and transitional care management codes; and Welcome to Medicare visits and annual wellness visits.

These are considered primary care services by CMS for the purpose of assigning beneficiaries to ACOs in the Medicare Shared Savings Program.

Psychiatric services include the E&M codes listed on this slide, as well as psychiatric diagnostic evaluation and psychotherapy.

One rationale for this approach is that some specialties other than primary care receive a high share of their fee schedule revenue from primary care services. As shown on this slide, for example, endocrinology received 76 percent of their fee schedule payments from primary care in 2016, and rheumatology received 68 percent from primary care.

The average share for all primary care practitioners was 54 percent, but there is variation among primary care specialties. For example, family medicine physicians received 70 percent of their payments from primary care services; whereas, internal medicine physicians derived 45 percent of their payments from primary care.

We modeled payment increases of 10, 20, and 30 percent to primary care and psychiatric services, using 2016 claims data. We assumed that the increases would be offset by an across-the-board reduction to all other services. Your mailing paper describes other budget

neutrality options, such as an annual numeric target for CMS to reduce prices of overpriced services.

So if we start by looking at the first column, which shows a 10 percent increase, this translates to an additional $2.7 billion for primary care and psychiatric services. This would be offset by a payment reduction of 4.5 percent for all other fee schedule services.

To show the specialty impact, we grouped individual specialties into larger groups. The net effect on each group varies based on the group's mix of primary care, psychiatric, and other services.

So staying in the first column, you can see that primary care practitioners would receive a net increase in payments of 3.4 percent, which reflects the net effect of a 10 percent increase for the primary care services they provide, and a 4.5 percent decrease for the non-primary care services they provide. Psychiatry would increase by 4.8 percent. Radiology would experience the largest net decrease of 4.4 percent.

And if we turn now to the last column, the 30 percent increase in payments, this translates to about an $8 billion increase, which would be offset by 13.4 percent

reduction to all other services. And primary care practitioners in this example would receive a net increase in payments of about 10 percent.

The second approach would increase fee schedule payments for primary care and psychiatric services provided only by certain specialties and certain clinicians within those specialties. Clinicians would be eligible based on their specialty designation of primary care or psychiatry and their share of fee schedule payments that are from primary care and psychiatric services.

As with first approach, this would be a budget-neutral change: higher payments for these services would be offset by a reduction for other services.

The rationale for targeting the increase to primary care is that PCPs, primary care practitioners, play a unique and important role in the delivery system. This approach uses the same definition of primary care and psychiatric services as the first approach and includes the primary care specialties that are listed on this slide.

So here are the modeling results for the second approach. As with the first approach, we modeled payment increases of 10, 20, and 30 percent to primary care and

psychiatric services. And on the slide, we've included the 10 percent and 30 percent increases to show you the range.

We modeled various alternatives for the share of total payments that come from primary care and psychiatric services that would qualify clinicians for the payment increase. These alternatives range from 40 percent to 75 percent, as shown in far left column. Your paper includes additional thresholds.

Where we set this threshold determines how many clinicians qualify for the increase and the size of the total payment increase. For example, at the 40 percent qualifying threshold, which is the first column of numbers, about 263,000 primary care practitioners and psychiatrists would qualify for the payment increase, and the total amount of the increase would range from $1.2 billion (corresponding to a 10 percent increase) to $3.6 billion (corresponding to a 30 percent increase).

To offset these increased payments, payments for services other than primary care and psychiatric services would decline between 2 percent and 5.9 percent. At the 75 percent qualifying threshold, fewer practitioners would qualify for the payment increase, and the total amount of

the increase would be a little lower, ranging from $1 billion to about $3 billion. And payments for other services would decline between 1.7 percent and 5 percent.

An important question is how to distribute the payment increase under the second approach. One option is to distribute it on a service-by-service basis. This would be easier for CMS to administer, but it would reward clinicians who provide more discrete primary care visits.

Another option is to distribute it on a per beneficiary basis, which is consistent with our recommendation from 2015. Paying clinicians based on the size of their patient panel rather than their number of visits could encourage non-face-to-face care coordination.

A per beneficiary payment would also provide funds to support investments in infrastructure and staff to facilitate care management. However, as the size of a per beneficiary payment increases, there are questions about how to attribute patients and whether to risk-adjust the payments.

Another idea is to consider a mix of both options. For example, you could begin by paying the increase on a per service basis and then move over time to

a per beneficiary payment.

To conclude, here are some key decision points to start your discussion:

Should Medicare increase payment rates for primary care services provided by all specialties or just primary care clinicians?

Should payments also be increased for psychiatric services?

By how much should payments be increased?

And should higher payments be distributed on a per service basis or a per beneficiary basis?

This concludes our presentation, and we'd be happy to take any questions.

DR. CROSSON: Thank you, Ariel.

So we're now open to clarifying questions. We'll start with Jack.

DR. HOADLEY: So thank you. This was a very helpful presentation. On Slide 12, where you break out some of the different specialties, I guess I had two questions. One is, you know, where you pulled out some of the non-primary care specialties and had some pretty high numbers there, were there any other specialties -- was this

all of the specialties that came in like at 50 percent or above, and were there others that are sort of close to that that sort of just missed that kind of a cutoff?

MR. WINTER: Right. So these are the major ones in terms of spending that came above 50 percent.

DR. HOADLEY: Okay.

MR. WINTER: There are some other variations of hematology and oncology that are also in that range, like oncology alone, hematology alone.

DR. HOADLEY: Okay.

MR. WINTER: There are some specialties that accounted for a very small amount of dollars that are above 50 percent, like preventive medicine, addiction medicine, certified nurse midwife, which is really small in Medicare in terms of dollars. We picked out the big ones that are above 50 percent.

DR. HOADLEY: Okay.

DR. GINSBURG: If I could follow up on --

DR. HOADLEY: And with hematology and oncology, are the drug costs counted in the denominator on this?

MR. WINTER: The costs of the Part B drugs are not part of the denominator, but the cost of drug

administration services, which are paid out of the fee schedule, would be in the denominator.

DR. HOADLEY: Okay.

DR. GINSBURG: If I can follow up on Jack's question, you know, we also -- within specialties, you know, a lot of specialties are very subspecialized today, so sometimes you have enormous variation within a specialty as to how much of their care is evaluation and management services. Brian and I were talking at lunch about his brother, who is in a subspecialty of ophthalmology called neuro-ophthalmology, and this subspecialty is almost no procedures. It is all evaluation and management services. We wouldn't call that primary care because these are very specialized services. But the issue is that subspecialty is not viable today and it is dying I think because of our payment distortions.

DR. HOADLEY: So I had one other one. You had mentioned -- I guess it was on the previous slide -- the chronic care management and transitional care management codes. I recall the last time we talked about those, there was very little take-up of those codes. Is that still the case?

MR. WINTER: So when we talked last time about this, we had data from 2015, and the total dollars were about $180 million for both. But take-up was increasing.

DR. HOADLEY: Okay.

MR. WINTER: Month by month it's growing. We don't have data yet for 2016. I hope to bring that to you for a future presentation. So it's still small, but I would say the take-up is growing.

DR. HOADLEY: It is growing. And the last question, if you were to do a per bene payment, I think this is -- I may have asked this question in a previous session. Is there a co-pay associated with that for the beneficiary, or how does that work?

MR. WINTER: Kevin and I were just talking about this right before the presentation. Under our recommendation from 2015, we said that the per beneficiary payment should be program dollars only. There should not be beneficiary cost sharing associated with it. And I think one rationale for that is that beneficiaries might be surprised to get a bill for cost sharing when they didn't receive the face-to-face service.

So in our modeling, you know, we thought more

about the per beneficiary payment for the second approach, and just for the sake of convenience, we assumed that however -- the dollars that would be distributed include both the program payment and the beneficiary cost sharing. If you distribute the increase on a per service basis, it probably makes sense to do that. If you do it on a per beneficiary basis, then there are pros and cons you have to think about whether or not to include the beneficiary cost sharing.

DR. HOADLEY: It becomes a policy option.

MR. WINTER: Yeah.

DR. HOADLEY: Thank you.

DR. CROSSON: Clarifying questions?

Pat.

MS. WANG: I am curious if you could say a little bit more about psychiatry in this. I don't remember in past conversations if we had explicit conversations about the psychiatry fee schedule. I think that some of the work here is meant to address perceived inequity, inaccuracy in the fee schedule, and some of it is to ensure that Medicare beneficiaries have access to the services that they need by making those specialties more attractive for physicians to

practice in.

Psychiatry is a little bit different, definitely much lower participation in all forms of insurance, that I think may have some reasons associated that go beyond just how much gets paid. It has to do with the hassle and just the way that people practice and the kind of scrutiny that insurance companies, whether they're private or public, place on high no-show rates, whatever it might be.

Is there -- can you talk more about why we included psychiatry and what we think an adjustment to the fee schedule is going to cure?

MR. WINTER: Right. So on -- just to clarify, the psychiatry -- psychiatric services are paid under same fee schedule as the other services we have been talking about, procedures, E&M office visits. So the reason we thought to include it or give you the option of including it, because it is a question we've raised for your discussion, is for a couple of reasons. One is they derive a lot of their fee schedule revenue for ambulatory services from the E&M office visits that are the main source of revenue for primary care physicians. So to the extent those codes are undervalued, it would affect both primary

care and psychiatry, so that's one reason.

Another reason is when you look at compensation by specialty, psychiatry tends to be at the lower end of that range. They're above primary care. Primary care averages 264,000; psychiatrists, 289,000. But if you look at the chart I put up over here, you can see that many other specialty groups are well above that. So there is a concern there about what could these disparities do to -- potentially do to access in the future.

When we've done our focus groups with beneficiaries and physicians, an issue that's been raised is that primary care physicians say they have a difficult time getting access for their patients to psychiatric and behavioral health services, and last year, Kate and Dana did a whole presentation about this topic more generally.

So those are some of the things we were thinking about. As you point out, it is certainly correct that there is an issue on psychiatrists participating in all forms of insurance, not just Medicare, and this could be -- so, therefore, Medicare's payment rates are not the only factor affecting participation in Medicare for psychiatrists. There are certainly other factors that

influence that as well.

So there are issues to think about, and that's why we thought to include it, but it's up to you to decide whether we should keep it in or leave it out.

DR. CROSSON: Yeah. I'd just make a couple points. I can't remember exactly when, but I think in one of our previous iterations of this discussion about the fee schedule, there were a number of Commissioners who said, you know, don't we want to take into consideration mental health providers, particularly psychiatrists. So that's one thing.

The second point I think is worthwhile making is I think in doing this work, we fully recognize that income is not the only issue impacting the decisions made by senior medical students, for example, in terms of what field they want to go into. Some specialties have come easier over time with the advent of technology. Some specialties, including some primary care specialties, have become much more arduous, longer days, harder, more complex patients.

There are aspects of that we can't solve. The one piece that we can attempt to solve is the income piece.

Brian.

DR. DeBUSK: On Chart 13, I really like the analysis you've done where you break that down by sort of who's affected when you use the E&M code-based thing. Do you have some of the underlying data that you could share with us or speak to on, for example, neurologists? Again, to Paul's earlier points, neuro-ophthalmologists, which is sort of an unfair question. I think there's about 500 of them in the whole country. So I'm pretty sure you don't have that one.

But I think sort of the classic neurologist who's probably making their income from E&M codes, could we get maybe just some points of reference? And the reason that I ask that question is if I look at nonsurgical nonprocedural, I'm guessing that's where a lot of these people fall, and that category, net, actually it's a slight decrease.

But what I'd like to see is what's going on under the waterline. If you could speak to that, that would be helpful because I would think there's probably a handful of canaries in the coal mine that we could look for.

MR. WINTER: Right. So on -- I'm just looking

for my notes. So we did look at -- within the nonsurgical and nonprocedural category, you're correct. Neurology is in there, and about 42 percent of their revenue is from primary care services. So presumably, my guess is they would get a small increase, but I have not modeled that. So I can come back to you with that information.

Also in that category is rheumatology and endocrinology, and both of them would receive increases. So the 10 percent level, for example, endocrinology would receive an increase of 6.5 percent, and rheumatology would increase by 5.4 percent. And in the future, we can come back to you with more disaggregated breakdown of specialties. For the purposes of this, we wanted to aggregate to show you the broader effects, but we can give you more detailed information.

DR. CROSSON: Paul.

DR. GINSBURG: If you could turn to slide 9, this is the bar chart, the income data from MGMA. I just wanted to make the point that multispecialty groups have a long history of having a smaller difference in relative incomes between proceduralists and primary care physicians and the like. So in a sense, it may be that MGMA -- the

disparities in MGMA are probably smaller than they would be in a more general data source.

DR. CROSSON: David.

DR. GRABOWSKI: Could you go back to slide 13? I wanted to follow up on Brian's questions.

I just want to see how you modeled this. You didn't assume a behavioral response here. This is just mechanical, right?

MR. WINTER: Correct.

DR. GRABOWSKI: I think it could be really important of how you pay more for primary care, you're going to get more primary care, and I think that's what we want here.

And to Jay's point, we want people shifting and entering this profession. I don't know if there's a literature out there, but I guess I'd encourage you to think about that and not just doing this mechanically because this may way underestimate the actual effect here.

Thanks.

DR. CROSSON: Amy.

MS. BRICKER: On the salary data that was provided, is that purely physician, or are mid-levels in

that number?

MR. WINTER: These are only physicians. I believe the survey only covers physicians.

MS. BRICKER: Okay.

MR. WINTER: That's correct. Yeah.

MS. BRICKER: So why -- I want to make sure I'm understanding. Are we suggesting that mid-levels would also get the increase?

MR. WINTER: Yes, we are. Under option 1 -- sorry -- the approach 1, any mid-level that billed for primary care and psychiatric services would get the increase, so that includes MPs, PAs, LCSWs, and clinical psychologists because they billed for a lot of the psychiatric -- behavioral health codes, so they would receive an increase.

Under the second approach, it would be limited to those -- it would be limited to PAs and MPs that focus on primary care.

MS. BRICKER: So just wanted to push on that a moment. So if the concern is we're worried about physicians choosing primary care, do we see in our data that mid-levels are -- I understood them to be increasing

in number and in primary care. So if we consider not adjusting their reimbursement at the mid-level, how does that change the economics of what you recommended? How much of that weighting is associated with a mid-level increase versus physician?

The other thing to know on this slide 13, I read the footnote that was available in the reading material, and other practitioners noted -- included social workers and psychologists.

MR. WINTER: Yeah.

MS. BRICKER: And I understood that to be what we were hoping to preserve in part two, so --

MR. WINTER: Right.

MS. BRICKER: Maybe if we go this route, we don't further harm them in the reduction that's outlined here.

MR. WINTER: Right. So other practitioners include a broad range of practitioners, and the LCSWs and clinical psychologists which are in this category actually would receive a fairly significant increase, around 8 to 10 percent under the 10 percent increase, because they billed so heavily. They so heavily bill on behavioral health codes.

The other practitioners in that category include chiropractors, podiatrists, other specialists that would not -- that bill very few of these services.

MS. BRICKER: So what is it then -- sorry. I misread it, then. So it says other practitioners include, and it lists social workers and psychologists in the footnote.

MS. BUTO: [Speaking off microphone.]

MR. WINTER: So what page are you looking at?

MS. BRICKER: Sorry, 32 in the footnote.

MR. WINTER: Right. It does include those, but the footnote also says includes chiropractors --

MS. BRICKER: Yeah, yeah.

MR. WINTER: -- physical therapists, podiatrists.

MS. BRICKER: I was just wanting to make sure that we weren't --

MR. WINTER: Yeah.

MS. BRICKER: -- hurting them in this when we're also trying to help them as part two. So if we need --

MR. WINTER: Yeah.

MS. BRICKER: -- to ensure that social workers and psychologists aren't negatively impacted by the

adjustment, that's all.

MR. WINTER: I'm sorry. This represents the average effect across all the specialties in that category, so some go up, like clinical psychologists. Others go down, like chiropractors and physical therapists.

MS. BRICKER: I see.

MR. WINTER: This is just showing the average.

MS. BRICKER: I see.

MR. WINTER: So I think for next time, we should give you more detail about the specialties within these categories.

MS. BRICKER: I gotcha.

MR. WINTER: They might be helpful.

MS. BRICKER: Thanks.

DR. CROSSON: Bruce.

MR. PYENSON: Thank you.

I've got three clarifying questions. On page 7, on the changes in productivity, do you have a sense of whether productivity improvements are more for recent procedures or existing procedures? Do they all improve? What do we know about that?

MR. WINTER: I would have to go back and look at

the literature, and maybe Kevin has come across this in his review of the literature. My sense is that for newer procedures, productivity tends to improve faster as through the process of learning by doing and as clinicians get more acquainted with the procedure.

I don't know whether this research on the change in productivity over time for a given type of service.

Kevin, do you know anything about that?

DR. HAYES: Yeah. Most of the work in this area has involved surgical procedures, and so to the extent there's anything on the service specific, it's going to be that. And so from there, you just would infer, well, okay, now, where else, you know, among the range of services that are provided -- where else have we seen the things that drive productivity improvements, like technological advances and so forth? And then you can just sort of extrapolate from that idea to what might be happening elsewhere in the fee schedule.

MR. PYENSON: Great. Thank you.

A related question, but on page 8, the time estimates and perhaps productivity, does productivity include things like a surgeon running two or three

operating rooms when they do those tabulations? Is that figured into the productivity?

DR. HAYES: When you say a surgeon running two or three operating rooms, maybe you could just sort of say a little bit more about what you mean by that.

MR. PYENSON: Concurrent surgeries. Concurrent.

DR. MILLER: You didn't know about this, Brian?

[Laughter.]

DR. DeBUSK: [Speaking off microphone.]

DR. HAYES: Well, if we -- so productivity is going to be outputs over inputs, and so the outputs are going to be going up if more services are billed relative to inputs, and so it's just a question of -- so yes. It would include whatever increases the outputs.

MR. PYENSON: But from a time standpoint.

DR. HAYES: Oh.

MR. PYENSON: So when you think of the time it takes to perform a surgery, if there's -- if it's a two-hour surgery, but you have three patients --

DR. HAYES: Right.

MR. PYENSON: -- does that count as a two-hour surgery? Does that count as a 40-minute surgery?

DR. HAYES: When we have asked contractors to look at time and how that time spent delivering services varies relative to the time that's assumed in the fee schedule, it's been the time for all the services billed under the fee schedule as assumed by the fee schedule relative to the actual hours worked.

MR. PYENSON: So it sounds like it's a patient --

DR. HAYES: Yes, it is.

MR. PYENSON: Okay.

DR. HAYES: The output, the productivity is measured at the patient level, at the level -- at the amount, the quantity of services that have been billed and the time assumed in the fee schedule for each one of those services, and if they're done concurrently, however they're doing, however they're billed, that's what's counted.

DR. MILLER: Right. But let's be clear so that there's not a misunderstanding here. You're talking about what we did in the contractor report.

MR. PYENSON: Yes.

DR. MILLER: Okay. I'm not sure what you're asking. If whatever was going on, legal or otherwise, they would bill for three surgeries, and the time that would be

assumed in paying them would be the time assigned to those three surgeries in the fee schedule.

MR. PYENSON: But it wouldn't be the actual -- so that's the time assigned.

DR. MILLER: It would not be the time they actually spent.

MR. PYENSON: So it's per patient. So it sounds like we're not dividing -- if there were three patients, we're not dividing the surgeon's time --

DR. MILLER: It really depends on what your question is, and this is what I can't get a handle on.

What Kevin was describing to you was an attempt where we went through and we were trying to see whether the time assumed in the fee schedule was concordant with the time that physicians were doing their stuff, and we were saying there is a difference. And Kevin was explaining to you how we asked them to measure that, which would say if you spent less them than is assumed in the fee schedule, we were trying to capture that.

I'm not sure what you're asking, whether you're saying in the actual fee schedule, is the actual time reflected. I would say no. There's an assumption about

time.

MR. PYENSON: Well, but very particularly, I think, Brian, were you volunteering to help?

DR. DeBUSK: If you look at the RMRVS and the RVUs for any given CPT code, you can unwind that and actually look at the pre-service time, the inter-service, and the post. So what you -- I think the thing -- because I've talked to you about this before. You basically just unwind the RVUs and look at how many hours or minutes, technically, the surgeon earned by performing those CPT codes, and then you simply look at basically a time card, how many hours did they work, and you look at that ratio, that discrepancy.

DR. MILLER: But that's what we did.

DR. DeBUSK: That's what you did.

DR. MILLER: Right, which I'm still not sure --

DR. DeBUSK: That's your top-down approach.

MR. PYENSON: That clarifies it because the time card would show 8 hours and not 24 hours. The time card would clock in and clock out.

DR. MILLER: Yeah. And we're using that in a stylized way, but yes. But the thing is that that data is

not available. We have a small micro study that did that, and just one more time -- and I just want you to nod when I do this to make sure we're communicating to each other. In his example, he said there was the time assumed in the fee schedule, and then there's the time card over here. No matter how much time I spent with that patient, the bill is implying that I have a fixed time, no matter how much time I spent.

MR. PYENSON: Correct.

DR. MILLER: We're good on that, right?

MR. PYENSON: Yeah.

DR. MILLER: Okay. sorry.

MR. PYENSON: Last clarification. Are there enough palliative care physicians to have palliative care listed as primary care?

MR. WINTER: I think we'd have to check if -- that is, if palliative care is a distinct specialty code in the claims data -- I think it is. I think it's hospice and palliative care together.

Kevin is looking right now.

DR. HAYES: We're not sure.

MR. WINTER: We're not sure. So we'll have to

get back to you on that.

And if it's not, I think it would be hard to identify with the claims data, but we'll look into it.

MR. PYENSON: Thank you.

DR. CROSSON: Kathy.

MS. BUTO: Yeah. So, I'm trying to understand, because I liked your analysis of, you know, actual time versus time assumed and the different fee schedule services. But I'm trying to understand how much of a role time plays in the payment rate. And I'm assuming that time plays a greater role in things like E&M services, at least it used to, I think, and that skill and whatever the other characteristics of the work are, play a greater role in other services.

So I'm trying to understand how you did -- you did just a straight comparison of time, actual time, versus assumed time in each of the services. Right? But does time play a significant role in the payment rate? So if we corrected for that, it would make a big different across the board, or just in the time-heavy codes?

DR. HAYES: If you look in your mailing materials -- do you have your paper from -- that we sent you?

MS. BUTO: Yep, I do.

DR. HAYES: If you look at page nine, Figure 1, you will see there the result of an analysis where we tried to show how important time is relative to intensity. All right? And so one way to think about those figures in there, you can see how time, as a factor, you know, ranges from 79 percent to 77 percent, and that's pretty uniform across services. You know, so the office visits, for example, are in that E&M category --

MS. BUTO: Yeah.

DR. HAYES: -- and then we've got some -- and all that's telling you is that if you know how long a service takes to perform, you've got quite a bit of confidence that you know what the relative value unit is going to be for that service, and that finding holds pretty much across the board for all categories.

Now what that's not saying is that all services are assumed to take the same amount of time. It's just that, right --

MS. BUTO: You're saying as a proportion of the total work value.

DR. HAYES: Right.

MS. BUTO: That's a percentage --

DR. HAYES: Exactly.

MS. BUTO: -- assigned to time.

DR. HAYES: That's right.

MS. BUTO: Okay. So --

DR. HAYES: And so if you -- so time -- if you get the time right --

MS. BUTO: Yeah.

DR. HAYES: -- then you have a good shot at getting the RVU right.

MS. BUTO: The overall RVU right.

DR. HAYES: Yeah.

MS. BUTO: Okay. Then on -- so I have a couple of questions from the mailing materials. Page 11, I think this related to someone else's question about productivity earlier. We talk about it's harder to increase the productivity, if you will, of primary care versus procedural services, and I have to say I'm not completely sure -- I know from the early experience with the fee schedule that E&M services grew much faster than procedural services, and that may have just been a function of they were underpaid even more, and so an increase in payment

then generated some utilization.

But I think the thing that troubled me about this comparison was we compared the growth in E&M service volume to the volume of tests in imaging, so the growth in those services. And yet I know that primary care physicians order tests and imaging. They either order it or sometimes they even provide it in the office. So it felt a little bit like a strange comparison, because we seem to want to use that to make the argument that, see, E&M is really -- has a harder time generating income. And I'm wondering if we've thought about that relationship in making that comparison, between the E&M -- the primary care doc actually ordering tests and imaging and so on.

MR. WINTER: Okay. I hear what you're saying. So our main point there was that because E&M are labor-intensive codes that involve the clinician's time, in terms of getting the patient's history, performing an examination, making medical decisions, it is harder to do more per day than it is for procedures, or tests or imaging, which rely more on technology on non-physician clinicians to operate the equipment, for example, and where there are more opportunities to improve productivity.

And then your other point was -- I think your main point was if primary care practitioners are also providing these other services, why would we be -- why do we think that the valuation of primary care is related to their income? And I think my answer would be primary care practitioners, they perform -- they get more of their revenue from primary care services, like E&M services, on average, than other specialty, or than all specialties put together, on average.

So primary care physicians, if you look at the prior slide, 54 percent of their revenue is from primary care services, most of which are E&M, which is on Figure 3 on page 11 --

MS. BUTO: Mm-hmm.

MR. WINTER: -- that you were talking about. And across all specialties, that share is 29 percent. So because they're getting more of their revenue from services that do not lend themselves to productivity improvements, volume increases, we think that plays a role in lower compensation.

MS. BUTO: Right. And I think -- I guess, to my mind, the best point that's made by that comparison is that

it's important to capture the time and productivity improvements around procedures and tests and so on. That point is well made, and I think that example helps that.

What it doesn't help me, you know, get my mind around is, and, therefore, we need to figure out how to increase the incomes of primary care physicians in some way to compensate. I mean, to me, those are two different kinds of things.

But, anyway, that's just a Round 2 conclusion.

On page 17, back to Jay's point, do we have any data on what entered -- what factors medical students consider are important in choosing primary care versus a specialty or a procedural specialty, I guess? Do we have any information on that, because I think that would help with the analysis.

DR. HAYES: Yeah. This has come up before, and we will want to get back to you on the details of it. But certainly some aspects of medical practice influence specialty choice, outside of just the issue of compensation. So compensation is up near the top of the list in terms of factors, but it's also issues having to do with, you know, the satisfaction of doing a certain kind of

job, of performing a function that's interaction with peers. There's a number of factors like that and we will bring that back to you next time.

MS. BUTO: Okay.

DR. HAYES: But there's been some good research on that.

MS. BUTO: Good, and if you could also, just a sense of proportionality for the different factors --

DR. HAYES: Sure. Sure.

MS. BUTO: -- that would be helpful.

And then my last comment is about Slides 13 and 15. So I thought that your Slide 13, which did the -- for instance, net impact by specialty group, 10.2 percent at the 30 percent increase level, positive impact on primary care payments, and then 14.4 percent for psychiatry. But on 15, I don't think we did -- and I wondered if you had -- the same kind of breakdown as to impact by some of the key specialties.

MR. WINTER: We have not done that. We can do that for the future.

MS. BUTO: It should be -- isn't it higher, or is it not higher?

MR. WINTER: For primary care?

MS. BUTO: My first -- yeah -- my first glance at this, it says 3.6 billion, but at the, say, at the 30 percent increase level, when 40 percent of physicians, I guess, are included. Is that right?

MR. WINTER: Yeah, so --

MS. BUTO: Or is it 40 percent of services?

MR. WINTER: It's clinicians who receive at least 40 percent of their revenue --

MS. BUTO: Right.

MR. WINTER: -- from -- fee schedule revenue from primary care services. So it's not all clinicians. It's not all primary care clinicians. It's a subset. And --

MS. BUTO: Do you have the percentages in terms of what level of increase this represents for those --

MR. WINTER: I think it would be very similar, if not identical, to what you see here on the 10 percent level. So taking the 10 percent column, look at primary care, on -- their revenue goes up by 3.4 percent, because in this case they're all getting the 10 percent increase for their primary care services. And if you go to Slide 15, those clinicians that qualify for the increase --

MS. BUTO: Mm-hmm.

MR. WINTER: -- are probably getting in the range of that same 3-point -- what did I say? -- 3.4 percent. Now there's going to be some differences probably the distribution of clinicians -- these clinicians here are getting more of their revenue from primary care. So I would say 3.4 percent is the floor. It's probably going to be higher than that, and we can come back to you with that information.

MS. BUTO: Could you? That would be helpful.

MR. WINTER: Yes.

MS. BUTO: Thank you.

DR. CROSSON: David.

DR. NERENZ: Just two clarifying questions on terminology. If we can go to Slide 11, it's on the definition of primary care, I just want to be sure. If a patient sees a surgeon, a pre-surgical consult, and that's billed as E&M, that's called primary care here?

MR. WINTER: Assuming it's an office visit --

DR. NERENZ: Yes.

MR. WINTER: -- which it probably would be, yes.

DR. NERENZ: Primary care. And a follow-up

visit, outside the global window, same surgeon, same office, that's called primary care.

MR. WINTER: Yes.

DR. NERENZ: Any specialist, one-time consult, that's called primary care.

MR. WINTER: Yes, if it's billed as an E&M.

DR. NERENZ: Billed as E&M.

MR. WINTER: Yes.

DR. NERENZ: Is there any distinction, then, in terminology between primary care and E&M, for this discussion?

MR. WINTER: Yes, because we are including a certain set of E&M codes as primary care. We are excluding inpatient E&M visits --

DR. NERENZ: Okay.

MR. WINTER: -- and ED, emergency E&M visits.

DR. NERENZ: Thank you.

MR. WINTER: Those are outside the definition.

DR. NERENZ: That was not clear, but if it's an office visit, no matter -- all those examples I gave, those are called primary care.

MR. WINTER: Yes. We'll clarify that.

DR. NERENZ: All right. Slide 16, distributed. I don't understand this. The options in front of us are about enhancements to the fee schedule, which basically suggests you perform a visit, you bill the E&M code, you get an enhanced payment. Not seemed to me that was pretty simple. Then you get a check, eventually.

So distributed suggests that there's a second step in this, somehow separate, that -- and I don't understand what -- how that would work. So if I'm a physician and let's say in a month I do a whole bunch of E&M visits and now in this model I get an enhanced -- well, that the question. Do I get an enhanced payment from that billing or is it held in some kind of pool or something and then distributed separately? I just don't know what "distributed" means.

MR. WINTER: Okay. So service-by-service basis would mean -- it's essentially what you said. If you bill for an E&M visit and you meet the criteria, you qualify for the bonus or the enhanced payment, you just get a higher E&M payment. Okay? That's the simplest example.

The other way of doing it is to take that money, pool it together, and distribute it to the same clinician

based on the number of beneficiaries that are attributed to them. So if they're attributed 10 beneficiaries and you figure out the average amount per beneficiary, that's what they get on a monthly basis. And you could do that either prospectively, based on estimate of the beneficiaries they treated in a prior year, or you could do it retrospectively, or a combination of the two, and settle up.

DR. NERENZ: Okay. So then to generate the money to be distributed, I need to do office visits, but then I may get the money, supposedly to do something else, but I'm not billing E&M codes for those other things, like the back room care coordination.

DR. MILLER: Okay. So we've talked about this in a past discussion of primary care, and I can't remember. I think -- I thought you were here but maybe you weren't.

So there's -- whether we use the word -- let's just use the word "pay," okay? So either it's a model where you say, I'm going to do an add-on based on some criteria. So let's just say we've come to some agreement, you know, some set of -- some amount, some set of services, E&M, primary care, and some set of providers. And one way

you get the money to them is every time you bill a service you get a bump up. Okay? That's the conversation you just had.

In other conversations, particularly when they were focused on primary care, many Commissioners said, well, I don't want it to be service-specific because I want the primary care physician to have more resources, but not necessarily to have all that time booked up in visits, so that they can do coordination. So then what you would say is, calculate the add-on that would have occurred on each check and just sum it up and say, I'll give it to you on a per-person basis, either at the beginning or the end of the year, or as Ariel said, some combination of the two, and you deliver it on patient count instead of service count.

DR. NERENZ: Yeah, except -- well, I mean, I'm probably slipping into Round 2. I still don't understand it because the only way I generate any money to be distributed is by doing more visits. It has nothing to do with how many people I see.

MR. WINTER: So I think the pool of dollars -- the total pool of dollars available for this per beneficiary payment would be based on, I think, the number

of -- the total dollars billed for E&M primary care services, let's say, in a prior year. Right? And then you distribute that money -- you divided that total pool of dollars by the number of beneficiaries who are receiving those services, and then you attribute those beneficiaries to primary care clinicians, and based on that attribution determines how many -- how much of that pool they get, each of those clinicians gets.

And as long as there's still some E&M services being generated -- and I would assume there would be, because we do not expect -- we do not anticipate that this per beneficiary payment would replace all E&M office visits. Right? We expect it would supplement what -- it would -- pay for service is that either they are already providing or hopefully provide, now that they have this per beneficiary payment, but they would still be providing office visits, so they will still be generating revenue that could be then distributed in the following year to clinicians who are providing primary care services.

DR. NERENZ: Okay. Well, that was something I guess I didn't pick up, this idea of a lag year, and I think you implied maybe something about grouping, or is

this still purely at the level of the individual physician?

MR. WINTER: I was going back to our 2015 recommendation on per beneficiary payment, and, Kevin, correct me if I'm wrong but my understanding was we determined a pool of dollars, which at that point was about $700 million as a starting point, and the way we distribute it -- I'm sorry, the way we paid it out to clinicians was based on clinicians who met the criteria for participating in the PCIP. That is, they had a designated specialty within primary care, and they provided at least -- they derived at least 60 percent of their fee schedule revenue from primary care services in a prior year. And then we had a mechanism for attributing patients, beneficiaries, to those clinicians.

MS. BUTO: But Ariel --

MR. WINTER: And that determined how the dollars were allocated.

MS. BUTO: I think just to be clear, if I'm hearing you correctly, that pool of dollars, the $700 million --

MR. WINTER: Yes.

MS. BUTO: -- wasn't just the -- obviously not

just the individual physicians' pool of dollars, but you pooled all the physicians who met that -- those criteria and then you did a per beneficiary amount, which then got paid out.

I think -- what you've just pointed out raises a question of maybe some duplicate payment, but I guess we can get into that later.

MR. WINTER: Yeah, and there are probably other ways of thinking about it, but I was thinking about the model -- I was talking about the model that was part of our -- that was discussed as part of our recommendation.

DR. CROSSON: Okay. We've got -- Dana, do you have a point on this point?

DR. SAFRAN: Just a really quick clarification. So that last bit of conversation raised this question for me, but I think it might have also answered it. How do you differentiate internal medicine doctors who have a subspecialty but mostly they're functioning as primary care versus mostly they're functioning in that specialty? If we want to go with your Approach 2, and we really wanted this, is the answer to that your attribution model, is how you differentiate the cardiologists who are really functioning

as a cardiologist versus a cardiologist who is functioning most of the time as primary care but they happen to have a cardiology subspecialty?

MR. WINTER: So, in the second approach they would have to meet two criteria. One is they would have to be -- their designated specialty would have to be a primary care specialty, so it could not be cardiology, right? Plus they would have to meet this threshold of sharable allowed charges related to primary care.

And so if you had an internal medicine -- a physician who had enrolled with Medicare as internal medicine, right, and they met this threshold for sharable allowed charges related to primary care, which indicated they were truly focused on primary care services, they would be in. They would be eligible for this bonus. But if they were subspecializing in cardiology, and most of their revenue is derived from cardiac testing, let's say, then they would not be eligible. Does that help?

DR. SAFRAN: Yes. Thank you.

DR. CROSSON: Alice.

DR. COOMBS: Two questions. I'll be brief. So someone who is a family practice doc who follows their

patient in the hospital, does an E&M code, that's not considered part of the primary care.

MR. WINTER: No. So, I mean, that E&M code was billed --

DR. COOMBS: Even though they are --

MR. WINTER: -- for an inpatient setting.

DR. COOMBS: So even though they are primary care. And then on page 12, you have internal medicine at -- share of a fee schedule at -- I'm sorry, Slide 12 -- as 45 percent. What are they doing in the other time? I mean, is it just that -- is that -- what do we say the proportion of other things is that are being done?

MR. WINTER: Right, so what other kinds of services are they doing -- is that the question.

DR. COOMBS: Mm-hmm.

MR. WINTER: So my guess is they're doing E&M visits in the ED setting, inpatient setting. I think they could be -- even though their specialty is internal medicine, they could be functioning as hospitalists, so it could be most of the revenue is from inpatient E&M visits.

DR. COOMBS: Mm-hmm.

MR. WINTER: They could be performing minor

procedures, imaging and tests, and we can drill down into this and get you more information --

DR. COOMBS: Okay.

MR. WINTER: -- from the claims data.

DR. COOMBS: Thank you.

DR. CROSSON: Craig.

DR. SAMITT: One suggestion and one question. I got intertwined in the whole descriptor of primary care services versus primary care clinicians, so I wonder if we want to use the term "non-acute E&M services" because that's essentially what we're talking about. The term "primary care" confuses things from my point of view.

My question is: Is it possible to get a comparative grid that is a combination of Slide 9 and Slide 13? In particular, what I'm interested in is the comparator of the differential incomes by specialty versus the impact -- you don't have to pick all these columns -- the impact of the model on that specialty. And, in essence, the reason I'm asking is I kind of want to see are there some higher-income disciplines that are actually going up as a result of this model. I think we lose stuff when we bundle it under non-surgical, non-procedural, and

so on and so forth. I think we need a level of granularity that says where are there high-income physicians that are also seeing a rise with this methodology, because that may drive to whether we like Approach 1 or Approach 2 better -- unless we have that somewhere that I didn't see.

MR. WINTER: Yes. So we can do it on sort of by -- we tried to do it by specialty but not the individual clinician level, because we don't have their income data --

DR. SAMITT: No, no. I mean by specialty.

MR. WINTER: Okay.

DR. CROSSON: Okay. We're going to have a discussion now. Bring up the last slide if we don't have it already, Slide 17.

As I mentioned earlier, we have been at this for a long time. This is still an ongoing piece of work here. We're not going to come to conclusions in the short run, but we do need to continue to provide input to the staff in terms of preferential directions.

So what I'd ask folks to do -- and we do have to be rather direct and efficient here -- is to focus on these four bullet points, yes, no, and the like, and we've got three individuals who have asked to begin, Paul, Kathy, and

Alice. We'll start in that order with Paul.

DR. GINSBURG: Thanks. Ariel and Kevin, you did a really good job at documenting the distortions in the Medicare physician fee schedule and also the longevity, the whole history of MedPAC recommendations to fix it. But I spent a lot of time organizing a conference on the Medicare fee schedule. Very consistent with what you're talking about, you know, it has not been -- you know, the fee schedule is distorted. The problem is the updating process. There has been a slight degree of movement, but not a lot. So it brings up two main points I want to make about this.

One is that every time you used the word "primary care" and in the Commission's discussion we use "primary care," I was wincing because all of the evidence about the distortion of the fee schedule, it's not about primary care, whatever that means. It's about evaluation and management services. So that's what's being distorted. And, you know, I don't know which one -- I don't necessarily agree or disagree -- or maybe I don't agree too much with how you've -- which evaluation and management services are in primary care. But I think we should be

talking in terms of evaluation and management services. There are problems -- you know, there are real problems in the primary care workforce, problems which probably would have been much more severe if not for the recent growth of nurse practitioners and physician assistants, a fair amount of whose time goes into primary care. But I'm concerned about some of these specialties that do not have a lot of income from procedures, that they're being hurt as much. I think we can have problems with supply in those specialties, and that we should rebrand this from -- I mean, primary care is a politically hot topic, but I think we should be thinking in terms of evaluation and management services and those physicians who perform them.

What I could see doing is -- you know, this doesn't come up in Option 1, but in Option 2, I would want to include specialties which have a low proportion of income from procedures along with the primary care specialties because I think the case is sufficiently compelling.

The other point I want to make is that, you know, this 25-year experience with the Medicare fee schedule, somewhat unique among countries in the world, as I

understand it, is an attempt to use science and measurement to set relative values -- relative payments for physician services. And that's the way I would like it to be, but I'm really concerned about the results so far and the magnitude of the distortions and thinking that we may have to make some decisions not supported by measurement, just supported by judgments.

This is what the Congress did in the Affordable Care Act when they had the unfortunately temporary increase in payment rates for primary care services provided by primary care clinicians. I would have rather them do it permanently, would rather they had done it for evaluation and management services period. But in the sense I'm comfortable with diverging from the science-based approach to make ad hoc adjustments based on our judgments about access to care, supply physicians in different specialties. So I'm really very comfortable with these options of going outside the measurement.

DR. CROSSON: Thank you. Kathy.

MS. BUTO: So I'm not so comfortable with the approach. I think the chapter highlights the issues of income disparity and concern about attracting physicians to

-- wince, wince -- primary care. I don't think at its best that the solution of raising fees is really -- again, this is my judgment -- at the core of the problem with the disparity, that, yes, I think fees should be adjusted to take into account overpriced procedures and looking to value those more appropriately, including those that have time built into them that productivity has since, you know, overcome.

But that to me is just a baby step because I think the issue is bigger and goes to the fact that primary care or -- it's really primary care, or management of patients by some physician, be they endocrinologists or family practice physicians, that that is kind of at the core and at the hub of what the Medicare program does or supports, and that the spokes are things like hospitalization, post-acute care, specialty care, and so on.

I think the fundamental problem is that Medicare has never fully recognized that critical role and signaled that it's an important role and ought to be rewarded justly. I think you can get to that reward through more of a per beneficiary payment. I don't think, having thought

about this a lot recently, that you can do it for all primary care physicians or even those other specialties who do a lot of E&M services. I think you would need to start more in a more targeted way looking at can we improve the management of the most difficult patients, maybe modeled after the monthly capitation payment for ESRD, so maybe a monthly capitation payment for endocrinologists or for rheumatologists or for some of the other specialties like that.

I don't think the paper makes a compelling case that E&M services are actually per service underpaid. I think there is some good arguments in there, and I think we should be about the business of trying to make those fees and that fee schedule better. But I really don't -- I guess I can't yet get to the point where Paul is where I'm willing to just make a judgment call about how much higher payments should be, because I don't know where the ceiling is for that. I don't know where we decide primary care physicians are being paid salaries or their income is high enough in comparison to proceduralists. I just don't know where that is, and I'm not convinced that proceduralists shouldn't be paid more for some things.

So I'm struggling with that idea, and so, consequently, I'm queasy about assigning an arbitrary percentage increase, 10, 20, or 30 percent, and then taking reductions in fees from every other service or every other physician. So, really, that's my major concern.

What I would like to support is that directionally I think we all feel that these services, E&M services, and primary care physicians, that we ought to address some of the inequities in the way fees have been computed and not updated, et cetera.

What I'd like to see us do potentially in the next phase is something that looks a little bit more like partial capitation, as I've already alluded to, with the goal of increasing and highlighting the central role of management and of primary care. And so, again, I think we could start with some of those really difficult chronic diseases, and I think that helps to address concerns about risk adjustment. If you take individuals who have certain characteristics, diabetics that, you know, meet certain criteria, or people with severe autoimmune disease or something like that, you have less of an issue of having to risk-adjust -- develop an adjustment mechanism across all

patients. And then, secondly, I think it also will help focus not just risk adjustment but help us focus better on what that payment should be so it's more uniform across patients.

You can also then be pretty specific about what's in that bundle and what's not in that bundle. When we were talking at the last round, the issue of, yes, you could go with a per beneficiary kind of primary care distribution of payments, but then what's outside of that gets to be pretty murky. I think it's really hard to navigate that, and I would just imagine, you know, opportunities for abuse are there.

So I'll just finish by saying that I do think we can go quite a way -- and you've done a lot of good work in this area -- to address some of the real inequities in the fee schedule itself. But I would hope that we could go beyond that and look at, you know, a much more comprehensive approach that will raise both the position and the funding for managing patients to a higher level. And I think you could get there step-wise. You wouldn't have to do everybody at once.

DR. GINSBURG: Excuse me. Can I answer one of

Kathy's points?

DR. CROSSON: Please, but let's not have arguments back and forth.

DR. GINSBURG: Sure. I just want to say, Kathy, I think that we could come up with or the staff could come up with an estimate of the magnitude of the distortions that we have now. There's a lot of evidence that could be used so we're not flying blind in saying -- I mean, it could be -- my first choice would be to get the update process fixed up, use better data to recalibrate the fee schedule, and continue to do it science-based. But in a sense, if that doesn't happen, I could see using our best analysis of the magnitude of the distortions and saying, well, there's this distortion, Congress has shown willingness to make judgments and, you know, it's our second choice but let's do that.

MS. BUTO: Yeah, and I agree with you, Paul. I think, you know, we do coding creep adjustments. With MA plans, we've looked at creep and I think the risk adjustment mechanism. So I think that is a possible route, and I would feel very comfortable with that.

The one thing I forgot to mention that you

reminded me of is this whole issue of how do you enroll patients in a model where somebody is managing their care. And if you start with the most difficult cases and they're fairly uniform, I think the way I imagine it possibly could be done is to offer those beneficiaries with those difficult chronic conditions sort of an extra benefit. So you'll have the additional benefit, and we'll allow you to do this. You know, we'll ask you to elect among these physicians or among the physicians that meet these criteria to be that person, your go-to person for a variety of things. And I think we'd be surprised at how many beneficiaries would like that kind of option, particularly if they have multiple chronic conditions and can't figure out how to navigate.

So I don't think you have to start big. I think you could start fairly small.

DR. CROSSON: Alice.

DR. COOMBS: So the title of this presentation was "Rebalancing the Fee Schedule for Primary Care." I want to drive us back home. But we've had a discussion around the table that has varied from everything to increasing primary care physicians, increasing primary care

services, and I think we'd like to have all of those things together. But for the number one bullet that's up there, I think that I would vote in favor of that for services. And I just wanted to read a couple of recent data points.

So for M.D. to A.P., advanced practice nursing, the ratio is expected to go from 3.6:1 to half of that by 2030. So there is rapidly increasing mid-levels. I think, Amy, you asked that question. For M.D. to P.A., in 2015 it was 7:2, and it's going to go to 3.5 to -- half of that. So rapidly increasing mid-level primary care influence is going to make a difference, I think, with some of the workforce issues. However, the AAMC has indicated that we are somewhere in the vicinity of 7,000 to 43,000 deficit in primary care.

So the question is: Do we want to do something to incentivize primary care workforce? And today in the New England Journal of Medicine, November 2nd, comes out in answer to our problem, but I don't know if we're going to be that cagey to deal with it, and that is, looking at primary care spending rate, which is a very different notion, and they've actually done this in the National Health Service in the U.K., and they looked at the absolute

percentage of all your dollars and how much is put forth toward primary care.

With that being said, they've shown in Rhode Island that they've gone from 34 to 74 million poured into primary care, which gives them a primary care spending rate of about 10 percent, that their overall capital spending has gone down tremendously to a fraction, 0.6, compared to other New England areas.

So I'm wondering how we decide to look at the bucket of cash that's necessary to distribute amongst primary care services can be determined by doing a calculation looking at how much money is poured into primary care. You could do that. I think that's not a hard thing to do. If you look at all the services and you say, okay, you know, the Medicare program is 570, 600 billion, what percentage of that is actually put toward primary care?

Now, the innovative things that they did with the study is they actually looked at how they poured the money into primary care. It wasn't in fee-for-service and volume. It was in things like, you know, medical home. It was in loan repayment. And the very thing that would drive

primary care doctors to say, "I want to be a part of this whole process," it's a very different way of thinking, but it's definitely something that actually has proven in the National Health, in Oregon, in Rhode Island, and I think that it's a plausible thing. So I'd refer you to that.

In terms of Bullet 2, absolutely, and I think, you know, if you talk to psychiatrists, they have a reaction not just to Medicare but to Medicaid as well. How should payments be increased? And should higher payments be distributed on a per service per beneficiary basis? I agree with Kathy with the per member per month incentivizing overall more global care.

How much should it be increased by? I would take the benchmark of once you've figured out the primary care spending rate, look at the dollars and say how much needs to be poured back to reach these benchmarks. The U.K. is 12 percent. We may not get to that. Rhode Island was 10 percent. It's a number that actually lets you know that when you're pouring this amount of resources into the primary care world, maybe you'll get to a better place with the overall capital spending. And that's what our goal is. I mean, rebalancing the fee schedule is one piece of this,

but the big picture is how can we get to more cost efficiency in addition to taking care of the patient and getting better quality outcomes.

DR. CROSSON: Okay. We now are short of time. So we're going to have continued discussion, but I would ask people to be fairly direct in what you say. Otherwise, we risk running well over on this very busy day.

And let's start this end now. Craig.

DR. SAMITT: So just a quick sense of context, I thought of this again through the lens of the problem we're trying to solve, which is to stabilize primary care and address where we think there is a shortage of supply, and from my vantage point, that very much is in the primary care and mental health-related fields, especially if we believe that those are crucial services as we advance to population health and value.

So through that context, I would say that I am more inclined to support the targeted focus on primary care clinicians. I'd want to see the list that I asked for because, again, we're not trying to solve all of the inequities from specialty to specialty to specialty. If this is about population health transformation, it seems

like that's where the greatest need is, so I'm more inclined to say targeted. But it may be more than just primary care clinicians. I'd like to see if there are others, not all specialties.

Psychiatric services, yes. Payment increases, I think we'd start with your lower threshold, 10 percent. I mean, it seems like it's probably too aggressive and perhaps untenable to go higher, and then similar to Kathy, I would say per beneficiary.

I don't think I'd wait with any changes until we move to a more direct capitation model. I see this as a stop-gap measure. Hopefully, our ACO efforts and other strategies will move us more to population health. The reality is in certain population health settings, some high-performing systems pay their primary care physicians today more than they pay their specialists. So a movement to value may accomplish that, anyway. In the meanwhile, I think we have to correct some of the short-term imbalances. We bridge the gap through a PMPM focus as opposed to a per-service focus.

DR. CROSSON: Which I would remind people is the current standing policy of the Commission.

David.

DR. NERENZ: I'll be brief.

I do share many of Kathy's concerns about features of this, but let me just emphasize a couple things. As laid out for us, this strikes me as a very, very blunt instrument for trying to address the problem we have in front of us, particularly option 1. It basically says we're going to pay more for all the non-acute E&M services, and I absolutely agree with Paul's point. I don't think primary care is the right label for what we're talking about. I was trying to hint at that politely in my Round 1 question. And we're talking about a lot of things I'd never call primary care.

But we're basically saying we're going to pay more for all of that without differentiation, and then by rebound, we're going to pay less for everything else without differentiation.

I'm not convinced that everything under E&M is valuable or worth more money. Two examples, follow-up visits, whether it's following a procedure, following a medication change. I sit in these discussions all the time. There's no consensus usually about what the

appropriate follow-up interval is. There's on evidence-based guidelines, but here, we're saying more is better and we'll pay more, we want more. I worry about that, and I know others may feel differently. But I've seen two, three independent studies and analysis finding no value in the annual physical, so we'll pay more for that. Well, why?

So I'd certainly encourage us to be much more nuances and a lot more attention to where's the value within these categories, not just one big one up, one big one down.

And then second thing is I know we try to be behavioral economists here, but I worry a little bit about what happens sort of on the downside of this among the procedural specialists, when pay gets caught on a unit-of-service basis. A lot of places have fixed monthly practice budgets to hit or other kind of financial goals to hit. You take down the payment in each service; you're going to do more services. What else can -- and we've just said that it's relatively easy for proceduralists to do that.

So I'd have to put that in the mix as a concern. There's got to be some answer to that.

DR. CROSSON: And there's some evidence

historically that that's exactly what takes place.

Okay. Bruce.

MR. PYENSON: Thank you very much.

On a stop-gap measure, I would support items 1 and 2 up there and the broader E&M approach. I recognize David does have a very good point on the -- many of the E&M services probably have no value.

However, on a broader issue, we're not going to reach the goals of reducing cost and improving value without having an expectation of productivity improvements reducing cost, and I think we have an opportunity here to institutionalize an expectation in the Medicare fee schedule for procedures, for virtually all procedures that productivity will increase.

The default assumption is that productivity doesn't increase. That's just wrong. So I think we should institutionalize in the recommendation an expectation that procedural productivity increases.

DR. CROSSON: Amy.

MS. BRICKER: Based on what Alice shared, I'm in support of, one, focused on the second primary care clinicians, not all, and two, do want to understand, again,

based on, again, using the data that Alice shared. If we don't have a mid-level problem, let's focus the resources on the physicians and what that would mean to pull mid-levels out of this from a financial perspective.

I don't have a sense of what the payment increase should be. It does feel a bit arbitrary. I think 10 percent is a good start, and understanding what we think through that increase the outcomes would be, sort of what David said, behavioral economics.

I'm generally, though, in support of a shift, at least as a step one in a longer-term plan.

DR. MILLER: Can I get you just to say whether you have anything -- any feeling about service or per bene? I don't mean to put you on the spot, just in case you did.

MS. BRICKER: No, I don't -- if it's easy to do per bene, I think that's cleaner. I get the sense that it's everything that we construct is very difficult.

And the notion to just try to get funds allocated and out, it feels easier and cleaner on it per service, but then you could say, well, then things are just going to be abused. So I can see both sides of that, but --

DR. MILLER: So you would be fine with 5.

MS. BRICKER: Yeah, there you go.

DR. MILLER: Thank you.

DR. CROSSON: In case you haven't noticed, this Medicare business is pretty complicated.

[Laughter.]

DR. CROSSON: Virtually everything here --

David.

DR. GRABOWSKI: Similar to Craig, I want to think about what's the distortion we're trying to correct here. Is it that we underpay for E&M services, as Paul suggested, or is it that we have too few primary care physicians? Maybe both.

But I think the chapter and the problem we're trying to address here is really the latter. We have too few primary care physicians, and so I would definitely favor kind of targeting the second approach there going through the primary care docs.

I also would favor increasing payments for psychiatric services. I also wondered a little bit about geriatrics. I don't know if that's been discussed at prior meetings, but that's another area of shortage here that could potentially be addressed. And then the interaction

of the two, obviously geriatrics could be an area for targeting at well.

For the 32 issue, how much should payments be increased? I really think this comes back to my earlier comment. We want to know the response here. If you put more dollars into the system, what effect does that have in terms of entry, in terms of movement into primary care?

And then to David's point, what happens on kind of the other side there for non-primary care physicians and their shift in payments? I do think you want to look at this at a system level, but I would hope we could do some more sophisticated modeling around that behavioral response for a 10 percent increase. What's the corresponding change in the supply?

And finally, I would favor a per-beneficiary approach on that fourth question.

Thanks.

MR. WINTER: And, David, just to note that geriatric medicine is included in our definition of primary care clinicians.

DR. GRABOWSKI: And I just wanted to say whether there was something worth targeting in addition to that, if

that was above and beyond, but perhaps not.

Thanks.

DR. CROSSON: And just one note, I mean, you talk about modeling. It is a modeling question because in dealing with it experientially, given the timeline we're talking about of going through residency and training program or even before that, the expectations set in medical school and then training programs and fellowship and potentially -- we've got a pipeline length that's considerable. To get feedback from actually experience would be probably well beyond all of our times on this Commission, so it is a modeling issue. Yeah.

Dana.

DR. SAFRAN: Yeah. Thanks.

So I, too, find it most constructive to think about this through the lens of we're trying to solve access issues as opposed to we're trying to deal with payment distortions because I don't think we could deal with the latter without basically getting rid of the whole RVU system and trying something else, so that's probably a conversation for another day.

But in terms of solving the access problems, I

found what Paul said really interesting, but I don't know the data -- and I'd love to know it -- on whether we have evidence that other nonprocedural specialties are really struggling, dying off, having a hard time attracting folks, but we know that's been a problem for primary care.

I can say in our market where there's so much move towards population-based payment that that's been mitigated, that we see movement into primary care and some positive signs, so that's a good thing.

But I think primary care and psychiatric care, for sure we know that we have access issues, so I'm really in support. So that means on bullet 1, I like the more targeted approach.

It means I am a "yes" on No. 2, though I will mention that I'm not confident that we can get greater participation of psychiatrists in Medicare just by the moves that we're talking about making here because I think there's quite reasonable payments offered through commercial for psychiatrists in the market that I'm in, and still, it's not enough to keep up with what they can earn by just private pay. So I'm a little concerned that upping payment on No. 2 isn't going to help us with the

psychiatric access problem.

I don't know how much payment should be increased. I agree 10 percent sounds reasonable, but I think we shouldn't try to answer that question without trying to tie our thinking to MIP, to the whole MIPS and A-APM conversation because, you know, it does strike me as kind of ironic that we're sitting here talking about sort of doubling down on like the volume part of the incentives, and so that probably tells you my answer to the fourth, which his I would rather not put it in the fee schedule and rather have it be a PMPM.

But I also feel a little queasy about that PMPM having no performance basis to it. It's just for being in a particular specialty. So as a starting point, maybe it's just a PMPM, but I would like us to sort of have our eye on having that have some performance component to it.

DR. CROSSON: Great. Thank you.

Brian.

DR. DeBUSK: Well, I know we've talked about it a little bit in the past and touched on it today. I do think the situation with primary care is dire, dire.

To begin with, any solution that gets them more

money, whether it's approach 1 or approach 2, I'm on board with.

Having said that, Paul made a really good point in his opening remarks about trying to address the distortion in the fee schedule, and I do think if you don't address it using -- looking at the chronic care codes, TCMs, E&Ms -- well, primarily E&Ms, you're going to create these cliffs, where you're going to have, for example, an endocrinologist who acts a lot like a primary care physician based on his billing patterns and how he treats his patients, but he's not going to qualify under the targeted approach.

So I would caution you. I like the solution 1, is a little bit more "hit it over the head." It does address the distortion issue. I personally think it could be implemented more quickly because imagine if you work with solution 2, you're starting to think about, well, how do you pay the money out? Is it per member per month? Well, now you've bought all the attribution issues. What defines a patient on the panel?

To me, it just seems it would be like it would be much more technically simple to implement the approach 1,

considering that time is of the essence here. I mean, we are on a ticking clock.

And that's it. Thank you.

DR. CROSSON: Pat.

MS. WANG: Okay. If it were possible to solve this issue by fixing undervalued E&M codes, it would be great. If that's not going to happen, though, I don't think that we should let the perfect be the enemy of the good here.

My personal priority is very primary care practitioner physician-focused, and I think that I have -- I'm a little bit more of a purist in what I consider to be primary care, so certainly approach 2.

A technical question, which I should have asked, which is whether the identification of this threshold of charges or fee schedule includes MA because docs who do -- see, that to me, we should think about a little bit because I think that the goal there would be to identify, first identify what we consider to be potential primary care specialties, and I think it's general internists, geriatricians, primary care geriatricians, family practice, and then within that, this sort of threshold of primary

care practice. MA, I think is an issue about how you include that.

I think that the issue that people have raised here about sort of protecting what I consider to be specialties that practice or that delivery E&M services that people consider to be primary care, whether they're psychologists or endocrinologists or rheumatologists or whatever is a very slippery slope. And I think it's important instead of just getting everybody's favorite like whatever that they think of, it's whether there is something that we can look to in research that says this is the commonly defined universe of what's considered to be primary care.

And maybe these are the other specialties that have a very low volume of procedural services that we would want to exclude or treat differently from any payment reduction to fund the primary care bump.

Within the identification of what I would consider to be a real primary care doctor who -- that's what they do -- I would give differential treatment even within that to primary care geriatricians. I really every day believe that my Medicare members would be a lot better

off if we could have more geriatricians taking care of them.

A lot of what family docs and internists and specialist who provide a lot of E&M services struggle to do, I think is what primary care geriatricians do. It's what they're trained to do. It takes an enormous amount of time for them to do what they do, but I really believe that the Medicare program has a direct interest in trying to invest in that particular specialty, so I would actually -- if anybody were to give a bigger bump, I would try to do that to encourage more people to go in. There aren't very many geriatricians in the country, frankly.

For psychiatry, you know, I have to say unless we really think that increasing the fee schedule is going to increase participation in Medicare, I wouldn't do it. I think that the issues that people have talked about that it is much more complex, I'm sure the fee schedule is part of it, but that there are other compelling reasons that psychiatrists do not participate in insurance including Medicare. And I think that I'd want to know that doing a fee schedule bump would actually increase that level of participation so that it's more intentional.

And finally, in terms of how should the payment be distributed, I'm honestly kind of indifferent. I think whatever is easiest to implement is the way it should go.

DR. CROSSON: Thank you, Pat.

Warner.

MR. THOMAS: I'll be brief. I would agree with approach No. 2. I think anything that gets more funds into primary care is going to be favorable.

I do think having some of those funds going to psychiatric care is important. I hear Dana and Pat's point on is that really going to make a difference, but I do think it will -- we need to try to attract more folks into this area, and I think there are a lot of reasons behind it. But I do think compensation is part of that.

As far as the level, just looking at the 10 percent versus 20 -- actually, if you went 15 percent, it would actually put the impact of primary care to about 5 percent, which may be an interesting middle grown to something to consider and think about.

I would agree with Pat. I think whether it's on a per beneficiary or per service, I would encourage to just go the most simplistic route.

I would agree with Alice that mid-levels are usually not an issue from a supply perspective. So I think if you could exclude them, if that can be done in a simplistic fashion, I think that would be fine. I really think we need these dollars targeted to physicians.

DR. CROSSON: Rita.

DR. REDBERG: I will also be brief because I agree with a lot of what's already been said.

I really support the shift in payment to primary care. I like approach 2.

I do prefer the per-beneficiary basis because I think it will encourage more innovation. Like we'll be talking later about telehealth and non-face-to-face issues.

With the payment rates for all specialties versus just primary care, I will say, as a cardiologist, I do primary care, and currently, I can spend an hour talking to a patient with new onset angina about medications, lifestyle changes, lots of things, but if I went to the cath lab and put a stent in, I would get paid a whole lot more, and I don't think we want to have that kind of imbalance, though it's not just primary care where we see the imbalance. I think you want to recognize that a lot of

specialties can provide really important E&M.

DR. CROSSON: Thank you, Rita.

Jack.

DR. HOADLEY: So I like the way Paul originally sort of framed some of this. I think a lot of this, what we're really -- what I think I'm trying to do here is look at the imbalance in the fee schedule, which is why I would apply it more. I would take approach -- the approach -- I guess it's No. 1 -- the primary care services provided by all specialties, including the PAs and MPs and so forth, in this.

I think maybe one way to add some measurement or another way to sort of present some data that might help us -- you have given us sort of averages for some of these other specialties like endocrinology. We might also look at what's the share of the physicians in those specialties who are over some threshold like 50 percent or 75 percent or whatever is a logical number, they're doing primary care, because I think as somebody said before, maybe the cardiologists are divided between the ones who mostly only go do procedures, and then maybe it's only a subset who do a lot of this. And I realize that the breakout you're

proposing would use that, but this would give us a sense of, well, it's a tiny subset of this specialty that's going to qualify under these rules. I think that just would be a helpful way to think of it.

And whether there's any data we have on who beneficiaries see or who they regard as their -- we used to use the term their "primary doctor," not their primary care doctor, but the one they mostly go to for just general things, and whether there's any way in the data to sort of pull out is there one doctor they see the most or from some other survey kinds of things, just the other ways to get a sense of where others are playing that sort of primary care role.

To the other bullet questions, I'd say yes on the psychiatric services. Like many of us, I'm not sure where to go on the amount of the increase.

I would side with the per service partly for the ease of doing it, but I also think the attribution issues could get pretty complicated, partly because of some of those things I was just talking about. Are you going to pick up a beneficiary who just saw that primary care doctor once, but that's not really who they spend most of their

time with or go to for sort of general things? And I think it's just going to get complicated to try to think about attribution.

DR. CROSSON: Okay. Thank you, Jack.

In summary --

[Laughter.]

DR. MILLER: Well, this, I got to see. Go ahead.

DR. CROSSON: I'm sorry. Alice, you have one last point?

DR. COOMBS: Yeah, just real quick, three seconds.

What he just said, it makes a lot of sense in terms of if you were a neurologist and you reached a certain benchmark, maybe not the 40, maybe the 70, but I think that's an important point. I agree with you.

DR. CROSSON: I do think that we have a pretty rough agreement that there is an issue that needs to be addressed. I heard some variances of that. I do.

And I think this discussion, although we have had a lot of different perspectives here at least, it will be helpful to the staff in terms of prioritizing the next set of discussions.

As I said when we began this, this has taken us a long time. We've been at this. We have a standing recommendation that calls for a per-beneficiary payment for primary care physicians providing primary care services. This has not been taken up by the Congress so far. So the recommendation we made some years ago, which provided a 10 percent increase for primary care physicians, has not been replaced.

On the other hand, I think this discussion has been very helpful in pointing out the complexity of the situation, and quite simply, I think we are going to have to spend more time on this to try to come to a point where we can come back and either just simply reaffirm our current position or augment that with some more detailed thoughts that might be helpful to the Congress.

I anticipate us discussing this off and on throughout this cycle and perhaps well into the next cycle.

So thank you for your points. They will all be taken into consideration, and the next time we come back, maybe we can get to a little bit of a sharper focus.

So, Ariel, Kevin, thank you very much for that presentation, and we'll move on to the next discussion.

[Pause.]

DR. CROSSON: Okay. I think we can move on to the next presentation, try to catch up a little time here.

Carol Carter is here with us in the dedicated Carol Carter seat to bring us back to the post-acute care issue, and we're going to talk a little bit about a topic that I think Kathy has brought up over time here, which is given the importance and the potential impact of our broader recommendation with respect to unified post-acute-care service payment system, are there things that we should be doing in the shorter run to deal with some distortions in the provision of services and, therefore, Medicare costs within specific post-acute-care settings? So if I haven't given your presentation, take it from the top.

DR. CARTER: Okay. As Jay said, today we are going to be talking about a way to use the post-acute-care Prospective Payment System design as a way to increase the equity of payments within each post-acute-care setting. I'll outline the approach and then ask if we should include it in our evaluation of the adequacy of Medicare's payments at next month's meeting. In this work, post-acute care

includes care furnished by home health agencies, skilled nursing facilities, inpatient rehabilitation facilities, and long-term care.

I'll start with a review of the goals of the Commission's payment recommendations and outline our concerns about the current payment systems for post-acute care. Then I'll briefly summarize our work on a unified PAC PPS and describe how one element of the design could be integrated into each setting's payments as a way to increase the equity of payments within each setting.

You may ask why we would want to do this before implementing the unified payment system, and there are several good reasons to do it. First, it would begin to correct the known biases of the current payment systems and redistribute and increase the equity of payments within each setting. Providers would have less reason to prefer to treat certain types of patients and avoid others, like medically complex patients. It would also encourage providers to begin to make the changes that they will want to make to be successful under a unified PAC PPS. And, last, it would support recommendations that would better align payments to costs without undesirable impacts. Some

of you will recall that in past years, the Commission has at times been constrained in its update recommendations because of the wide disparities in financial performance across providers.

By law, each year the Commission has two goals in mind when it reports on Medicare's fee-for-service payment systems. First, it considers the level of payments and evaluates whether total payments to a setting are adequate to ensure beneficiary access while protecting taxpayers and the long-run sustainability of the program. Second, the Commission considers changes to the payment systems to improve payment accuracy and equity. Payments need to be aligned with the costs of care for all types of conditions so that providers have minimal financial incentive to prefer to treat some beneficiaries over others. Making recommendations to correct the known biases and distortions in the payment systems is another dimension of the work we do on payment adequacy and their accuracy. The accuracy of fee-for-service payments carries over to MA plans and alternative payment models, such as ACOs and bundled payments, since fee-for-service costs and service use form the basis of MA benchmarks and APM payments.

For many years, the Commission has raised concerns about Medicare's current Prospective Payment Systems for PAC. First, the level of program spending is high relative to the cost of care, with Medicare margins in the double digits for three of the settings.

Second, the current payment systems have one or more of the following shortcomings. They encourage providers to: furnish therapy unrelated to patient care needs; prefer to treat some types of patients and avoid medically complex patients; extend lengths of stay to avoid short-stay payments or, in the case of SNFs, to extent their stays; and, last, to code clinical conditions and frailty to raise their payments.

Partly reflecting differences in providers' practices, the financial performance of providers differs widely. For example, there is more than a 10-percentage-point difference in the Medicare margins for nonprofit and for-profit SNFs and more than a 20-point difference between nonprofit and for-profit IRFs. The Commission has made recommendations to correct all of these shortcomings in the past.

Other concerns about post-acute care have framed

the Commission's discussions of the need to reform the way Medicare pays for these services. First, similar beneficiaries can be treated in each of the four settings, but Medicare uses separate payment systems for each that can result in quite different payments. Further, there are few evidence-based guidelines for post-acute care, so it's not always clear when this care is needed, where the care would be best provided, how much care is required, or when more care is results in better outcomes. PAC placement decisions often reflect clinical factors such as local practice patterns, financial arrangements, and the availability of PAC in a market. Given these factors, it is not surprising that per capita Medicare spending varies more for post-acute care than for any other service, and it has led the Congress to include mandated studies of a unified payment system in the IMPACT Act.

As mandated, in June 2016, the Commission recommended a design and the design features of a unified payment system and estimated its impacts. To complete this work, the Commission used 8.9 million PAC stays in 2013 and other readily available data and focused on over 30 different patient groups defined by their clinical and

other characteristics.

We found that a unified payment system would redistribute payments across conditions, increasing payments for medically complex patients and decreasing payments for rehabilitation care that's unrelated to a patient's characteristics. The redistribution would narrow the relative profitability across conditions, and as a result, providers would have less incentive to admit certain types of patients over others.

We concluded that a unified PAC PPS was feasible, could be implemented sooner than contemplated, and would result in more equitable payments.

The broad outline of a PAC PPS is consistent with the design of any prospective payment system, which I've outlined in green. I'm going to take a minute to go over this because the mechanics are key to the approach we're going to consider to increase the equity of payments.

In the first green box, you see there is a base rate that reflects the average cost of a stay. This base rate gets adjusted up or down, based on the patient's characteristics using a case mix adjuster to reflect the stay's relative costliness. That's the second green box.

The adjusters include characteristics about the patient, including the primary reason for their treatment, their age, co-morbidities, severity, cognitive status, and impairments -- information that is readily available from claims and from an enrollment database. Other adjusters, in the third box, vary payments to reflect things like differences in wages across markets. The base rate multiplied by the case mix and the other adjusters computes the payment.

I want you to notice the relative weights in the second box because it is this part of the design that we're going to propose integrating into each setting's payments to make them more equitable.

The basic approach to increase the equity in payments across each setting is to take the relative weights of the PAC PPS and use them in setting payments within each setting.

Within each setting, payments would be calculated based on a blend of the current setting-specific relative weights and the relative weights from the unified PAC PPS. This would begin to redistribute payments across conditions. Total payments to the setting would remain at

the recommended level of spending. So this approach doesn't affect the level of payments. It's all about redistributing payments within a setting.

This chart illustrates the redistribution of payments within and across settings. I'm sorry that's so dark. This should have been in white. I don't know why. Sorry. We have the wrong version loaded here. So the implementation begins in 2021, and that's at the bottom. And that arrow shows the redistribution that would occur across the settings.

That's not what we're talking about today. Today we're talking about the green arrows, and that's about redistributing payments within each setting. Payments to each setting would remain at the recommended levels, and, again, what we're focusing on is just redistributing payments within a setting. By blending the relative weights that are in current use with the relative weights from the PAC PPS, the resulting payments would shift across conditions. Payments would be more closely aligned with the costs of care, so the equity of payments within each setting would increase.

So then going back to the mechanics, what we're

talking about is that second adjuster. We'd make changes to the relative weights, and those would affect the payments.

I want to walk through a simple illustration to see how this blending of the relative weights works and changes payments.

Okay. I can see we can't read the second line on there. All right. Imagine a provider that treats two patients. One patient has an orthopedic condition and the other is medically complex, and that's the one that's really hard to read. The top two rows show the relative weights, and the bottom two rows show the resulting payments using those relative weights.

Starting at the top, under the unified PAC PPS, the relative weight for the orthopedic condition decreases from 1.2 to 0.9. And if we blended that rate 50:50, the relative weight would be 1.05. In the second row, we show the medically complex case, and that relative weight increases from 0.8 to 1.1, and when blended, the relative weight is in the middle.

In the payment rows, you see the impacts of the changes to the relative weights on payments. For the

orthopedic case in this example, the payment decreases from $7,200 to $5,400 under a PAC PPS, and when blended, it would be $6,300.

In the next row, payments for the medically complex case increases from $4,800 to $6,600, with a blended payment of $5,700. The blending begins to shift payments across conditions in the direction the Commission has called for, while keeping total payments the same at $12,000, and you see that at the bottom. In the approach we're outlining, we've assumed the same volume and mix of patients, so aggregate payments to a setting would remain the same, but the payments would be redistributed across the conditions.

As outlined in the paper, we estimated the changes in payments within each setting if total payments remained the same, but payments were based on a 50:50 blend of the relative weights established by the PAC PPS and the current setting-specific PPSs. We focus on the impacts on providers since that's the most relevant for the update discussion.

Within a setting, payments to providers would be redistributed based on the mix of conditions they treat,

how their costs compare to the average, and their current therapy practices. Within each setting, payments would increase for nonprofit providers and hospital-based providers and decrease for for-profit facilities and freestanding providers. These shifts reflect the mixes of patients they treat and their practices, not their ownership or provider type per se.

Our work on SNFs, for example, has shown that hospital-based SNFs treat a disproportionate share of medically complex patients. Under this approach payments based on the blending of the weights would increase to them. The redistributions would have the effect of raising payments to low-margin providers and lowering payments to high-margin providers. And I want to remind everyone that at current levels, aggregate payments to a setting remain well above the cost of care.

In conclusion, it is possible to increase the equity of payments within each setting before implementing a unified PAC PPS. The redistribution would correct the biases of the current PPSs, increase the equity of payments across conditions so providers would have less incentive to favor treating certain types of patients over others, and

encourage providers to begin to make the kinds of changes they would want to make to be successful under the unified payment system. It would also support update recommendations that would better align payments to the cost of care without undesirable impacts.

Next month, the Commission will discuss the adequacy of payments for each PAC setting and make a judgment about what, if any, update is needed, just as it does every year. The Commission could also consider a policy option that would increase the equity in payments within each setting by using a blend of setting-specific and PAC PPS relative weights to establish payments.

Some of you have asked how to integrate the Commission's recommendation regarding the unified PAC PPS and its update discussions, and here is one way to do that. We would like to get your reactions to this option and whether we should include it in the December update chapters.

DR. CROSSON: Thank you, Carol. Very clear.

Clarifying questions? We'll start with David.

DR. NERENZ: [off microphone] -- sorry. Slide 14, the word "before," should we take that to mean we're

really talking about a transitional temporary approach before something more permanent kicks in? Is that what "before" means here?

DR. CARTER: What I meant here was the Commission has a recommendation to start implementing and beginning the transition to the PAC PPS in 2021, and so the "before" here refers to '19 and '20.

DR. NERENZ: Thank you. Okay. And then so as we think about sort of the full implementation of this, if we can jump back to Slide 12, the center column there, unified PAC PPS, those are the weights that then would be applied under full implementation? And the illustration here, I understand it's a hypothetical, just those two patients.

DR. CARTER: Yes.

DR. NERENZ: But what would happen for an individual provider, in fact, even during the temporary part, is if two different providers had different mixes of these two types of people, there would be money going up and down within, between providers but within --

DR. CARTER: Between providers but within a setting, yes.

DR. NERENZ: Thank you. Okay.

DR. CARTER: That's right.

DR. CROSSON: Clarifying questions? Alice.

DR. COOMBS: So I noticed there's a little bit of -- because this is the transition, so there's that gradient between the joint versus the non-joint. Are we looking at three hours of rehab and saying that it's going to be equivalent to the medically complex patient after this transition period? Is that the ultimate disposition for us to be...

DR. CARTER: I'm not quite sure. So we haven't talked about -- so is your question asking are we thinking about waiving regulatory requirements during the transition?

DR. COOMBS: Well, we talked about that already.

DR. CARTER: Yeah, okay. So you're not --

DR. COOMBS: We talked about that, so the next question is: There's still an incentive to go with the joints in the PAC --

DR. CARTER: There would be less incentive, but you're right.

DR. COOMBS: Okay. So is that --

DR. CARTER: Because we're still just blending

current incentives with future incentives, right.

DR. COOMBS: So the blend is -- do you think the blend is narrow enough in terms of the calculation? I mean, this is a transition, but are we going to go to a different type of blend, a little bit narrower bandwidth for the permanent?

DR. CARTER: So we could talk about -- and I don't know if the Commission would want to get specific about what the blend should be kind of before you begin the implementation. Once you start implementing, we talked about a three-year -- our recommendation was for a three-year transition. That's full PAC PPS rates -- right? -- folded in over three years, but you're allowing the money to get distributed across settings.

DR. COOMBS: Okay.

DR. CROSSON: Kathy, questions.

MS. BUTO: I may be missing this because I know we're doing this within settings. But let's take SNFs, for example. If SNFs have a disproportionate number of patients whose care is being overpaid because of rehab services, for example, when you go to a blend with a unified PAC, won't the total money involved, even at a

50:50 blend, won't that potentially go down for the whole category of SNFs?

DR. CARTER: No, because we've actually made -- you could adjust the relative weights in a way that --

MS. BUTO: So we're deliberately keeping it budget neutral, is what you're saying.

DR. CARTER: Yes.

DR. MILLER: Exactly. You're out of model holding it neutral to each [off microphone].

DR. CARTER: Yeah.

MS. BUTO: Got it. Okay. I know that's more acceptable, but I think --

DR. CARTER: Yeah.

MS. BUTO: -- my preference would be to take the next step.

DR. MILLER: Your preferences have been clear throughout this process.

[Laughter.]

DR. MILLER: But you see what we're trying to do here. We're trying to accommodate those preferences and then also stay within the silos for the short term until we get to the bigger -- right.

DR. CROSSON: Questions, questions, questions, question. Pat.

MS. WANG: This is going to be very imprecise. When you did the first set of work you showed some of the changes that would result from implementation of the full PPS across sectors and shifts based on the condition of the patient. Do you feel like doing this for a couple of years, where within the sector payments would shift, changes the, in some instance, kind of makes the transition to the full PPS more traumatic rather than less? So in the example of SNF, if certain services get a payment increase because of this interim, and then the full thing happens, a SNF has been living with increased payments for its medically complex patients, but then, when the full thing comes in, it drops even more precipitously than it would have because money is shifting out of the sector.

Is that a concern that we should have about the transitions, because I think, you know, one of the things that all of the providers are going to have to sort of adjust to is sort of managing their businesses with different levels of resources. So if there's a temporary boom because the sector is overpaid, and since it's budget

neutral within the sector it's like wow, you know, this is great, you know, is there a potential that the cliff will be even steeper, when the whole thing --

DR. CARTER: I don't think so. I think what this is really going to get providers thinking about is decreasing the amount of therapy that's not related to patient characteristics. That's the biggest change that's going to need to go on under a unified PAC PPS. This puts their toe in that water, because it is a baby step towards doing that.

So I think the kinds of changes in practices that a provider is going to need to take on are -- would be the incentives here. So they are moving -- what you were suggesting is sort of, oh, these things take us in one direction and then we're going to be going here, so the drop is going to be even larger, and all of these incentives, actually, are parallel.

DR. CROSSON: Warner.

MR. THOMAS: So on Slide 12, and I may have missed this, and if I did I apologize, explain to me exactly how you're getting what the -- are there different categories than the two? I mean, do you see having more or

would it just be the two categories?

DR. CARTER: Oh, no. So we would be using all of the patient characteristics that we've been using. I just showed two here.

MR. THOMAS: That's what I thought, so it would be -- you know, so, I guess, how do you see setting that weighting? I mean, what exact process would you use to --

DR. CARTER: Well, you could do something fairly simply like calculate what the current payment would be, which is how, when a claim comes in, CMS processes that claim, and then you could take that same claim and run it through the alternative, that is the new unified payment system, get that payment, and then do a blend.

MR. THOMAS: But in the new payment system you're coming up with a weighting.

DR. CARTER: Well, that would just be a weighting of the two different payments, yeah.

DR. MILLER: Warner, are you asking like where do those unified PPS weights come from?

MR. THOMAS: Correct.

DR. MILLER: Okay. So one place they could come from, Carol, is --

DR. CARTER: Well, I mean, our design has --

MR. THOMAS: It sounds like you have an idea.

DR. CARTER: Well, we have a payment system that would be calculating payments.

DR. MILLER: She produced these weights as part of the report that we did on this.

DR. CARTER: Yeah.

DR. MILLER: We wouldn't insist and say, CMS has to use those weights, but that's a place they could go to. We could turn that research over to them and the weights over to them, or they could replicate them in some way.

MR. THOMAS: Okay.

DR. MILLER: But there is a set inside Carol's office right now.

[Laughter.]

DR. CARTER: Yes, there is.

DR. MILLER: And, Warner, if you want me to take you over there, I'll show you.

DR. CROSSON: Okay.

MR. THOMAS: I'm sure I don't have clearance, so, you know.

[Laughter.]

DR. CROSSON: I've got Paul and Alice.

DR. GINSBURG: Just one clarifying thing. I was wondering if one of the advantages of doing this is that it opens up another pathway to reform. I mean, there's the ultimate reform, which is the unified PPS system, but if there should be resistance to that it's possible that there could be less resistance to this and at least you start making these changes that are part of the big system. And I like the fact that it's phased because we're -- this is for '19 and '20, and the full system isn't scheduled to be implemented until '21.

DR. CROSSON: Alice and then Dana. Alice.

DR. COOMBS: So, Carol, your last trip at the rodeo we talked about home health, and this is really huge because there is such a trend now for same-day joint surgery and discharge home. So I was wondering if we were going to model that juxtaposed to the other options.

DR. CARTER: So in this scenario we have just assumed constant volume. But what you're suggesting is payments to a setting might not remain the same if there are fewer patients going to SNF, and that's --

DR. COOMBS: I am telling you the train has so

left the station with people going home after same-day joint surgery --

DR. CARTER: Right.

DR. COOMBS: -- and we've got to upscale it to say that, oh, they have to go to the ERFs or the SNFs or whatever. But that -- we talk about the advent of a new intervention and how the cost of something post-PAC will change.

DR. CARTER: Mm-hmm.

DR. COOMBS: I think this is an area that we could be ahead of the curve and kind of simulating that.

DR. CARTER: Right. And, of course, the redistribution would still happen for the cases that still remain in the setting. But I think what you are suggesting also points out the importance of recalibration and revising the weights over time, because we know the practice patterns are shifting already, and they're going to continue to shift. And I know Anne and Kathy really pushed for us to have, in our recommendation and that whole discussion, how important it is to revise and rebase and recalibrate. And so you're sort of making that point and I think it's a good one.

DR. CROSSON: Dana.

DR. SAFRAN: So this is a new topic for me. I wasn't here for your last rodeo, so I'm just trying to get caught up.

So my question is with respect to the changes that are scheduled to take effect in 2021. It sounds like there's some question around the table about whether that will really happen, and so that prompts my question about whether doing this makes it more or less likely that the 2021 changes will actually come to pass. And if it makes it less likely, kind of how far down the field does it take us that we're doing this first?

DR. CARTER: So in 2021, is our recommendation, but CMS is not required to do that. In fact, the Impact Act required studies of a unified payment system but didn't actually require one to be implemented. So that's sort of our timeframe. But there's -- you know, there's been no action, shall I say, at least so far, about something actually being implemented in 2021.

I do think that this kind of redistribution is something that would be desirable anyway.

DR. CROSSON: Okay. So we're going to proceed

with the discussion now. I'm thinking that we haven't heard a lot of opposition to this proposal, but the proposal is that if we have significant amount of support here then as we take on the post-acute care discussions in December and January that, in addition, as Carol has pointed out, and to just doing the update recommendation, that this be included as a policy option within that.

So if there's significant disagreement with that idea, I'd like to hear that, and if you want to augment support that's fine as well.

David's going to start.

DR. GRABOWSKI: Great. Thanks. First, Carol, great job, as always. That was really super. I'll start by saying, Jay, that I'm very supportive of this kind of incremental step towards implementing the unified PAC, so count me as supportive.

I just wanted to provide a little bit of context, because I think there's distortions at two levels in post-acute care. There is within-sector distortions and then there's across-sector distortions, in terms of how we pay and deliver services. So the within post-acute care sector, for example, SNFs, we tend to value and pay for

therapy at the expense of medically complex patients, and so that's the sort of within-sector type of distortion.

Then we have this across-sector distortion as well, where, you know, you think about skilled nursing facilities and inpatient rehab facilities. The same patient may be paid very different across those two sectors with unclear impact on their outcomes. So, ultimately, the unified PAC system will correct both of those distortions. By 2021, Kathy, you'll have your full correction there.

But in the meantime, I like this step, and I think there's actually some experience in implementing post-acute care payment reforms incrementally, going back to the skilled nursing facility prospective payment system. That was implemented when we moved from cost-based to prospective payment in 1998. We did it in 25 percent increments, so we had this one --

DR. CARTER: Then we jumped very fast.

DR. GRABOWSKI: Then we jumped very fast. That's right. But it went, you know, kind of in -- and my sense is that was a positive, and I think going here, in that same incremental fashion, could also be a positive, whether that's kind of one-third in 2019 and then two-thirds in

2020 and then the full step in 2021. I like that approach.

My final comment, and I think it's a really important one and timely, is around budget neutrality, and it goes back to Kathy's point. I do think we need to hold this budget neutral within each of the sectors. We just saw yesterday that CMS announced they're not going to go forward with home health -- new home health payment model. That payment model is different than what we're proposing here but it shares some similarities in that it was going to pay higher rates for medically complex patients and sort of less for therapy. It also was going to take about $1 billion annually out of the home health payment system.

So I think there's obviously going to be winners and losers, as Carol described, but I don't think we want to pull dollars out of -- we don't want to shrink the pie. We may want to reallocate. But I think that's very important that we keep this budget neutral.

So, once again, I am very supportive of this and I'll stop there. Thanks.

DR. CROSSON: Thank you.

DR. MILLER: Can I add just one clarification? So the way we've been talking about budget neutrality

throughout this presentation is that you come in like you do as a regular order, you evaluate the sector, and you say, you know, this sector, no update, or this sector, an actual reduction. Then this distribution is budget neutral to that decision.

DR. GRABOWSKI: We're on the same page, yes.

DR. MILLER: That's what I wanted to know. Thank you.

DR. CROSSON: Okay. So the question on the table is, is there enough support for bringing this policy option forward in December and January? Discussion? Kathy and then Alice. I saw thumbs up from Craig.

MS. BUTO: Yes, I would definitely support that. I think this is great work. The only thing I'd ask us to leave open is, you know, as whoever the Commissioners are in 2019 and '20, if it looks like we're not going to get the full PAC PPS, then I think it is time to look at the issue of budget neutrality across sectors, that broader issue, or even within sectors. I guess you'd start there first. So looking at not just keeping everybody -- every sector or setting whole.

But I do very much support the idea of

introducing this in January with the updates.

DR. CROSSON: Okay, Kathy. Alice, Paul.

DR. CARTER: But I just wanted to make one point. Of course, some of your level conversation with the update will get at that issue. Right?

DR. COOMBS: Well, I just want to go on record to say I support it.

DR. CROSSON: Okay. Paul.

DR. GINSBURG: Yes, I'm very enthusiastic about this and I've been reflecting about the question Dana posed, about whether this will make it easier to do the whole thing later. I think it will, because I think this is going to get some of the adjustment out of the way, so, in a sense, the full system will be less daunting if we've already done this.

DR. CROSSON: Further points? I've got some thumbs up and then we've got Jack first and then Warner.

DR. HOADLEY: Some very brief. I mean, I am very enthusiastic about this approach, and like Paul, I think the answer to Dana's question is, yes, it moves us in the right direction. Now I suppose politically, at some point you could say if we get close somebody may say, well, we're

close enough. But I think that's, you know -- that will still be judged on its merits, and it just means it's less disruptive, so hopefully less reason for stakeholders to push back if, you know, if some of the changes have already been made.

I do think -- I'm just thinking about Pat's question, and I wonder if it's worth checking to see if there are any cases -- I think they would be rare -- where this step would push somebody upwards where they would eventually come down under the unified, just because that sector is coming down, but they might fall just on the positive side within the sector. Just to be aware of that. I suppose you could even say if that was the case then we won't do it, or something. But mostly it would be just a reassurance that that's quite rare.

DR. CROSSON: Okay. Warner.

MR. THOMAS: I think directionally I'm in favor. I would like a little more clarity and transparency around the weighting and how that is -- at least how the proposal is put together, or what the methodology or the thinking is behind how that weighting would come forward. I'm not sure if we're going to make a recommendation around how the

weighting ought to occur or the fact that it would just be essentially budget neutral within that discipline and then CMS is going to, you know, going to generate the whatever weighting they determine.

So I just would like to understand more about that. But directionally, you know, I agree.

I would just like to comment on Alice's point that I think it's important that, you know, as we see, you know, more and more components -- you know, more and more care in the hospital that's really being done on more of an outpatient basis with follow-up home care versus going to a post-acute facility, that I think we need to make sure that we are funding that appropriately. Because, once again, I think it's probably a more intensive home care process for the beginning components of that post-outpatient, you know, if you're thinking of some sort of joint replacement. So I think we want to make sure that that's funded appropriately so that we continue to see folks get discharged to home and have the appropriate home care that's funded right, versus going to another inpatient setting, even though it's a post-acute.

DR. CROSSON: Okay. Thank you. A good

discussion, Carol. Thank you again for a good policy option clearly presented, and I think you have the support you were looking for. So we will be looking forward to your presentations in December and January.

And we will move on to the last presentation of the day.

[Pause.]

DR. CROSSON: Okay. We're going to move on to the final presentation today, and that's a relatively new issue for the Commission. We're going to be looking at durable medical equipment, specifically the issue of non-competitively bid medical equipment, prosthetics, orthotics, and supplies. That's easy for me to day.

[Laughter.]

DR. CROSSON: Brian is going to start off.

MR. O'DONNELL: Good afternoon. This presentation continues the Commission's work on medical devices. The Commission's June 2017 report to Congress and the presentation at last month's public meeting focused on providing a broad overview of the medical device market and policy issues surrounding implantable medical devices.

Today I'll discuss another segment of the device

market: the market for durable medical equipment, prosthetics, orthotics, and supplies, referred to collectively as DMEPOS. DMEPOS comprises a large number of products that vary in cost and complexity, ranging from complex power wheelchairs to diabetes testing supplies to knee braces.

For background, I'll first review the two main ways in which Medicare sets payment rates for DMEPOS products -- through a fee schedule and through the Competitive Bidding Program, or CBP -- and also provide an overview of Medicare spending trends for those two broad categories of DMEPOS.

I'll then present some analyses suggesting that Medicare's payment rates for DMEPOS products paid on a fee schedule basis are likely excessive.

Finally, I'll discuss and seek the Commission's feedback on potential policy options to address those excessive payment rates and protect beneficiaries.

I'll begin with a discussion of how Medicare sets fee schedule payment rates.

Medicare's current fee schedule is largely based on average reasonable supplier charges from 1986 and 1987.

The fee schedule payment rates are not routinely evaluated for accuracy and instead have been mostly updated for inflation over the past 30 years.

DMEPOS fee schedule rates have often been excessive. OIG and GAO have issued numerous reports over many years demonstrating that Medicare's DMEPOS fee schedule rates have often been far higher than rates set by many other purchasers, suppliers' costs, and the direct purchase price -- that is, the price at which beneficiaries could purchase the device outside of insurance coverage.

Excessive payment rates resulted in rapid growth in expenditures and high rates of inappropriate utilization and potential fraud and abuse. In response to these trends, Congress required CMS to implement the Competitive Bidding Program, or CBP.

CMS has the authority to phase in CBP starting with the highest-cost products or those products with the highest potential for savings. However, CMS is prohibited from including certain DMEPOS products in CBP. I've listed several of those products on the slide.

And just a little bit of foreshadowing here. Some of the products that I'll be talking about in a few

slides were not among highest-cost products when CMS first developed CBP, while others are statutorily excluded from CBP or CMS has faced industry pressure not to include them in competitive bidding.

CMS was also required to phase in CBP in terms of the area covered. So in 2011 the agency implemented the first round of CBP in nine large urban areas. Since then, CMS has expanded the number of areas included in CBP so that, as of 2017, the 99 largest urban areas are included in CBP.

CMS is also required by statue to use the information from competitive bidding to adjust fee schedule rates for products covered by CBP but for beneficiaries who live outside the 99 largest urban areas.

The next slide summarizes the impacts CBP has had on prices, volume, and beneficiary outcomes. I've included more details on these topics and the structure and criticisms of CBP in your mailing materials.

Since CBP was first implemented in 2011, payment rates have fallen substantially. Among the 25 highest-expenditure items, rates have declined by a median of around 50 percent from 2010 to the most current round of

CBP.

CBP has also resulted in substantial utilization declines. For example, after studying a CBP round that was implemented in July 2013, GAO found that the reduction in volume was higher for the same products in competitive bidding areas versus non-competitive bidding areas.

CMS has routinely stated that no negative changes in beneficiary health outcomes have resulted from CBP. CMS bases this finding on its monitoring of secondary outcomes, such as emergency department use, for beneficiaries who use CBP products, beneficiaries who might need to use CBP products, and all fee-for-service beneficiaries.

Moving on from the background, this slide provides an overview of the spending trends of those two broad categories of products I just reviewed -- those included in CBP and non-CBP products.

As you can see in the second row of the chart, Medicare expenditures for products included in CBP decrease by 42 percent from 2010 to 2015. The decrease in expenditures has been particularly dramatic for certain product categories. For example, expenditures for diabetes testing supplies fell by 79 percent over the same time

period.

In contrast to these large declines, expenditures for non-CBP products have increased steadily over time, growing a total of 24 percent from 2010 to 2015. Given these divergent trends and the history of abuses among products paid on a fee schedule basis, the next three slides examine non-CBP products for evidence of excessive payment rates. If products have excessive fee schedule payment rates and are supplied by multiple companies, they could be good candidates for competitive bidding.

To evaluate whether products had excessive payment rates, we mainly focused on the highest-expenditure non-CBP products, as Medicare spending is concentrated in these products. For example, roughly half of Medicare spending on non-CBP products was concentrated in the top 25 products in 2015.

To evaluate the pricing accuracy of those top products, we conducted two analyses. First, we compared Medicare's payment rates to private payer rates; and, second, we looked for rapid growth in utilization and spending, which are classic signs of excessive rates, as suppliers are encouraged to bill for highly profitable

items.

So for our first analysis, we compared Medicare's fee schedule payment rates for the top ten DMEPOS products in 2015 to the median private payer rate for the same products in the MarketScan database, which is a database of private payer claims. We found that Medicare's payment rates were higher than private payer rates for nine of the ten products we examined.

For those nine products, Medicare's payment rates were anywhere from 18 percent to 57 percent higher than private payer rates. For example, Medicare's payment rate was 35 percent higher than the median private payer rate for bone growth stimulators. For the products we examined, we estimate that Medicare would have saved roughly $192 million in 2015 if Medicare's payment rates were equal to private payer rates. Additional savings beyond this estimate are likely position for a few reasons.

First, Medicare payment rates for products outside the top ten are also likely excessive. For example, Medicare would have saved an additional $47 million in 2015 if Medicare rates were equal to the median private payer rate for off-the-shelf orthotics outside the

top ten. And, second, private payer might more appropriately represent an upper bound on Medicare rates rather than an ideal rate.

Our second analysis examined the growth in volume and expenditures of non-CBP DMEPOS products because rapid growth in volume and expenditures can be a sign of excessive payment rates. Among the ten highest-expenditure non-CBP products, the average growth rate in expenditures was 21 percent from 2014 to 2015.

For several products, the rapid growth was part of a longer-term trend and continued into 2016. For example, Medicare expenditures for an off-the-self back brace grew from $46 million to $190 million, or more than 300 percent, from 2014 to 2016.

Before moving on to the discussion of policy options, I'd like to note that three or more suppliers billed for all but one of the top 25 non-CBP products in 2015, suggesting that including these products in CBP could lower payment rates as suppliers would be expected to compete with one another based on price.

So given the seemingly excessive payment rates we found, the rapid growth rate for many products, and the

abundance of suppliers for most non-CBP products, the first option for the Commission to consider is encouraging CMS to use its current authority to include more products in CBP and expand the agency's statutory authority to include other products in CBP.

As I discussed in your mailing materials, it would likely take CMS several years to include many new products in CBP because, for instance, the agency would need to develop special rules for certain products. So including many more items in CBP could be thought of as a medium- or long-term option.

To address excessive payment rates in the short term, the Commission could consider an option of immediately reducing payment rates for those products that will eventually be included in CBP. The payment rate reductions could continue on an annual basis until Medicare's payment rates are roughly similar to private payer rates or the items are included in CBP.

This next policy option for the Commission to consider is not directly related to reducing excessive payment rates. Rather, the option is designed to better align balance billing and participation rules for the

DMEPOS sector with the rest of Medicare and to add a protection for beneficiaries who use DMEPOS products in situations where assignment is not mandatory. But before I review the option, I'll give some background on the issue.

Participation and assignment rules are different for DMEPOS compared to many other Medicare services.

First, outside of CBP products used by beneficiaries from a competitive bidding area, assignment is not mandatory, meaning that suppliers do not have to accept the fee schedule rate as payment in full and can balance bill beneficiaries.

Second, there is no limit on balance billing. Other providers face limits on how much they can balance bill. For example, physicians are limited to balance billing 115 percent of the physician fee schedule.

And, third, DMEPOS suppliers do not face a penalty for enrolling as non-participating. In contrast, physicians who enroll as non-participating face a 5 percent reduction in the allowed amount under the physician fee schedule. Non-participating suppliers can accept or reject assignment on a claim-by-claim basis; whereas, participating suppliers accept assignment on all claims in

a given year.

So the option for the Commission to consider is to cap balance billing at a percentage of the fee schedule rate and to reduce the allowed amount by 5 percent for non-participating suppliers.

So this last slide just boils down some of the information I've talked about today. Roughly half of all Medicare spending on DMEPOS is for products that are not competitively bid, and our analyses indicate that many of those products appear to have excessive payment rates.

To address this, I discussed a policy option of shifting many products currently paid on a fee schedule basis to competitive bidding and to reduce the payment rates for those products while CMS works on incorporating them into CBP.

I also highlighted another policy option that is intended to align balance billing and participation rules for DMEPOS suppliers with the rest of Medicare and to further protect beneficiaries.

I am seeking the Commission's feedback on the policy options discussed today and the Commission's suggestions for any further context or analyses that should

be added to the current mailing materials should these findings be incorporated into a June chapter.

With that, I look forward to your comments, and I turn it back to Jay or Jon.

DR. CHRISTIANSON: Thanks, Brian.

Let's start with Jack and work our way around this way this time for clarifying questions.

DR. HOADLEY: So I have two. One, do you have a number of the share of overall Medicare expenditures that's represented by this category of spending?

MR. O'DONNELL: No, I don't, but you could take whatever, $8 to $10 billion divided by, you know, $570 billion, or whatever the number is.

DR. HOADLEY: It just always seems useful to have that as a context-setting thing. We sometimes talk about that in some of the other areas.

The other thing, I don't know that this was in your slides, but in the mailing material you talked about $42 billion total savings over ten years that was $25 billion in program and $17 billion for beneficiaries, which is about a 60/40 ratio, which surprised me given the general 80/20 thing. Does that reflect the balance billing

issue, or does that reflect some other things going on?

MR. O'DONNELL: So that number is a CMS estimate, but what I think it reflects is, you know, the 80/20, right? So part of that 80 percent being paid is beneficiary premiums, so I think it reflects that, that premium effect.

DR. HOADLEY: Okay. Thank you.

DR. CHRISTIANSON: Rita.

DR. REDBERG: Thanks. A very well done chapter. I was just curious. Maybe I missed it. Do we know what percentage are non-participating suppliers?

MR. O'DONNELL: Right, so I have the share of claims that were paid on a non-par basis, which is 60 percent. I haven't calculated the share of providers. I could do that on a tax ID level or on an NPI level. But from conversations, I think it's right around that same level as the claim percentage. But that's just anecdotal. But I can calculate that for you.

DR. REDBERG: If it's not too much trouble.

MR. O'DONNELL: Yeah.

DR. REDBERG: And the other, do you know why in the MMA certain categories were excluded from competitive

bidding, like Class III devices?

MR. O'DONNELL: Right, so I've asked that question multiple times, and I've tried to read the Committee report, and I don't think it was, you know, particular to certain concerns. I mean, it has kind of a topical appeal, like Class III devices are serious maybe. So maybe they were just being overly cautious. But I haven't found a great answer for you, is what I found.

DR. REDBERG: Okay. We'll stay tuned.

DR. CHRISTIANSON: Warner, any clarifying questions? Pat?

[No response.]

DR. DeBUSK: And if this was in the reading, I apologize --

DR. CHRISTIANSON: Mic, please, Brian.

MS. BRICKER: If this was in the reading, I apologize, but I read through it a couple of times and couldn't find it. The off-the-shelf orthotics portion of the non-competitively bid items, what percentage does that make up?

MR. O'DONNELL: So if you look at the off-the-shelf orthotics the way CMS defines it, in 2015 it was

about $400 million in total allowed charges. So total non-CBP is about $4 billion, so, you know, 10 percent.

DR. DeBUSK: Okay. So about 10 percent of the $4 billion is -- I'm obviously very familiar with that industry. I just wondered what it was. Okay. Thanks.

MR. GRABOWSKI: I was really taken by the section of your report on critiques of the competitive bidding process. We didn't talk about this in the policy options, but is that something that we could think about in terms of recommending that they make some changes? I mean, the bids are non-binding, as you write. The prices are set -- they use a median price rather than the pivotal bid. Composite bids are used. The system lacks transparency, so there's a lot of issues. Maybe this is a Round 2 comment. I'm tucking it into Round 1. Or maybe it's politically not viable, but I'm curious as to why we can't think about making recommendations here.

DR. MILLER: It's going to start a fight between Jon and me, which I'm always happy to have.

[Laughter.]

DR. MILLER: But maybe it's better done in Round 2?

DR. CHRISTIANSON: Yeah.

DR. MILLER: We'll talk about it in Round 2.

DR. DeBUSK: Let me ask you a question. What [off microphone]?

[Laughter.]

DR. CHRISTIANSON: David, do you have anything else for this round?

MR. GRABOWSKI: No, no.

DR. CHRISTIANSON: Okay. Amy.

MS. BRICKER: More on the question that Brian had around off-the-shelf. Is it just orthotics that have a cash price or other things have a cash price, direct-to-consider price?

MR. O'DONNELL: So in the paper, we highlighted orthotics as an example, but certainly, you know, you can look at direct purchase prices for other items. So in the past, I know people have looked at the direct purchase price for some diabetes testing supplies, for instance, but I didn't in my paper.

MS. BRICKER: But would you say the majority of the non-CBP products are available direct to consumer? You're not going to go out and buy an AED or defibrillator,

but, okay, aside from that, like most things -- can you do that?

DR. MILLER: Jim is.

MS. BRICKER: Can you do that?

[Laughter.]

MS. BRICKER: Does Amazon sell these?

[Comments off microphone.]

MS. BRICKER: Okay. Well, some other thing that I -- a ventilator? I mean, do you buy these things on Amazon. A ventilator.

DR. REDBERG: You can get almost anything you want [off microphone].

MS. BRICKER: Okay. Good to know. Okay.

[Laughter.]

DR. MILLER: Would you like us to get you one? We're going to get some [off microphone].

MR. PYENSON: I understand there's some drugs that are categorized as DME, and I'm curious what they are and whether there's a sort of -- how that's defined, if there's more drugs that could be considered DME and brought into competitive bidding.

MR. O'DONNELL: Right, so just for context, there

are drugs that are infused or inhaled with DME, and just as background, I think relatively recently -- so those used to be paid on AWP up until the last couple of years or year or two. It was one of the last vestiges of being paid at AWP. So they were recently switched or transitioned to paying 106 percent of ASP now. So payment changes have occurred for those drugs, just as context. But CMS does have the ability to include infused drugs, DME infused drugs in competitive bidding. And I think there's a heart drug that's kind of top-billed as of a few years ago. But they haven't done it to this point, and I suspect at least part of it was because there were some changes going on in payment reductions for those drugs that happened in the last couple of years.

MR. PYENSON: So what's a DME-infused drug? What does that mean?

MR. O'DONNELL: So the DME would be like the pump that you purchase, and then the pump, you would kind of administer the drug through the pump.

MR. PYENSON: For example, insulin that's used in a pump would flow through the DME --

MR. O'DONNELL: That's right.

MR. PYENSON: -- or inhalers that come with a device, is that --

MR. O'DONNELL: So like a nebulizer?

MR. PYENSON: Yeah.

MR. O'DONNELL: You use drugs with a nebulizer would be an example of an inhaled drug.

MR. PYENSON: How about a handheld? Not the nebulizer, but --

MS. BRICKER: Inhaler.

MR. PYENSON: Inhaler.

MS. BRICKER: Yeah.

MR. O'DONNELL: Yeah. I don't think that's -- I don't think that's a DME. That's a --

DR. HOADLEY: It's a drug.

MR. O'DONNELL: Yeah.

DR. HOADLEY: The drug is the device.

DR. CHRISTIANSON: Kathy.

MS. BUTO: Brian, I just wonder how much authority CMS has to make some adjustments. I think you mentioned sort of phasing in to using the commercial price as at least the upper limit. Is that something they could do under current authority? I know there is inherent

reasonableness authority, but that's very cumbersome to actually do. Do they have authority under the DME competitive bidding to do something like that?

MR. O'DONNELL: So I think the answer is no. So sans the inherent reasonableness authority, which you already know about, I think that the fee schedule is the exclusive payment rule for DME not included in CBP. So I don't think they could do that without some kind of legislative authority.

MS. BUTO: Do you have an overall savings amount related to -- if they were to set, if Congress were to put a limit on payment for DME at the commercial -- widely available, I guess, commercial price, do we know if there is significant savings there?

MR. O'DONNELL: Right. So I've only done it for kind of a thimbleful of products.

MS. BUTO: Yeah.

MR. O'DONNELL: And that's all I could really speak to now.

DR. CROSSON: Questions? Alice.

DR. COOMBS: Brian, I was curious. Certain states have balanced billing rules and regulations, and

Massachusetts is one of them. There might be other states as well. Does this sector have the same -- does this follow the sector for a balanced billing for physician fee service? In other words, in Massachusetts, can you balance-bill for this kind of thing as well?

MR. O'DONNELL: Right. So that's a good clarification, and I was referring to kind of the federal policy. So if there are state-based things, I didn't highlight those.

DR. COOMBS: So I was just curious because if there are other states that have no balanced billing on this type of equipment, that might be important because that would be one of the limitations.

DR. CROSSON: Okay. Seeing no more questions, we're ready to proceed with the discussion. I'd point our attention to the center of the slide, which is the two or three policy options, depending on how you look at it.

And I would request CMS to add more products to the competitive bidding process and produce rates in the interim. You can divide that, if you wanted.

And then the issue of beneficiary protection related to balanced billing.

And I think we've got two requests to lead the discussion. Brian first and then Rita.

DR. DeBUSK: Well, thank you, and congratulations on a very well-written chapter.

I want to start off by making a couple of blanket statements about the noncompetitive-bid items. I think, in general, it is very good policy to expose those items to market forces. So I think the idea of moving forward with CBP is a good one.

Having said that, I would also take care because I think depending on the product segment, I think the tactics that we're going to have to use are going to differ a little bit, and I'd like to build on something that David said. I wouldn't advocate a complete overhaul of CBP, but I would advocate that we make it a little more clever, make it a little more effective.

And by means of example, you know, I work in two segments, one that has been through CBP, negative pressure wound therapy, and then for 45 years or so, basically virtually my whole life, I've been in prefabricated bracing and orthotics. And it's interesting to see because I think the application in negative pressure was very, very

effective, and I think what made it effective was at the end of the day, the machine does one thing. It creates pressure, negative pressure on a wound to remove exudate and encourage healing.

And poor choices made along the supply chain in that case, for example, if someone makes an economically poor decision -- they buy a machine that maybe is lower cost, higher maintenance -- the brunt of that is felt by the DME provider. They basically have to live with their choices.

Bracing -- and this is again only a 10 percent segment of the non-DME post-bid items. But I'd like to -- hopefully, there will be some generalizations that we can take from this. Bracing is an area that has a tremendous number of degrees of freedom. For example, the L code descriptors vary very widely, and, you know, David, you really set the precedent of this when you brought a prop because I had to bring a prop. Okay? I'm inspired.

[Laughter.]

DR. DeBUSK: This is an L3908. It's a wrist and form splint. You can't really see it from here, but it's got a metal stay in it. This is for carpal tunnel. This

is for sprains. We've all had them.

Well, this is also an L3908. This is not going to get the job done. It's about a quarter of the price, but you'll see within that category, within the same billing code, literally, a 400 percent difference. And so it's always easy to say, well, if you look at this product, it's overpaid, and by the way, there's no question there are inductive effects created by overpayment in this sector. Hopefully, that didn't get taken too far out of context, but I will repeat it. There are inductive effects created by overpayments in this area.

The issue, though, is there's also latitude in how they even choose to bill for this brace. So for example, I can conservatively code it or I can aggressively code it, and the challenge here -- and again, I think this would apply broader to other CBP areas. The challenge is you've got so much latitude in how you want to manipulate the margin on any given billing code, and you've got a large number of very good actors in this industry. I mean, the physicians, the hospitals that are trying to put these braces on, and the vast majority of the DMEs are trying to do the right thing.

The problem is you get a small number of bad actors in a segment where the margins can be so easily manipulated. If we just take a "hit it over the head" approach and cut the rates across the board, which by the way will reduce program spending, one of the problems is you're going to penalize the good actors. Well, the bad actors are simply going to adjust their behavior.

I mean, Mark made a joke earlier about how quickly they can adapt. They can do that in 30 days. This industry will adapt.

And I'll give you another good example. For example, there are a lot of parallel codes between customs and off-the-shelf prefabricated. A great example is a back brace. Well, the industry has been preparing to make the leap from prefab to customs for years now. I mean, we've anticipated that coming.

If you take an off-the-shelf back brace and you pull the support out of the back of it, the vast majority of them are Kydex. They're already thermoformable. That brace, as it's shipping to you today, they're ready to flip that switch and turn that into a custom product.

So I just want to emphasize when you see

something with this many degrees of freedom -- one is a physician's office trying to conscientiously use a brace for conservative treatment as opposed to opioids. There's another segment that's just a mail order house that's advertising on late night TV about a brace that can be shipped at little or no cost to you. There's this huge delta of how these margins can be manipulated.

We've all seen them. Actually, one of our people in the negative wound pressure segment, she came from Liberty Medical, and she was telling me, she said, "The competitive bid people, all they need to do is watch 'Jeopardy,' 'Wheel of Fortune,' and 'Matlock,' and they can get everybody they need to put out to bid. It will be right there."

[Laughter.]

DR. DeBUSK: But anyway, that's pretty much the technology that they use.

Anyway, back to my original point, I think in some of these situations -- and I think bracing would be one of those examples -- I think we need to get clever, and we need to figure out how to rein in some of those practices and to be specific like let's narrow the L code

descriptor so that this and this don't get the same code. Let's require PDAC letters on more products. Let's look at preauthorization for some products. Let's put some type of face-to-face or some type of visit-based encounter in before a brace and even be prescribed.

Let's also, for example, try to keep the prescribing and the dispensing closer together. For example, I don't lose a lot of sleep over hospitals or physicians prescribing a brace to their own patient on their own premises because when the patient opens up that bill, he's going to see the name of that physician's practice on the copay. There's almost a check-and-balance there. You can't dispense a low-quality product, charge -- up-code it at a very high rate. You still have to deal with that patient. That's much easier to do when you're a mail order house a thousand miles away and you're never going to lay eyes on the patient.

So my one recommendation -- this is why I want to circle it back to CBP. I think it's a great program, and I think it's been very successful. There are some people who would feel like, well, it's a somewhat flawed program applied to a somewhat flawed industry. And I would want to

point out that two wrongs still don't make a right.

I mean, Medicare should adhere to a higher standard. It's been a very successful program. I hope to see it continue. I just would advocate that we make it smarter because I think there's a real opportunity there to make it smarter and ultimately more effective.

DR. CROSSON: Rita.

DR. REDBERG: Thanks.

I would also like to compliment you on a really excellent chapter.

Before talking -- which I support the recommendations to move towards more competitive bidding, but as always, I'm always interested in not just the price, but what are beneficiaries getting for this?

I looked at the list that's in Table 1 of the mailing materials, and a lot of these devices have no data actually showing patient benefit. For example, the bone growth stimulator, that was the Class III. So Class III means it went through a premarket approval of the FDA.

So I looked up the summary of safety and effectiveness that the FDA publishes, which is what they base the approval. So this bone growth stimulator, there

were 323 subjects randomized, 25 percent dropped out, including died, noncompliance, broken hardware, suicide, and they didn't follow -- they didn't include them. And they say the success or failure of those is not known, obviously, because the dead ones are not -- it's pretty clear.

These unavailable data could possibly or negatively affect the overall success of the study. Then the whole endpoint of the study was an x-ray done, profusion at 6 months which they said was different, but then at 12 months, there was no difference between the two groups in this x-ray. And they had a clinical endpoint, and at no time was there any difference between the two groups for this clinical endpoint. And that's just one example. I could go on and on.

But I will just tell -- I mean, the enteral formulas, there's no data that -- and we're trying to get away from all of this enteral and parenteral nutrition because there is no data that it improves outcomes, and it often just makes people miserable for all kinds of different reasons, the same with the oxygen.

So even before we look at payment, I think the

appropriateness and sort of the benefit is, unfortunately, we're talking billions of dollars here when you add all of these up, and then, of course, the prices -- I mean, I remember when I worked in the Senate in 2004, we had a hearing on power wheelchairs. Actually, Herb Kuhn, one of our former Commissioners, spoke because he was at CMS and at the hearing, and besides the fraud and abuse -- and again, the front-end abuse, I should say, as you put in the materials, is there for bone growth stimulators, but it's also this was about fraud and abuse. It's actually, in a sense, taking our taxpayers for a ride, the story of the power wheelchair.

[Laughter.]

DR. REDBERG: But at that time, it said Medicare was paying like $1,200 for these wheelchairs, and you could get them online for $300, I believe. That was 13 years ago.

So I think I don't see why Medicare is paying more for these prices than you can get online, by private payers, or anywhere else. It's clearly not a benefit to the program or beneficiaries. We're all concerned about solvency and value, and those are some clear examples.

So I support the options to add more products. I don't, as I said, understand why some things are excluded from the competitive bidding process, and to add the beneficiary protections and also to try to go to more sort of value-based payment because I think some of these are just not worth anything.

DR. CROSSON: Thank you, Rita.

Brian, if I could just return to you one second. I don't want to put words in your mouth, but I want to see if I understood what you were saying with respect to the policy options that we have in front of us. So I'm going to say what I think I heard, and then tell me if that's right.

That in terms of adding more products to the competitive bidding process, since you feel it's a pretty good process, you would be in support of that with some provisions.

In terms of reducing rates across the board, you would not be in favor of that at sort of a large, across-the-board, interim, not specific level. You might be in favor of it once some of the corrections in the coding that you described were put in place.

And in addition to that, you have some additional ideas about how Medicare expenditures could be improved in this area, which you would like to add.

And lastly, I didn't hear you say anything about the beneficiary protection piece.

DR. DeBUSK: I would support the beneficiary protection piece.

DR. CROSSON: Did I summarize it correctly or not?

DR. DeBUSK: You did.

I noticed the reading material spoke to this idea of doing a precut. I would like to achieve the same or better level of savings but do it through using that couple of years that we need to clean up the billing practices and the coding practices. I think you'll easily get -- I think the reading materials maybe was talking about an 8 to 9 percent -- was it 9 percent? What?

MR. O'DONNELL: Ten.

DR. DeBUSK: Ten. Okay.

I think you'll do vastly better than 10 by applying that, by making the billing practices, by tightening those up, and getting rid of some bad actors.

Then I think what you would do is take the net result of that and then subject that to competitive bid, because then you won't have those same people who can adapt their practices so easily.

I think that an up-front cut is a great blunt hammer, but I think you're going to push the good guys out of the market and probably keep the bad guys, if not -- if anything, double them down.

DR. CROSSON: Right. So since you're knowledgeable in this area, as we evolve this policy -- and I assume that you would be helpful in providing some more specifics to the staff about your ideas.

DR. DeBUSK: I can get very, very specific.

DR. CROSSON: I know that.

[Laughter.]

DR. CROSSON: I know this would come very hard for you.

DR. DeBUSK: I'm not a details guy.

[Laughter.]

DR. DeBUSK: Thank you.

DR. CROSSON: Okay. Thank you.

So now we're open to a broader discussion. Let's

start over this way this time. Jack.

DR. HOADLEY: So I like the direction we're going here. I thought this was really helpful material. I certainly learned a lot from it.

I think the comparisons of how much the prices came down with the competitive bidding -- I remember when the competitive bidding was just cranking up, and there were all these issues about getting it started, but I hadn't really seen sort of these results. And it's impressive, and I think it's particularly impressive with the decline in utilization that came along with it. So often, we figure, well, you lower the price; there will be generated volume to make up the difference. And there's another logic. You've articulated why that may play out differently, but so often we lose on volume when we make progress on price.

And I'm certainly open to the kinds of suggestions Brian has to refine the short-term things.

I'm very much in favor of the beneficiary protections, and I think my default would be to go to the levels that the physician now in billing rules has. That's worked well on that side, and I think that's important.

It is an interesting question that Alice raised about what's going on in some of the states. Of course, there's balance -- I mean protections for commercial insurance in a number of areas. I think there's only a couple of states that have had their own sort of Medicare balanced billing rules, but as you pointed out, Massachusetts is one. But I have no idea either whether that was applied to this particular sector. So I think that's just a useful thing to have in the context.

But this is really helpful. I think we're moving in a good direction.

DR. CROSSON: Other comments?

David.

DR. GRABOWSKI: I wanted to pick up on my comment from earlier during the first round. Brian, you called this a flawed program for a flawed industry, and I think -- is there a way to correct some of the flaws in the current CBP? I don't know if that's an additional policy option, so I'll put that out there.

I will say before kind of stopping that I am supportive of both adding more products and adding those beneficiary protections, but in adding more products to the

CBP, I would like to see it strengthened. Some of the issues that Brian raised in the chapter and his critiques on page 15, could we think about recommending some corrections there?

Thanks.

DR. CROSSON: Paul, I'm sorry. I missed you, passed you buy.

DR. GINSBURG: It's fine because I was going to raise the issue about the -- and have Jon and Mark discuss some of what they've said before about refining the option process as to whether that -- but otherwise, the program is very impressive, what it's accomplished in savings, and despite very strong political opposition.

DR. MILLER: Hold that thought.

DR. GINSBURG: Yes.

[Laughter.]

DR. GINSBURG: Despite very strong political opposition.

I think especially as revised by Brian DeBusk, I think I'm very much in favor of the policy options.

DR. CROSSON: Okay. Amy.

MS. BRICKER: I am in support of the

recommendations, also in support of where David was going around reform. I'm very interested in what Brian can teach us about the details that you referred to you, and this is your world. I'm interested in your perspective.

One of the things that struck me with respect to this comparison of what's available on Amazon or what have you is that in drug reimbursement, it's customary for when you're reimbursing pharmacy so you're paying for drugs, you do lower of logic, lower of the contracted rate or the cash price. Medicare should get the benefit of that.

So I don't know if what I'm missing is the providers that are billing Medicare are not the providers that are selling these direct, and if that's the case, then that won't fix it. But if it happens to be the same entity that will bill Medicare and also bill direct to a cash payer, we should be given the benefit of that and also encouraging beneficiaries in the interim that they don't have to use their benefit. I mean, can you just not be a Medicare beneficiary in that case and take advantage of the cash price that's considerably less than presumably what would be the exposure you would experience if you had gone through the plan?

So I don't know all that I have suggested there, if that's doable and possible, but I'm just drawing those parallels with respect to how we pay for drugs.

DR. CROSSON: Other comments?

[No response.]

DR. CROSSON: Okay. Seeing none, Brian, thank you for introducing us to this topic. There is more work to do. I think we'll spend probably a year or more working this through before we're done.

I'm sorry. Did I miss someone?

DR. MILLER: So you want to do that bidding thing? Go to David's question.

DR. CROSSON: I'm sorry.

DR. GRABOWSKI: I think you were out of the room.

DR. CROSSON: Oh, okay.

DR. GRABOWSKI: I raised this bidding issue in the first round, and they told me it was the second round. I tried to take advantage of Jon when you were out of the room.

DR. CROSSON: Oh, okay. I'm sorry. Go ahead.

But Jon didn't bite.

[Laughter.]

DR. GRABOWSKI: No, Jon didn't bite, and so Jon and Mark were going to go back and forth on this issue of bidding.

DR. CROSSON: And what did they conclude?

DR. GRABOWSKI: They didn't. They haven't.

DR. MILLER: Do you want to --

DR. CHRISTIANSON: Sure. I'll start.

So I have a little history on this. Way back when they started contemplating competitive bidding for this and also for the lab, they brought me together with a couple of more theoretical competitive bidding experts to advise them on how they should design the competitive bidding system for DMEPOS. And we came up with some very -- a set of very elegant, I thought, recommendations, none of which they really followed. And a lot of them were along the lines of what you saw there, with this letter, you know, in the chapter with the letter of how to do bidding better and so forth. And then I also was brought in later to go visit some suppliers and see what they were thinking about their strategies for competitive bidding for DMEPOS.

So my takeaway from this is that a lot of this

stuff that you would do in a competitive bidding system with a more standardized product to maximize the value of the system really weren't needed here. I mean, I'm amazed at the results that got -- with the competitive bidding system design that they used. And I guess -- and then we had a discussion about why they didn't do some of the stuff that we thought would be useful to do, and Mark was explaining somewhat the politics of it, from the standpoint of CMS, and why they couldn't go all the way down the road and do a competitive bidding system, like setting the price for government securities and other things like that.

DR. MILLER: Yeah, so the -- and I want to be clear that I think I understand enough of the economics that I agree that, in the abstract, it would be better to do it the more theoretically pure way. And as I understood the argument at the time it came to this, the way the auction, or bidding works is you have a series of binding bids. So each person steps up and says, "I will bid $100 per bed and I will provide 25 percent of the market for hospital beds in this MSA." And then you accumulate bids up until you've covered 100 percent of the market, and then you say, "That's my price and these are my people." Okay?

And if you bid was above that, you're out, and you've covered 100 percent of your market.

The theoretical point is it's a binding bid. I can't walk away. This market, I would be worried, and particularly early on, that people could walk away. You know, so if I say I'll do 25 percent of the market and then I'm gone, what is the government's recourse? And I could pursue you and, you know, try and put you -- fine you, and whatever the case. But meanwhile, if I were the administrator of CMS -- I know that's unnerving -- but if I were the administrator of CMS I have a 25 percent gap in my market.

And so the flexibility to take that price and say, okay, I can bring in another supplier, and then with the results that occurred -- I mean, Brian, the average kind of reductions that we were getting --

MR. O'DONNELL: Fifty-ish.

DR. MILLER: Fifty-ish, price reductions, clearing whole sets of providers who weren't good enough to qualify and get into the bid -- I saw that as a huge success, and given the political resistance, like go and stand and declare victory. Now maybe it's far enough along

that, you know, people could revisit it, but I do want to say, there is still considerable resistance out there, and lots of people who have complained about access for the beneficiary, and to me, that's the Achilles heel, and leaving some flexibility for that administrator to say, "No, I'm bringing in another bed supplier because I've got a gap," I felt like was evil worth entertaining.

DR. CHRISTIANSON: Yeah, you raise a good point, too, because to qualify to be a bidder you had to submit a lot of information about you, and I think CMS really didn't have that information before. And the folks that weren't able to do that were not able to bid, and, as you said, it kind of cleaned out a lot of that from the market. And that was a positive effect of the way they designed the system.

DR. DeBUSK: If I could build on that -- they have come a long way in making sure that qualified bidders -- they're not there yet but they're doing better. I can tell you, firsthand, the day they announced negative pressure wound therapy bid winners, there were companies calling us, saying, "We have no volume, no business. We've never done this before. We've never bought a unit. But we

won bid. Would you like to buy our company now?"

[Laughter.]

DR. DeBUSK: And there was an industry, a cottage industry that popped up around building these paper companies to participate in negative -- in the competitive bids, so that you could sell them off.

DR. CHRISTIANSON: The reason for that was they were so concerned that they wouldn't get bids in that initial round that they were welcoming a lot of bids from a lot of different folks, but over time they --

DR. DeBUSK: Well, now you can actually create somewhat of the opposite effect. Let's say that you're very well established in, say, wound care and negative pressure wound therapy, and now you want to take on bracing. Well, if you can't answer the question that you have bracing in that business, even though you've dealt with an even more difficult segment, now you're on the outside looking in. So you can -- you know, that door works both ways.

MS. BUTO: I'm just going to say, Mark, that I thought, in the original -- and maybe Jon knows -- design, they built in extra capacity. They didn't just go up to

100 percent but went beyond that, so they would have extra capacity in case somebody dropped out.

DR. MILLER: That is, but that was the complaint. The complaint was this isn't the true market clearing price. You could get a lower price. So there was a big push when this was being --

MS. BUTO: Right.

DR. MILLER: -- you know, implemented, and there was a set of economists, led by economists, I think from the University of Maryland, if I'm remembering properly, who were saying, this is not the pure model. You've done this little boost and you could get a more, you know, correct market clearing price.

MS. BUTO: Right. But, you're the government --

DR. MILLER: If 40 or 50 percent --

MS. BUTO: -- you've got to cover your bets.

DR. MILLER: Yeah, 40 or 50 percent reduction, and you had the latitude to cover the beneficiary, I thought was like a worthwhile tradeoff, was my view. But I also want to acknowledge, to any of the economists and purists out there, they are right. You can probably get a cleaner market-clearing price using a strict 100 percent.

DR. CROSSON: Paul.

DR. GINSBURG: Yeah, actually, from our perspective, this is probably a topic that's hard to get policymaker attention to, and that there seems to be a lot more upside in bringing more items into the competitive bidding than we find in the competitive bidding. So I'm comfortable just focusing there.

DR. CROSSON: Okay. Good discussion. Brian, thank you for bringing this to us. I think you've got some good input here, and we'll look forward to the next iteration of this topic.

We've come to the end of the sessions and so now we have time for public comment. If there are any of our guests who wish to make a public comment on the items discussed this afternoon, please come forward to the microphone so we can see who you are.

Seeing none, we are -- I'm sorry. Come, come, come. Let me give my little speech first. Just to point out, not necessarily to you but to the audience that this is an opportunity to provide input. It's not the only one and it's not necessarily the best one. The MedPAC staff is open both in person and through electronic communication to

input prior to the discussion that we have here. But we do offer this opportunity. I would ask you to say who you are and the organizational affiliation you have, and confine your remarks to about two minutes. When this light comes back on that will be the end of the two minutes. Thanks.

MS. NUSGART: Good afternoon. My name is Marcia Nusgart. I am the Executive Director of the Alliance of Wound Care Stakeholders. We represent all the clinical associations whose members treat patients with wounds. Wound care is multidisciplinary, so we have the vascular medicine, vascular surgeons, podiatrist, physical therapists, nutritionists, nurses all under one umbrella.

But we are also a member of the Alliance for HCPSC Coding Reform. So I would suggest that when MedPAC and its staff, and all of you, start thinking about other products to add -- and I didn't have the opportunity to see which products you're really thinking about because I didn't see the chapter, obviously -- but exactly -- I want to echo what Brian had said, and the fact that you are absolutely spot-in in terms of before one adds any other types of products to competitive bidding, coding is aligned with payment, and one needs to be able to perhaps recommend

that CMS needs to reform its HCPCS coding system, because the trend for CMS is to be able to take disparate products and instead of giving a new billing code or a HCPC code for a specific set of products, it will give a code that will say "any type."

So exactly what he had said, he was absolutely correct, is that you'll have disparate products, many defined technologies under one particular HCPC code, and it's -- they are all very different, and yet it will only have one price.

Just to let you know that in a 1998 GAO study, the Need to Overhaul Costly Payment Systems for Medical Equipment and Supplies, they summarized the current process results and codes that are so broad as to render CMS unable to identify what products Medicare contractors are reimbursing when they process claims.

So we would ask you to be able -- before you decide to be able to do that, we are happy to serve as a resource and we'd be happy to be able to meet with any of the MedPAC staff to be able to address this. And again, we have a whole group of people that can help you with this.

So thank you very much. We appreciate your

attention.

DR. CROSSON: Thank you. Seeing no one else at the microphone, we are now adjourned. We would ask our guests if they could move along and we'll be finished with this meeting in due course.

[Whereas, at 4:22 p.m., the meeting was recessed, to reconvene at 8:30 a.m. on Friday, November 3, 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, November 3, 2017
8:34 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
DAVID GRABOWSKI, PhD
JACK HOADLEY, PhD
DAVID NERENZ, PhD
BRUCE PYENSON, FSA, MAAA
RITA REDBERG, MD, MSc
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AGENDA PAGE

P R O C E E D I N G S

[8:34 a.m.]

DR. CROSSON: Okay. Good morning, everybody. I think it's time to begin our morning session. Welcome back, Commissioners, and welcome to our guests.

We have two topics this morning. The first one is going to be a discussion of the treatment of biosimilars in Medicare Part D. Rachel and Shinobu are going to present, and Shinobu is starting up.

MS. SUZUKI: Good morning. Today Rachel and I are going to discuss policy issues related to biologics and their follow-on products, or biosimilars, in Part D.

We first discussed this topic in the fall of 2016. At that meeting, we discussed how certain Part D policies may affect the takeup of biosimilars in Part D, one of which was related to the price distortions created by Part D's coverage gap discount program.

In April of this year, the Commission again discussed this issue. At those meetings, we heard a general consensus for policies to treat the biosimilars and their reference products in the same manner. So based on your feedback, we are coming back to you with a Chairman's

draft recommendation.

In this presentation, I'll provide a quick review of some of the background materials on biologics and biosimilars and spending and use in Part D.

Rachel will describe Part D's coverage gap discount program as it relates to biosimilars and how that might affect the plan incentives to use biosimilars. She will review the Commission's 2016 recommendations that could help address some of the issues around plan incentives and also present the Chairman's draft recommendation.

The term "biologics" refers to therapies derived from living organisms and manufactured through biological processes. It includes a wide range of products such as insulin and therapeutic proteins used for conditions such as cancers and inflammatory diseases like rheumatoid arthritis and multiple sclerosis.

Biologics are typically injectable or infusible, and they tend to have high prices. Biosimilars are follow-on products that are highly similar to the originator biologic. As with generic drugs, biosimilars may be an important means for improving access while keeping the

spending down by introducing price competition.

But biosimilars are different from generics in important ways. Because of their complexity, biosimilars are not exact replicas of the originator product. But it should also be noted that even a manufacturer of an originator biologic may experience lot-to-lot variations.

Part D covers biologics that are self-injectable and dispensed through an outpatient pharmacy. Part D plans include their estimate of spending for biologics as part of the bid they submit to CMS for delivering the drug benefit.

Medicare pays plans a monthly capitated amount based on bids, and Medicare also provides individual reinsurance by taking on the risk of enrollees with high drug use and spending by paying 80 percent of spending above the out-of-pocket threshold.

From the combination of Medicare's payments and enrollee premiums, plans pay pharmacies rates they've negotiated with them. Plans also negotiate rebates with manufacturers.

Enrollees who use high-priced biologics tend to reach the out-of-pocket threshold, often early in the year. After that, they pay 5 percent of the price, which can

still be a lot of money. For example, above the out-of-pocket threshold, a drug that cost $5,000 per month would mean out-of-pocket cost of $250 per month. Medicare pays for 80 percent of that price for the remainder of the year, so the taxpayer bears most of the cost of the high price and use.

This table shows spending and use of biologics in Part D. In 2015, Part D's gross spending for biologics, before rebates, totaled $18.7 billion, accounting for nearly 14 percent of total Part D spending. This is up from 8 percent in 2011. That's a growth of 29 percent per year, which is much higher than roughly 13 percent for Part D program as a whole.

Notice that prescriptions for biologics as a share of total has remained stable at less than 2 percent during this period. This means that prices are driving the growth in spending for biologics.

Three categories of biologics account for nearly 80 percent of spending for biologics: insulin and therapies for inflammatory diseases like rheumatoid arthritis and multiple sclerosis. Those three categories accounted for nearly 90 percent of the growth in spending

for biologics between 2011 and 2015.

Insulin makes up the largest share -- about 60 percent 2015, followed by therapies for inflammatory conditions and multiple sclerosis. Between 2011 and 2015, average prices for medications in these three categories grew by between 16 percent to 20 percent annually.

We discussed some of the hurdles that biosimilars may face in gaining market share in our previous sessions. They're also summarized in your mailing materials. The remainder of this presentation will focus on one specific Part D policy: the coverage gap discount. If biosimilars are going to win much in the way of market share, their manufacturers will need to get on the Part D plans' formularies. Generally, you would expect plans and PBMs to be excited about biosimilars because we expect them to have lower prices than the originator and offer highly similar therapeutic effects. Putting lower-priced therapies on formulary or on a preferred tier is what plans and PBMs do to keep premiums low.

However, this coverage gap discount program only applies to originator biologics and not biosimilars, which distorts their relative prices. From a plan's perspective,

this means it will often be preferable to put the originator product on its formulary. And from a beneficiary's perspective, under current rules the enrollee is likely to have higher cost sharing with the biosimilar.

Now Rachel will show you how this works.

DR. SCHMIDT: This slide shows the Part D benefit structure in 2020, with an originator biologic on the left and a biosimilar on the right. We're looking at 2020 because that's the year that Part D's coverage gap is scheduled to be phased out.

Let's focus first on the right-hand side -- the biosimilar. You can see that the coverage gap is phased out because the enrollee (in light blue) pays a consistent 25 percent cost sharing all the way from just above the deductible until she reaches the catastrophic phase of the benefit. Generally, only the enrollee's own out-of-pocket spending counts towards the out-of-pocket threshold, not supplemental coverage. This is called "true out-of-pocket." So this orange area shows what is counted towards the out-of-pocket threshold for the biosimilar. After the enrollee reaches the threshold, she pays 5 percent, her plan covers 15 percent, and Medicare pays for 80 percent

through reinsurance.

Now let's look at the originator biologics on the left. Notice the gray area in the middle. That's the 50 percent discount that the manufacturer pays in the coverage gap. It only applies to the originator biologic, so there's no gray area on the right. Under current law, that discount is counted as true out-of-pocket spending. It gets added to the enrollee's cost sharing for purposes of determining when she will reach the catastrophic phase. So here the orange area shows what's counted towards the out-of-pocket threshold for the originator biologic. You can see that by including the manufacturer discount, the enrollee reaches the catastrophic phase at a lower level of total spending than the biosimilar.

Now from the plan's perspective, they're only responsible for covering 25 percent in the coverage gap for the originator biologic compared to 75 percent for the biosimilar. So that's one financial advantage in favor of the originator. But, in addition, since the originator biologic pushes the enrollee into the catastrophic phase at a lower level of spending, after that point Medicare starts paying 80 percent, and then the plan only has to cover 15

percent. So that's a second way this is a financial advantage to the originator over the biosimilar. You can see that Medicare reinsurance pays for more of the originator.

This slide has a different view of what we just saw, using a numerical example from your mailing materials. It is comparing an originator biologic (on the top) and a biosimilar (on the bottom). Note on the left that the invoice price for the originator is $30,000, and the manufacturer offers a 20 percent rebate. The biosimilar has a price that's 15 percent lower ($25,500), and its manufacturer also offers a 20 percent rebate. If you look along the axis at the bottom of the chart, the length of the bars reflects those prices net of rebates. If there was just this simple comparison and the two products worked equally well, the plan would want the biosimilar on its formulary because it has a lower price. But that's not what happens.

The bars show the sources of funding for each product after you apply the Part D benefit structure, from the beneficiary cost sharing, manufacturer discount, plan benefits, and Medicare reinsurance. In the top bar, you

can see that the originator biologic has a light gray piece to it. That's the manufacturer discount. There's no gray area or discount in the bottom bar for the biosimilar. The darker parts of the bars show what the plan is responsible for covering, and you can see that the plan liability is much larger for the biosimilar than the originator. That's because the manufacturer discount gets counted as though it were the enrollee's spending, so she reaches the catastrophic phase more quickly. The plan sponsor has a strong financial incentive to put the originator on its formulary. The flip side is that Medicare reinsurance is paying a bigger proportion of the spending.

Now let's look at a different policy option in which the coverage gap discount applies to both products. You can see this by the fact that there's now a gray section in both the top and bottom bars. Also under the policy option, the discount would not count as true out-of-pocket spending for either the originator biologic or the biosimilar. This is consistent with the Commission's 2016 Part D recommendations, which I'll review in a minute. With standardized use of the coverage gap discount, incentives are better aligned. Now, the plan liability for

the biosimilar is a little bit lower than for the originator biologic because it's reflecting the fact that the biosimilar has a lower price rather than a lopsided manufacturer discount. A lower plan liability means plan sponsors would be more inclined to put the lower-priced biosimilar on their formulary. Under the policy, Medicare would also pay lower reinsurance.

This chart compares current law with the policy option. Under current law, shown on the left, the 50 percent discount applies to brand-name drugs, including originator biologics, but does not apply to biosimilars. Also under current law, that 50 percent discount gets counted as though it were the enrollee's own out-of-pocket spending -- again for brand-name drugs and originators, but not biosimilars. The right side shows the policy option in which the coverage gap would apply to biosimilars as well as originators. Consistent with the Commission's 2016 recommendations, the option would also discontinue counting the 50 percent discount as true out-of-pocket spending for brand-name drugs, originators, and biosimilars.

We've focused on brand-name drugs and biologics because they account for about 75 percent of gross

spending. Kathy, when we've talked about this before, you've asked why we don't apply a discount to generic drugs, too. One reason is that even though we've seen some big price increases for certain generic drugs, in general generics' prices are relatively low. We don't want an exit of generics. They're an important source of price competition. Given that prices for brands and biologics are relatively high, a 50 percent discount for them in the coverage gap can be sizable, but the discount would not be nearly as large for generics.

In 2016, the Commission recommended a package of changes to Part D, some of which relate to the coverage gap discount. The Commission recommended changes because we saw that Medicare had been taking on more of the benefit risk over time, and there's been rapid growth in Medicare's reinsurance payments. The core idea was to give plan sponsors greater incentive and more tools to manage spending for enrollees who reach the catastrophic phase.

I'm not going to go through all the details, but I want to point out those bullets that are highlighted here. One part of the recommendation was to discontinue counting the coverage gap discount as true out-of-pocket

spending. At the time, we talked about how the coverage gap discount disadvantages generics relative to brand-name drugs and acts in a similar way as a co-pay coupon, encouraging beneficiaries to use higher-priced therapies. But we also recognized that some enrollees would pay more in cost sharing. To put a limit on that burden, the recommendation eliminated cost sharing about the out-of-pocket threshold. That same dynamic would take place under the policy option I just described. Some beneficiaries would have higher cost sharing, but there would be a hard out-of-pocket cap. We think that these pieces of the 2016 recommendation would work in concert with the Chairman's draft recommendation that I'm about to show you.

So the draft recommendation reads: The Congress should change Part D's coverage gap discount program to require manufacturers of biosimilars products to pay the coverage group discount by including biosimilars in the definition of applicable drugs and exclude biosimilar manufacturers' discounts in the coverage gap discount from enrollees' true out-of-pocket spending.

We do not yet have an estimate of the spending implications of this option. We will consult with

Congressional Budget Office. Remember that few biosimilars that fall under Part D are as yet on the market, so the near-term savings are likely to be small. However, over the longer term, we expect more entry of biosimilars that would be covered under the pharmacy benefit, so savings could be larger. We think the draft recommendation would send better price signals and could make it more likely that Part D plan sponsors put lower-priced biosimilars on their formularies.

Relative to current law, manufacturers would pay more in discounts. Medicare would continue to pay the same 74.5 percent subsidy for Part D, but there would be more spending covered by plan liability and Medicare's capitated direct subsidy payments would be higher, and there would be less spending covered by Medicare's reinsurance. Enrollees with spending that reached the coverage gap would have higher cost sharing because the manufacturer discount would no longer count as their spending. However, under the Commission's 2016 recommendation, Part D would eliminate cost sharing above the out-of-pocket threshold, so there would be a hard cap. Because prices for biologics have been increasing faster than for Part D as a whole, that

hard cap would become more valuable over time. And to the extent that the Commission's recommendations led to net program savings, policymakers could consider lowering the out-of-pocket threshold.

Going forward, after your conversation today, we will take your comments and make any necessary revisions. Then we'll be back in January, when we would normally present a status report on Part D, for you to vote on a draft recommendation related to the coverage gap discount. Our intent is to include this as part of the Commission's March 2018 report to the Congress.

DR. CROSSON: Thank you, Rachel and Shinobu.

We're now open for clarifying questions. Okay. I saw Kathy and then Jack and Paul.

MS. BUTO: Thanks, Rachel and Shinobu. Do we know what's actually happened in practice, even though there are very few biosimilars, in terms of Part D plans putting them on formulary or not and what the experience has been with the use of biosimilars?

MS. SUZUKI: So it's a little bit early, and it's not technically biosimilar, but we have checked a couple plans' formularies for Basaglar, the insulin analog that's

now a follow-on product, and it depended on the plan. Some plans did have that on the formularies; others did not.

DR. SCHMIDT: But it's kind of a special case because it was approved through a different pathway, and technically, that manufacturer is subject to the coverage gap discount.

DR. CROSSON: Jack.

DR. HOADLEY: So I just wanted to clarify on Slides 9 and 10. On 10, you're very specific about sort of incorporating the 2016 recommendation in terms of the brand-name drugs. On Slide 9, where you're showing the policy option, you're not incorporating the reinsurance, the shift in the share of reinsurance that's in our 2016 recommendation. Is that right?

DR. SCHMIDT: Right. This is just applying the coverage gap discount and the true out-of-pocket treatment.

DR. HOADLEY: So, I mean, it might be useful at some point just to have even if it's a second version of that graphic to show if our -- if all of our recommendations were taken into account, what would this look like? It might just be useful to illustrate the sort of joint effect.

DR. CROSSON: Yeah, I think, you know, just maybe as a philosophical point -- I don't know -- we very much consider these recommendations as part of our -- you know, as an extension of but in many ways part of our recommendation in 2016. So our hope would be that if this totality of recommendations was considered by Congress, that they all be taken together.

DR. HOADLEY: Right, and that's why I thought it would be useful sort of where we're showing the effect of our policy option, we could show it alone if we want to, but it would also be useful to show it in conjunction with those other recommendations.

DR. CROSSON: That is the intent.

DR. HOADLEY: Exactly in that spirit.

DR. CROSSON: Paul and Brian.

DR. GINSBURG: Yeah, I was wondering if the current policy with the way that the manufacturer's 50 percent discounts, you know, does not affect the patient cost sharing is analogous to the coupon issue outside of Medicare, where in a sense the Medicare program does not permit coupons, but as far as the deal in Part D changes under the ACA, the Congress actually permitted a coupon

scheme within Medicare for drugs in the coverage gap.

MS. SUZUKI: We agree with that, that it does act -- by lowering the cost sharing for the beneficiary at the point of sale and getting them to the catastrophic more quickly, it has the effect similar to co-pay coupons.

DR. CROSSON: Brian?

DR. DeBUSK: On Chart 7, I thought that was a really good graphic for describing the incentives and how to align -- well, actually, the whole presentation was, but that chart really brought it to a head about the misalignment of incentives. And I really appreciate where you're taking us, you know, again, trying to correct these market price signals.

Is there another layer here, though, when you look at how these plans, particularly when a PBM puts together a formulary -- is there another layer here that we could be missing around the rebates that get paid on, say, a preferred brand versus on a generic? Is there one more set of misaligned incentives that we should at least be aware of or factor into our calculations, and could you speak to those?

I'm a little bit interested in particular about

the Pfizer and J&J lawsuit regarding Remicade. That would be a great one to focus on. Could you speak to that?

DR. SCHMIDT: I don't know that I can speak to that particular case, but the general issue about rebates, we had a presentation -- was it April? -- where we kind of described some of that. And I think Bruce has brought up this issue before about how the Medicare program makes a decision about how much of the rebates to hold onto to offset its costs of reinsurances versus how much the plan retains. I don't know if you remember that conversation or not.

So the way that allocation takes place now, we have some concerns about it's more generous to the plan, perhaps, but I don't know that that's getting at what you're asking.

DR. DeBUSK: What I was looking at is let's say you have a biologic that is on, say, tier 5, but it's paying a very generous -- or it's paying some type of rebate back to the PBM, which again has to be handled through DIR.

What happens of a biosimilar comes in or a generic in general? This isn't really restricted to

biologics. They want a more favorable place on the formulary, on the tier, but due to the rebate -- I mean, basically, there could be a rebate, an incentive that would encourage the plan or the PBM to want that higher-tier drug. Again, I need to dig in a little bit more on this Remicade thing, but it seems like there were sort of some overwhelming barriers that that particular biosimilar was going to have to come up with to overcome that originator biologic.

DR. SCHMIDT: Yeah. I think I've seen financial analysts refer to that as a rebate trap, where, yeah, you could lose all of your rebates on one drug if you switch to the biosimilar, and they're very sizeable, indeed. So that is a big problem.

DR. DeBUSK: And again -- and I'll get off this subject for a second -- I love this work. I would just hate to see us maybe not take that next step where we claim 75 percent of the problem, but there's still this other issue there regarding the "rebate trap." I like that term. I'm going to use that.

[Laughter.]

MS. SUZUKI: One thing I'll comment on is in our

June 2016 recommendation, we had a policy to shift more of the catastrophic risk to the plans, and in those cases, we thought some of those incentives that may have been misaligned would be addressed.

DR. DeBUSK: That's a great point.

DR. CROSSON: Let's see. I have Dana, Jon, and Amy.

Dana.

DR. SAFRAN: Thanks.

So I also really appreciated this graphic on 7 to show the misaligned, and the graphic on 9 really made a strong case for correcting the pricing signals.

The question I have relates to when you got to the kind of implications of the policy recommendations and the fact that we could be facing higher beneficiary out-of-pocket costs in a coverage gap piece, and I just wondered whether you considered -- could you go to slide 10? -- whether you considered having the discount treated as out-of-pocket across the board rather than taking it away and then keeping the out-of-pocket cost share after the catastrophic level.

Maybe financially, that doesn't work, and it just

costs too much. But it just felt -- I just wondered whether the beneficiary would have a better experience and also whether you'd get better acceptance from the industry if you kept the out-of-pocket treated as -- the discount treated as out-of-pocket and just added in the biosimilars to that. Did you consider that?

DR. SCHMIDT: Well, the implications of it are that so that the dollar point at which the reinsurance kicks in, so from this graphic on the left-hand side. You'd see a similar thing happening over on the right-hand side now. So Medicare reinsurance would be paying for a whole lot more of it, and it would start at a lower level of spending and subsequently pay for more of the price of the drug.

I suppose if you were able to implement the 2016 recommendations where the reimbursement of the reinsurance from the federal government was at 20 percent instead of 80 percent, that might alleviate some of that higher cost, but it is much higher program spending.

Go ahead.

MS. SUZUKI: I would just add that the original idea about not treating the gap discount as true out-of-

pocket was that it was the brand versus generic comparison. So you would continue to have that issue.

DR. CROSSON: Jon.

DR. CHRISTIANSON: Yeah. Back to slide 13. I think the last time we talked about this issue, we acknowledged that some beneficiaries could have higher cost sharing, but we also said that putting a hard cap would benefit some beneficiaries. So there was a little bit of give-and-take there.

But I think what's new on this slide -- and it's probably worth having you walk us through very quickly -- is this notion that the value of the hard cap would grow over time, which would seem to me to imply a better situation maybe for beneficiaries than we've talked about in the past.

MS. SUZUKI: So one thing that happens is beneficiary parameters grow by the average spending in the Part D program, and that historically has been lower than the growth rate we see in the prices of the high-priced products. So it may be something like 4 to 5 percent growth in the benefit parameters versus 16 to 20 percent price growth for certain medications.

So what happens is the people who take those expensive medications get to the catastrophic threshold quickly in the year, and that value grows over time because of the discrepancy in the growth rate.

DR. CHRISTIANSON: Okay. Thank you.

DR. CROSSON: Amy and then Bruce.

MS. BRICKER: So Brian touched on this with some outstanding litigation that's pending between two manufacturers, and that's separate, though, from -- what's mentioned in the chapter is reference to some pay-for-delay settlement agreements. Particularly, you reference one from AbbVie and Amgen.

But you go on to mention that there are no reporting requirements to the FTC with respect to those settlement agreements. Can you comment on that further?

DR. SCHMIDT: Sure. So under the Medicare Modernization Act, back in 2003, they established a reporting requirement that was basically under the context of Hatch-Waxman. So it was thinking of pay-for-day or settlement agreements related to generic and brand manufacturers, and at the time, this biologics pathway wasn't even law. Of course, that happened later.

So the large-molecule drugs are not subject to this reporting requirement. So as a result, the FTC is not getting settlement information for situations like the one that's described in the paper at all.

DR. CROSSON: Bruce.

MR. PYENSON: Thank you very much. I think the graphics are really terrific.

I would wonder about the value of creating similar graphics and analysis for the low-income subsidy population, which I think is a pretty significant portion of the total Part D spend and in particular the Medicare cost implications of that in this situation.

DR. SCHMIDT: So you're saying that because of the fact that the low-income subsidy is picking up so much of the cost sharing for the LIS, you would like to see that demonstrated, right?

MR. PYENSON: Yes. And the low-income subsidy population uses more specialty tier drugs than the regular population, so this might even be a leverage impact.

DR. MILLER: I have no objection to the notion of showing the LIS effect. I mean, you know, mapping is out for the LIS. The LIS aren't incurring any out-of-pocket,

right?

MS. SUZUKI: Is what you're asking that once the biosimilar is on the formulary that the cost sharing subsidy implication is there as well? Is that what you're getting at?

MR. PYENSON: Well, I was more concerned with the federal share since CMS is picking up the --

MS. SUZUKI: They pick up the 100 percent cost --

MR. PYENSON: -- of what it would be in cost sharing. And there's not a manufacturer discount.

MS. SUZUKI: Right.

MR. PYENSON: So some of the dynamics -- I was thinking as you -- to see that split out by CBO. When you talk to them about the budget impact of this, that to consider those two pieces separately, the two populations separately.

DR. CROSSON: I thought I saw -- yeah. Pat.

MS. WANG: Would you just for clarity sake, going back to slide 7 -- can you kind of verbally redraw what this would look like under the policy option that's being proposed? I guess, can you just describe what the change in this picture would be if we were to adopt the

Commissioners' recommendation? The biologics and biosimilars would be treated identically, but how would this work?

DR. SCHMIDT: Right. So I guess the one on the left, you'd see kind of maybe the enrollee cost sharing continuing up to maybe a comparable height, as the one on the right, but there would be a gray area in both the right and the left. So the enrollee cost sharing would be 25 percent, and the manufacturer would be paying 50 percent but up to a higher level of spending, up to a higher price there. Does that make sense?

MS. WANG: I think so.

So it's essentially -- I was looking on the -- well, it doesn't really matter -- on the left-hand side. As you say, this solid section would rise the manufacturer and the plan shares above initial coverage would be split just they --

DR. SCHMIDT: Exactly. So all of those layers in the middle there, what's called the "coverage gap" on the left-hand side would be up higher --

MS. WANG: Okay. Thank you.

DR. SCHMIDT: -- kind of to a comparable height

to the right.

MS. WANG: Okay.

DR. MILLER: We went around and around internally on how to visualize this.

The other answer to her question is that's what we were trying to do, I think, with 9 and 10, although it's displayed a bit differently than this because we tried to do it with this picture, and things got a bit hairy. And so we moved to these to try and make the point, and the difference between the dark area on 8, I think -- if you can back up one? -- and the plan liability shift between this picture and then 9, which is what we were trying to show, and you see a more comparable layout. You see both 50 percent discount and plan liability.

MS. WANG: Got it, got it, got it, got it.

DR. MILLER: But this is kind of grouping all of the spending together --

MS. WANG: Yes.

DR. MILLER: -- as opposed to the other picture, which parsed it out by people, discount plan, all of that.

MS. WANG: Yes, yes.

DR. MILLER: And it just got hairy, and so this

is what we were trying to do to get at that variable.

MS. WANG: And I see that. I just --

DR. MILLER: We've messed around with that picture for a while --

[Laughter.]

DR. MILLER: -- and then finally, Shinobu said, "That's enough."

MS. WANG: And can I just ask -- and I apologize for not knowing this. The implications of the phase-out of the coverage gap are represented here already because it's a 2020 view. What does it look like today? Like I don't actually understand how the phase-out works, like what the implications are for beneficiaries or the program. I don't understand what it means.

You had many references to it in the paper, which was great, but for me, anyway, it was just like I need just one more, like backing up, one more piece, if you wouldn't mind.

MS. SUZUKI: So currently, enrollees' cost sharing is higher than the 25 percent. So if you look at the originator biologics on the left-hand side, that manufacturer discount is 50. Plan liability is lower than

the 25 percent. So there is a little bit of shift there.

It gradually takes down the enrollee cost sharing, and in 2020, it's 25 percent.

DR. CROSSON: Just as an editorial comment, my own experience with this particular policy area has been that every time we enter the coverage gap, it's like abandon all hope. You enter here.

[Laughter.]

DR. CROSSON: It's one of the more complicated pieces of analysis I think we do here at the Commission.

Okay. Yeah. Rita.

DR. REDBERG: Thanks. The chapter was great, and I like the graphics.

But I'm just having a really hard time understanding this manufacturer's discount and how it actually works. Like say the drug costs $5,000. Does then the manufacturer say, "Oh, it's $2,500," and then the plan only pays $2,500, or does the plan pay $5,000 to the manufacturer, and then the manufacturer takes $2,500 and hands it back to the plan? Who gets this discount? I don't understand it.

DR. SCHMIDT: Neither of those.

[Laughter.]

DR. REDBERG: Okay.

DR. SCHMIDT: Yeah. It's kind of applied on top of the benefic structure. Whatever plan the enrollee is in, they might have a deductible that they go through, and so the $5,000 price deductible applies towards that. And then there is this initial coverage range of spending where there's about 25 percent cost sharing or copay equivalence to that, and that's all applied to the $5,000 price.

And then you hit the coverage gap, and at that point, it's where the manufacturer is providing a 50 percent discount at the point of sale. So that's where there's some billing that takes place that ultimately is between the plan and the manufacturer to cover the 50 percent, but it's only in that range of spending. Does that help at all?

DR. REDBERG: So it only kicks in at the time you enter the coverage gap, that black hole area, but at that time, I'm still interested in how does that money exactly -- who is getting -- is there actual money changing hand? Is it just the price is reduced in that period? I'm having a hard time understanding the mechanics.

DR. SCHMIDT: It's changed over time. It used to be that the Medicare program would kind of front some of that money until they could reconcile exactly that a claim had been paid, and then there was a billing that would take place to the manufacturer, but now I think it's more direct.

Bruce, you sounded like you wanted to speak to it.

MR. PYENSON: There is a coverage gap discount liability that the manufacturers have to book on their financial statements. The cash is fronted by the Part D plan, and then through reporting from the federal government, there's periodic charges against the Part D plan.

In recent years, due to reporting issues, some of the pharmaceutical companies have under-accrued the liability for the Part D discount, and they had actually report that in their financial statements as it got corrected.

So it's sort of a classical insurance runout cash-flow issue.

MS. BUTO: [Speaking off microphone.]

MR. PYENSON: I am looking at Rachel for confirmation.

[Laughter.]

DR. SCHMIDT: That makes sense. We haven't gone and audited anybody's books or anything like that.

MR. PYENSON: You can actually see line items in the publicly traded companies at the end of the year for that liability that they're going to owe.

DR. MILLER: But beyond the accountability, what was the question about how the money changes hands?

DR. REDBERG: Well, I'm interested in who is benefitting from that 50 percent discount. Like did the plan now pay less, or did Medicare get the money back, the patient get the money back, or they just charged -- do you see what I mean? And then you're saying it's this -- whatever it is, it occurs only during the coverage gap. Then the price goes up. So it's just a way to get to Medicare paying 80 percent faster.

MS. SUZUKI: So the idea behind closing of the coverage gap was to have enrollees pay 25 percent ultimately in the coverage gap phase, and the plan benefit would cover 75 percent. But it's expensive to provide that

extra coverage, and the manufacturer's gap discount helps with the closing of the coverage gap.

So instead of plans, which means the plan bid and subsidy and everything goes up by that amount, that's reduced by the manufacturer discount. Does that make --

MR. PYENSON: It's not a point-of-sale discount; that is, nobody sees a smaller retail price or transaction price at the pharmacy. So it's handled in the back, background.

You can imagine an expensive drug that starts in the initial coverage zone, and so the discount only applies to the portion that's above the beginning of the coverage gap. And then it stops at the catastrophic, so it's a retrospective calculation.

MS. BRICKER: And the plan's benefitting. You said, "Who's benefitting?" The plan's benefitting. And the enrollee, and that --

DR. HOADLEY: And the enrollee. The beneficiary at the point of sale is seeing a lower out-of-pocket cost even though the invoice cost at the point of sale wouldn't look lower.

DR. REDBERG: So I can see the plan benefits, the

beneficiary benefits, and Medicare pays a lot more. And then, you know, so it's a way to kind of keep up the higher prices and just shifting those higher-price costs to the federal government.

MS. BRICKER: Yeah, I mean, Medicare pays more because you're getting through that catastrophic -- that coverage gap phase faster.

DR. MILLER: Right.

MS. BRICKER: So that's how they pay more.

DR. CROSSON: Okay. Rachel and Shinobu, thank you for taking us on the perilous journey once again through the coverage gap. I think we survived it.

So now we'll have general discussion. Normally, we start with the recommendation. We have a recommendation on the table. But I did solicit requests yesterday, and so Jack and Amy are going to begin the discussion. We'll start with Jack.

DR. HOADLEY: So thank you for this chapter, and there's a lot of good material in the reading materials well beyond what you've covered, had time to cover today. And I think, you know, taking us back to the starting point that you started us from, which is that biologicals are, in

fact, a major source of the rising costs that Part D is facing, much more than traditional drugs, and that it's price more than use, I think those are just important markers. And because a lot of these are clinically important drugs, the price is really sort of holding the program and the beneficiaries hostage to a degree. You know, these are drugs that people need; therefore, you know, those prices get paid, and it comes out of the pockets of beneficiaries; it comes out of the program.

And the biosimilars really should give us, as you pointed out, the potential to create some savings, and what we've got is a number of barriers that are getting in the way of that. I mean, there are some important barriers that we're not talking about today because they are not Medicare specific, but it's the whole process of getting these biosimilars through the FDA. That's obviously going a lot better than we thought it might some years ago. There's the interchangeability policies that the FDA still is working through. There's the patent disputes that have already been referenced where manufacturers -- the originators are blocking the biosimilars from coming to market even when they've got FDA approval. There's what

you called the "rebate trap," the various maneuvers that the originator manufacturers are using to try to protect their market share. And then there's the state laws that limit the automatic substitution of the biosimilars at the pharmacy in some states and require that -- only allow that to be done in a comparable way to what we see with traditional generics, you know, if that interchangeability requirement or other kinds of ways that states have done that.

So we've got a set of barriers that are not Medicare-specific barriers, and I think it's important, and I know you do in the chapter talk about a lot of these, to keep those on the table. You know, we may decide that they're outside of our scope, although I think it's worthy to keep talking about those issues and whether there are any levers that we have to sort of raise those.

What you've got here -- and I think it's an important one -- is the fact that Medicare has, probably unintentionally, created another barrier through the way the coverage gap discount rules work. And I think that the recommendation is an important one in terms of sort of correcting, again, what I think is probably an

unintentional -- at least I'd like to believe it's an unintentional design flaw and, therefore, you know, might not be so controversial to get fixed.

And I think, you know, putting that in the context of our 2016 recommendations is important, and I do think in terms of just language, we had, I think, in the language that you put up the notion of the exclusion from the true out-of-pocket cost. And I think it's important that in the text we make it clear that that should be done in conjunction with -- and, Jay, you've already really made that statement -- the 2016 recommendations, because I would hate to see Congress sort of going in and grabbing this little piece and still treating the biosimilars in a different way than other drugs, than other regular brand drugs are treated. So, you know, we need to emphasize -- figure out what's sort of the best way within our document to emphasize that these continue to be as part of a larger package.

We had some back-and-forth back in 2016 over the specifics of getting there. We ended up with a package that folks could agree on around this table, and so I think it's important to keep it in that context.

One other thing you mentioned in the chapter was the question of -- and this, again, relates to the 2016 recommendations -- what are the CMS rules for adding a biosimilar to a formulary midyear. And I think to the extent that if you think that what we said there incorporates -- you know, applies to biosimilars the same way that we intended it to apply elsewhere, we should make sure to make that point. Maybe it doesn't need to go in the recommendation, but it is, again, part of the text that is sort of aligning our package of recommendations together.

The only other thing I wanted to mention -- and I know on Slide 13 you specifically reminded us of the very last bullet there, that to the extent that the recommendations result in a net savings, we could consider lowering the out-of-pocket threshold. I think in that context it's worth pointing out -- and it's not something that everybody's familiar with -- that there's actually scheduled in 2020 to be a substantial increase in the out-of-pocket threshold -- some are calling it a "cliff" -- because of the way the law was structured held the out-of-pocket threshold to a lower growth rate between the time

that law was created in 2010 and 2020. And then that particular provision expires, so there's this sort of catch-up. It goes back to where it would have been, and it amounts, from what I've seen, to about a $1,200 increase in the out-of-pocket limit in 2020. And so we've already sort of said that ideally we'd like to see that out-of-pocket threshold lowered, you know, in this contingency. I think, A, at the very least that's worth flagging in our discussion, and I actually would love to see us maybe think about sort of incorporating that somehow in this recommendation to not have that increase step in because that's going to be a significant increase in out-of-pocket costs, as well as, in the absence of other changes, government reinsurance costs.

DR. CROSSON: Well, at the very least, I think that -- and I was not aware of that. I would think that that would provide context for this point that's being made here.

DR. HOADLEY: Absolutely. At the least we need to reference it, put that in that context, and if we felt the willingness to go further, you know, that would be great.

DR. CROSSON: Thanks, Jack. Amy.

MS. BRICKER: Slide 12. Thank you both for the chapter and for the recommendations. I am in support of both of them as outlined and agree with what Jack has mentioned around it's really hard to just pull out this piece and address this piece of the Part D benefit without also considering all of the other implications to the Part D plan. And so to ensure that we're casting a wider net as part of the recommendation, I think it's important.

I want to pick up from a comment or question that I had earlier in the session around the pay for delay or settlements that are now occurring with and between manufacturers. You know, we sit here today thinking about how we can ensure that policy is aligned or biosimilars, yet I fear we will not see biosimilars come to market in the way that we absolutely need. It was surprising to me, I wasn't aware, you know, as MMA was constructed and designed, that FTC would not have access to the settlement agreements that today are being made in this space. And if nothing else, I would encourage us to encourage the Congress to change that.

AbbVie in the case of Humira, Humira is the

number one drug in specialty spend, $16 billion a year. And the settlement agreement, as I understand it, between AbbVie and Amgen now delays access to that biologic in the United States until 2023. And yet as part of that settlement, they're allowing the biosimilar to be allowed in the EU. So Europe will see the biosimilar for Humira and the United States will not -- for years. And this is the thing that I think is most critical to addressing the spend in Part D. We have to have competition, and we have to have disincentives for manufacturers to, you know, together work through these settlement agreements, and yet taxpayers are on the other end of those deals.

So I'm in support of this, but I think we've got to have a louder voice with respect to what's going on in this space and ensure that actually biosimilars do come to market.

DR. CROSSON: Thank you, Amy. And I think in writing this up, we can broaden the context a bit to include some of the points you made.

Warner, yes?

MR. THOMAS: I just would echo Amy's point, and I think that, you know, just the -- and I appreciate, Rita,

having you go through just what's the rationale behind the rebates, which we all know the rationale behind it is to keep the patient in a more expensive option and to push more of that cost to the Medicare program.

I would agree with Amy's point that -- I mean, what she just referenced really doesn't make a lot of sense, and it is not fair to the program to be able to push this type of cost on to the program.

I would just also -- you know, we constantly kind of talk about drug costs, and I think in Part D this is a place where we could be challenging ourselves and the program to look at setting pricing around drug costs. And it is essentially we are -- here Medicare is purchasing drugs directly, essentially. We are using Medicare funds to do that. And I think it's an opportunity for us to take a broader approach. I agree with the recommendations that are here, but I would like to see us in the chapter indicate that due to these situations, due to the escalating costs, due to the issues that Amy comments on, this warrants a broader look at pricing and setting drug pricing in the Part D program.

DR. CROSSON: Okay. Again, I think we're hearing

some request to broaden the context and, you know, both in re-referencing the 2016 recommendations and making sure that this recommendation is incorporated in the sense of a unified set of recommendations, but also broadening the problem statement, if you will, that we're trying to address. I think that's right.

Yes, Alice, Kathy, and Bruce.

DR. COOMBS: So I really appreciate Jack and Amy's comments. One of the things I thought about was, you know, the reversal of the reinsurance so that -- one of the recommendations in 2016. The amount that that would contribute back to the program in conjunction with the current recommendations, as we have discussed, only because I think that large number will persuade to take the whole menu, to look at the whole menu, because it will be more persuasive in terms of looking at the impact of that, the dollar amount. And so I guess we could go back to the chapter that we had previously and just kind of --

DR. SCHMIDT: I just want to clarify, though. So by bringing the reinsurance down, that was -- actually, we were keeping the overall Medicare program subsidy the same, so about 75 percent of it. So we were just -- we were

substituting a capitated payment for back-end reinsurance. So to the extent there are program savings, it would be from having stronger incentives for plans to be managing really high cost folks.

DR. COOMBS: Right.

DR. SCHMIDT: I just don't want to leave the impression that all of that, bringing the 80 percent to 20 percent wasn't going to be pure program savings. Some of it will go back to the plans as --

DR. COOMBS: And you did a calculation of how often that happens that you're in that phase, so I think that's kind of important that if we were to reverse the reinsurance such that the government would be on the hook for only 20 percent versus 80 percent back in the 2016 recommendations, in conjunction with what we're talking about now in terms of the percentage of discount within the catastrophic phase, the out-of-pocket.

DR. MILLER: Yeah, I have to say for myself I need another pass at that. Actually, let me say one thing. Were you saying that you wanted to see the impact of this in the context of the other recommendations? Is that what you were saying?

DR. COOMBS: Exactly [off microphone].

DR. MILLER: Okay. Our intent, like we always do, is to try and have those ranges of impacts, and I am assuming that when we get that and work with CBO to get it, it's going to be in the context of our larger package as opposed to a one-off, which, you know, to Jack's original comments, we're considering this all in the context of our 2016 recommendations. Can I get a nod there? Okay. So --

DR. COOMBS: So this cost savings that would be accrued because of the two together.

DR. MILLER: Right, but what I -- and I'm going to want another nod, so -- which I don't get often. What I might not -- and I don't know if you're asking this, but what we may not be able to do and I would guess that we were unlikely to do is tell you the separate effect of adding this to the old package as opposed to here's the whole deal now including this.

DR. COOMBS: So that's exactly what I'm asking [off microphone].

DR. MILLER: Yeah, and I'm not sure we're going to be able to say okay and these ten dollars are specifically related to this change as opposed to here's,

you know, the new range of estimates. And, remember, we don't produce -- for very specific reasons -- point estimates on these policies. We give ranges in our consultation with CBO. So I think that's a long way around of you're not going to see the actual point estimate I think you're asking for, if I understand your question.

DR. COOMBS: So we can't get a number with the two together as to this is the savings that would --

DR. MILLER: No, I think we can give you a big blobby range of the whole thing together, meaning this new thing and our old thing. But if you said yes, but I want to know the specific number of this change on the whole package, I'm not sure we're going to be able to produce that. Is that correct, guys?

DR. SCHMIDT: And bear in mind it's usually a one-year/five-year time frame, and there's, you know, very little on the market now in the Part D space.

DR. MILLER: Right, that's the other --

DR. SCHMIDT: We'll see in five years.

DR. CROSSON: Okay. Kathy, Bruce, and then Pat.

MS. BUTO: So terrific work, as usual, and I'm always very struck by the fact that this issue again

highlighted the importance of changing the structure above the catastrophic cap because ultimately, even though what we're talking about is level playing field for biosimilars and originator biologics, the real constraint will come from having the plan continue to have skin in the game above the cap to manage through the cap and then above it. So I was very struck by that, and I really hope you'll highlight that interrelationship between the two.

I still have some concerns about the beneficiaries in the coverage gap if the 50 percent discount for both the originator and the biosimilar doesn't count, and I can't remember the number of beneficiaries who we estimated would not reach the cap as a result of that change, at least just on the originator side. Do you recall what that number was? It was some percentage or some fairly large --

MS. SUZUKI: Right, we wrote up something where we thought that roughly half of the people would end up with higher cost sharing because they do not -- no longer get to the catastrophic phase of the benefit.

MS. BUTO: Right.

MS. SUZUKI: But we also thought that half the

people will reach the catastrophic phase and benefit from --

MS. BUTO: And they'll get the zero co-pay -- or the zero coinsurance.

MS. SUZUKI: Right, exactly. But that was 2013 data, didn't have behavioral effect. We just sort of took the data as it is and tried to estimate that.

MS. BUTO: Okay. So just in my mind and back to Dana's question, it raised the question of whether we think that the changes in the -- above the catastrophic cap in the plan picking up a bigger share of cost would actually mitigate some of the savings we would have gotten by not having those 50 percent actually enter the catastrophic cap. But I realize we don't have that specificity right now. Just a question that I still have about the policy.

And, lastly, I just want to comment on sort of the tone around the manufacturer's motivations. I was involved in some of the discussions -- not on the Hill but really internally -- and there was a lot of pressure during Part D coming from beneficiary groups to reduce cost sharing in the coverage gap, and the government did not want to pick up the cost. And so as part of the working

together to try to get some of the changes made, the industry agreed to the discount. I think true to what people have been saying, the industry quickly realized that, you know, given this structure and the government picking up so much after hitting the cap, that, in fact, that would benefit manufacturers. There's no question about that.

But I just want to make sure people understand. There wasn't a cynical view that if the discount was provided that, oh, boy, this is terrific for us. It was pressure on the other side to do something to make this more accessible for beneficiaries, at least at the time of the discussions. Now, a lot has happened since then.

DR. CROSSON: On that point, Jack?

DR. HOADLEY: On Kathy's first point, I mean, I think one of the things to keep in mind from our previous recommendation discussion -- and it goes right to what Shinobu said about the numbers -- there were some people who would be worse off, and that's partly why we added that notion. It was in that bottom bullet of potentially if there were enough savings to spend some, to get the out-of-pocket threshold down.

But the people who benefit, the beneficiaries who benefit, particularly benefit from the highest-spending beneficiaries, who were now protected by a cap on out-of-pocket spending, was a key element of that. It's a cap on out-of-pocket spending comparable to a lot of the out-of-pocket caps we've seen in other federal policies, and the people who were benefitting were generally benefitting for a lot of dollars. Some of those were liable for thousands of dollars of out-of-pocket cost, up above the catastrophic cap.

And even in terminology, we talked about a catastrophic cap, but it's sort of a leaky cap. And so we were proposing to make that, and so I think it's -- you know, it was a complicated tradeoff that we all had different sort of pros and cons of, but I think one of the big pros was that some of the people who were being hit the hardest, beneficiaries who were being hit the hardest would now be protected.

DR. CROSSON: Bruce.

MR. PYENSON: Thank you.

In listening to the discussion this morning, I'm struck by the contrast between two approaches. On the one

hand, the 2016 approach, which as Kathy put it, kept the plans with skin in the game because of the liability they would have, the increased liability they would have in catastrophic. That would create incentives to manage costs and hopefully reduce costs, since that's our goal.

The other, I contrast that with the interest in -- affect price controls on particular drugs, and those could, of course, both happen. But I want to point out that those are probably two distinct policy options and could be presented that way.

In particular, if we don't do the one and create the incentives to reduce cost through the 2016 recommendations, then there's perhaps no choice but to recommend the price caps.

From the standpoint of the price controls, I think the place where we have the recommendations and the structure in place to pursue further is on the Part B drug side, where there is a direct schedule and process for direct federal payment. And I think that would be the place to start the process, if we want to go there.

As Commissioners may recall, I spoke out in favor of not an inflation cap, but a deflation requirement as

appropriate in that structure.

So I just want to contrast those two different policy options. One is the 2016 recommendation, which would have, I think, important incentives that would reduce costs, and compare that to what could appear to be throwing up our hands and saying, "Well, instead of that, let's keep our current structure and recommend something with price controls."

DR. CROSSON: Okay. Thank you.

Warner.

MR. THOMAS: It's just a question because I just don't know the answer to this, but going to Kathy's comment around that it's kind of a collaboration to do the rebate for the patient, which I think is great, do we do that in other parts of the program? Can you do that in -- can hospitals do that? Can they do rebates? Can other -- I mean, I just don't know.

MS. BUTO: Actually, there have been efforts over the years even for physicians to waive --

MR. THOMAS: Right.

MS. BUTO: -- the 20 percent coinsurance, and I think there's a long history at the Inspector General's

office saying that, yeah, it's a violation of either anti-kickback or something else. And so it was pretty clear that if they were going to do something like this, they'd have to do it in statute. It really wouldn't pass the anti-kickback stuff.

MR. THOMAS: It might just be something to note as well that it's inconsistent with the rest of the program.

DR. CROSSON: Pat.

MS. WANG: You know, just to pick up on comments of several of the Commissioners, I would also -- the way that I would describe it is -- I mean, Bruce described it as kind of like two really different approaches, and I don't disagree with that.

I think the thing that's important to note in this recommendation, which I think is a good recommendation -- the 2016 efforts, I wasn't here at the time. What we're talking about is shifting risk for the cost. That's really largely what these proposals have been to do.

There's a belief if the plans have more skin in the game, as Kathy put it, something will happen maybe, and some plans might be in a better position to do that than

others. But the fundamental issue of the size of the cost is really not -- is the big elephant -- Wooly Mammoth in the room here. And so these proposals are really important, but I think that it's hard for us as Commissioners to ignore the fact that what we are talking about is just trying to shift who takes the risk for the cost, the beneficiary, the plan, Medicare and the catastrophic, what have you, but that the real big issue here and the reason that people are grappling with this is that the size of that cost box is just way too big.

And just even the simple things that Amy mentioned, just greater transparency, so that taxpayers can actually see why the size of that cost box is as big as it is or some of the drivers. The fact that even those fundamental things are not there or the fundamental ability to kind of really understand what's going on is a problem.

So I think that however we talk about this, I realize that it's sensitive, but it's hard to -- people who run the Medicare program are not alchemists, and so it's a matter of just shifting risk.

The second thing that I wanted to just encourage -- and I think that you guys are going to do this -- is

somebody asked the question before about sort of the take-up of biosimilars, and since it seems like Europe is going to have a big head start on availability of biosimilars, I guess I would be curious to know.

They're not interchangeable. The molecules are different. It's not a generic substitution kind of thing. I think that we should continue to track the factors that either seem to support, encourage, or just look at the take-up, clinician acceptance of biosimilars, that kind of thing, because I suspect there will be other kinds of barriers there besides what happens in the coverage gap.

DR. CROSSON: Thank you.

I saw Rita and then Alice.

DR. REDBERG: I support the recommendations.

I did want to share Pat's concern because we are talking, and it's very important because the plan -- the cost to Medicare for the reinsurance part has grown very rapidly. But the bigger -- the Wooly Mammoth, as you said, is that these drug costs are just astronomical. I mean, who could conceive of a drug launching at a half million dollars per year? It's more than average income in this country, and there are lots more of these drugs, clearly,

that are getting approved. And that the first or the second two CAR-D drugs are now approved, you know, the drugs that have been approved in the last few years.

There won't be biosimilars. I mean, we're just talking about huge costs. We're just now talking about we're all paying for it -- Medicare, taxpayers, private plans. And some of the issues, it's very disturbing how biosimilars have bene so slow to come to market, as Amy referenced what you outlined in the chapter, the Humira case with AbbVie and Amgen entering an agreement so that even though the patents expire in 2016, there won't be any biosimilars launched until 2023 in the U.S.

And then there's also, again referenced in the mailing materials, Allergen is attempting to transfer its patent to the Mohawk Tribe in order to lengthen the patent. I mean, these incredible extensions on these very expensive drugs are all of great concern because we're talking about when there are biosimilars available, but this is large prices and not a lot of competition in the market.

So I think this is a big area for program integrity going forward because these costs are just inconceivable, just to mention because it impacts the

program. We don't have control, obviously, on all of those pricing things, but we hope that the Congress is certainly attentive to it.

DR. CROSSON: Thank you.

Alice.

DR. COOMBS: I support the recommendation.

Pat made me think of one of the reasons why I asked the earlier question. It's not only that you're shifting the risk, but does that change behavior, and does it change decision-making for the different entities? And I think that's an even more important question, is how does that risk translate to what happens to the beneficiaries in terms of choices and what happens with the action on the manufacturers, the plan's part, and the prescriber as well. So I think those are the things that we don't often think of in terms of carrying it out to the beneficiary.

And my question was just if the catastrophic reinsurance was a more important -- the reinsurance was a more important strategy. I know we can't prioritize and say this is the number one thing that we want; number two, if we had a choice.

You know, to say that all of the things on the

list are equally important, I think they are, but there's some things that actually rise to the surface and have a greater impact. And I don't know whether or not that's something we're interested in doing.

MS. WANG: I think the thing that is very concerning to me is that what we're talking about here with these high-cost drugs, these are sole-source specialty drugs. Like there is no sort of management of beneficiary trying to encourage them to take the cheaper drug until biosimilars perhaps really have some take-up here. People are kind of -- I mean, honestly, these are very important drugs. They're life-saving drugs, but as far as the cost, you're kind of held hostage. There is no management of beneficiary choice and options. It's not a generic substitution.

DR. CROSSON: Okay.

MS. BRICKER: Just on that point.

DR. CROSSON: Yeah.

MS. BRICKER: There is. I agree that there isn't a biosimilar or a generic to these, but Part D institutes prior authorization and ensuring that you can't just willy-nilly get the drug. You have to meet certain criteria.

But completely agree with what you're saying that we've got -- you know, we're the largest payer of prescription drugs in the country, the benefit, this plan, the largest payer of prescription drugs. And while we would think about how could we modify policy with respect to the beneficiaries certainly and access, we have to encourage competition and think about this differently than we would, I think traditionally in all of our other discussions. What is it that we're doing? And as part of our recommendations, it's either stifling competition or encouraging competition, and especially in this space, I'm very concerned that we just won't see the problem that these policies aim to address because we won't see biosimilars in the market in a way that we absolutely must.

For pharma to be able to have these settlements or make these deals in silos, behind closed doors, and there really isn't anyone that's looking into that to say, "Hang on a second," do you know who that hurt? That hurt the taxpayers. So that's what I'm hoping we can become a little bit louder about as a Commission.

DR. CROSSON: Bruce and then Jack.

MR. PYENSON: Just a comment on what we're

spending money on. Many of the -- the biggest category of biosimilars are the insulins, right? Those are biologic drugs, no question about it, and they're interchangeable. Some may -- not technically interchangeable, but you look at how Part D plans have switched, you know, formularies and so forth. They're interchangeable.

I think the interchangeability argument is one that needs to be picked at, and in some of the -- just because of the history of that, there's other categories, the growth hormones and so forth.

So I'm not satisfied with saying, well, the biologics, we have trouble managing because of X, Y, and Z. I think challenging some of those assumptions would be really instructive.

The European experience there has been pretty interesting, where, of course, a single-payer system can wholesale and move the entire population from one product to another, and some of those countries have very good tracking of what the outcomes are.

So I think to the extent that Medicare has concerns or rules in place that restrict interchangeability, I think that's something that we could

address in this process.

DR. CROSSON: Okay. Jack.

DR. HOADLEY: Just a couple of quick follow-up points. On Amy's last point, I mean, she's exactly right. Plans have tools, things like prior authorization. They're tools in the nature of, okay, you're being held hostage on price, so you go to prior authorization. You go to other restrictions on use. That becomes a limitation on access. It's the right strategy from the plans, from the PBM's point of view, but it plays out in the system in a particular way. And I think what we're trying to do is figure out ways to avoid needing that.

Second, going back to Amy's earlier point on the FTC reporting, I think that's a really important thing and maybe is one where I wonder if we couldn't certainly raise that very strongly in the text. I mean, I'd love to see it also as a recommendation. It is something that goes back to Medicare Modernization Act. So even though it's not directly a Medicare policy, it has been legislated in the context of Medicare legislation in the past.

Bruce kind of already said this, but, I mean, Pat, you raised the question of the European experience,

and I think we've seen some of that in the materials in these chapters. But there is some interesting experience where they've been willing to do substitution on drugs that at least so far are not rated as interchangeable, partly because we haven't sort of gone that path yet in this country.

But it does seem -- there's various hints that the standard that FDA is looking at for interchangeability may be stricter than clinicians are willing to work with.

And then last point was based on what Rita mentioned, the CAR-D drugs. We are beginning to see some of these value-based contracting things. They're difficult to do in Medicare; in some cases, probably impossible to do. But it may be something -- and I'm not convinced whether all of the different value-based contracting schemes that are appearing in the commercial sector are necessarily all good ones, but maybe it's something to look at down the road on whether there looks like a good experience there and whether that's something where there could be or should be adjustments in Medicare rules to allow some of that.

I don't know if they're good, but I think it

might be something to look at.

DR. CROSSON: Okay. Kathy and Dana.

MS. BUTO: Jack reminded me of something, which is that CMS and FDA have a relationship around Medicare coverage. There's even the possibility of joint coverage decision-making.

So I'm wondering whether, I guess, a hook into the FDA could be something like our looking at greater exchange of information at the time of coverage or approval, collaboration around studies. There might be some things that would get at this disconnect between some of the issues of FDA approval and CMS decision-making.

I'm not sure exactly what those are, but I would say why not at least raise the question because there's already some statute in that direction.

DR. CROSSON: Last comment, Dana.

DR. SAFRAN: So just to pick up on the point that Warner made about kind of how unique this is within the rest of what Medicare does and understanding that there's a long history here, I'm just sitting here wondering. We heard this incredibly powerful presentation yesterday about how competitive bidding has helped us in the DME space. So

I just wonder why we can't contemplate that here.

I understand there's a very long challenging history to overcome, but I just put that out there.

DR. CROSSON: Okay. So this has been a good discussion.

My sense of it -- and I'm going to test this, but in terms of the recommendations that we actually have on the board there, I did not hear any opposition. So failing that, I think our plan, as Rachel laid out, was to come back in January with the same recommendations that will be then incorporated into the March report.

However, I did find a couple of valuable themes here. One was, I think, the notion -- and I strongly support that -- that we make clear that this is to be considered part, an extension in part of our 2016 recommendations.

And the second one is the latter part of this conversation, which was a lot about not just expanding the context that we create in this particular write-up, which I think is very important, but longer term, challenging the Commission to at least repeatedly emphasize, if not try to take on in some new and different ways, that elephant or

Wooly Mammoth or larger question here, which is are we on a path, particularly with the newer drugs, that is simply unaffordable for the nation, and I firmly believe that that is the case. And that to the extent that we can do that within the construct of our mandate, that over time we should be doing that.

Rachel, thank you. Shinobu, thank you.

And we'll move on to the next discussion.

[Pause.]

DR. CROSSON: Okay. We're going to have our last discussion for the November meeting, and it's the third part of our mandated report on the use of telemedicine in the traditional Medicare program. Amy, Zach, and Andy are going to be presenting that, and, Amy, it looks like you're starting off.

MS. PHILLIPS: Good morning. This will be the third installment of telehealth this cycle. For this presentation we will be turning our analysis to how Medicare could consider expanding coverage of telehealth services.

In the larger context of our telehealth mandated report, this presentation specifically addresses the third

and final question of our mandate concerning ways in which telehealth services covered by commercial insurance plans might be incorporated into Medicare coverage.

In this presentation we will begin with an overview of the definition of telehealth; then summarize our comparison of Medicare and commercial plan coverage of telehealth that we discussed in detail at October's public meeting. Then we will go over the principles we have developed to evaluate telehealth services, and finally we will provide you with examples of how those principles can be applied within Medicare.

Telehealth services are defined broadly, and they continue to evolve. These services encompass a variety of combinations of clinical services, technologies, and modalities.

At our last meeting, you mentioned that you would prefer a narrower scope on what types of telehealth we are talking about when we mention the term.

As you read in your mailing materials and can see above, we have narrowed, for the sake of our discussion and Medicare focus, telehealth down to three forms.

Direct to consumer, or DTC, involves such

services as what Teledoc and American Well provide, simple acute illnesses revolved via two-way video at any time from any location.

Provider to provider, or PTP, encompasses such services as telestroke and tele-ICU where a clinician consults with a specialist in the presence of the patient.

Remote patient monitoring, or RPM, can involve a patient at home or in a facility being monitored by a clinician at a distant location. This is often used to monitor patients with chronic conditions at their homes.

To begin our comparison, I will first briefly review what we have discussed in our previous presentations about Medicare's coverage.

Medicare's coverage of telehealth is flexible throughout most of the program where taxpayers are indemnified against volume incentives including some parts of the physician fee schedule, within MA and CMMI programs and Medicare is most restrictive in the fee-for-service environment where volume incentives occur.

The table you see above has been compiled from results of our survey of the Medicare program and the 45 commercial plans that we presented to you last month.

Focusing on the first three rows where the differences between the Medicare physician fee schedule and commercial plans are more pertinent, we see in the first row that Medicare and commercial plans diverge on payment incentives.

Within the physician fee schedule, there exists provider and patient volume incentives while commercial plans are able to use various tools to curb this incentive. These tools do not exist in the fee schedule.

Moving to the second row, we see that variance occurs in the originating site locations with Medicare only allowing rural originating sites and commercial plans being less restrictive, due in part to the prevalence of 24/7 DTC services for minor acute illnesses that allow any originating site.

In the third row we see that the Medicare physician fee schedule and commercial plans have taken a similar approach to cost sharing; however, Medicare beneficiaries are often shielded from cost sharing by Medigap plans.

Finally, in the second table on the slide, we move outside the physician fee schedule to a comparison of

Medicare Advantage managed care plans and CMMI testing and pilot programs with commercial plans. Here we see that there are differences in how telehealth is financed and where the focus of testing telehealth services differs.

We have developed three principles based on Commissioner discussion over four public meetings spanning 2015 and 2017 related to telehealth that could be used as the basis for evaluating telehealth services or policies for potential incorporation into the Medicare program.

The first is expanding access, which includes the availability of services or providers (such as in the case of tele-mental health), facilitating more timely delivery of care (such as in the case of telestroke), and increasing convenience (such as for beneficiaries with disabilities).

The second is improving quality of care, which would be assessed through outcomes, patient experience, or added value.

The third is reducing cost for either the beneficiary or the Medicare program.

While a telehealth service may not possess all three qualities, it should strike a balance between them for consideration for implementation. For example, if a

service is going to cost more money, the service should be justified in the increase with greater value in access or quality.

Zach will now go into further detail on how these principles could be applied to telehealth services.

MR. GAUMER: Good morning. Several Commissioners expressed concern that expanding the coverage of telehealth under the physician fee schedule could increase the volume incentive of providers and that the program lacks the tools for controlling this incentive in the fee-for-service environment. In light of this concern, policymakers should use the three principles to evaluate telehealth services individually.

Based on the Commissioners' discussion, we have assembled four illustrative examples of how the principles could be used. Our use of these examples is not an endorsement of their inclusion in the Medicare program. But, instead, they are merely examples of how policymakers should rigorously evaluate these services.

The first example is telestroke. These services are currently covered under the Medicare fee schedule in rural areas. They are offered by several health systems

and paid for by many commercial plans. Policymakers could consider expanding telestroke to urban originating sites. By applying the three principles, we believe telestroke may improve access by enabling more timely care to neurologists, which some contend are in limited supply. This access improvement may result in improvements in quality, and the health systems we spoke to cite reductions in mortality and disability.

Telestroke services are likely to increase program costs because the program would begin paying for more of these consults. However, cost increases and the risk of misuse may be lower in this service because telestroke is not a common service every beneficiary is likely to use. In addition, some researchers assert telestroke might reduce long-term spending by reducing disability. Therefore, the Congress could decide that the improvements in access and quality justify the extra costs of telestroke services.

The second example is the expansion of telehealth to beneficiaries with physical disabilities and treatment-intensive conditions. We have observed some home health agencies and commercial plans using telehealth to serve

patients with chronic conditions. Policymakers could consider expanding telehealth coverage to patients with conditions such as Parkinson's disease or ESRD patients that use home dialysis. This policy may increase the convenience of care for patients with mobility limitations. This access expansion may improve quality, but the evidence of this quality improvement is thin to date. This policy is likely to increase program costs because it would generate more standard physician visits, which also increases the risk of misuse. However, these increases might be mitigated by the smaller chronic condition population groups we are considering and the potential to implement visit caps or prior authorization. Overall, the Congress could decide that telehealth coverage could be expanded to patients with physical disabilities and treatment-intensive conditions where improvements in access might justify the added costs.

Our third example is tele-mental health services, which are currently covered under the Medicare fee schedule in rural areas and by many commercial plans across urban and rural areas. Policymakers could consider expanding tele-mental health services to urban originating sites or

could go further and expand to patients' residences. Tele-mental health services may expand beneficiary access to mental health clinicians, which may be in short supply. It might also allow beneficiaries to avoid the stigma of seeking in-person services. Of course, this potential access expansion presumes that there is a mental health clinician available to provide service. If these clinicians are not available, the resulting expansion of access would be less.

Quality improvement is likely to stem from the greater availability of clinicians, but the evidence of this is unclear to date. Program costs are likely to increase as the result of expanding these services because the potential pool of users is large. This suggests the risk of misuse would also be high. Policymakers might mitigate potential cost increases by implementing visit caps or prior authorization. Overall, the Congress could decide that expanding access to mental heath clinicians, especially in light of a perceived lack of access to mental health care, justifies the potential for significant cost increases.

Our fourth example is direct-to-consumer

telehealth services, which are not covered under the Medicare program, but are common among commercial plans.

Policymakers could consider covering DTC across all areas and for all beneficiaries. DTC may expand access to clinicians and improve convenience. The impact on quality is unclear because we do not know if DTC replaces or supplements existing in-person visits. DTC may significantly increase costs because the potential pool of users includes all beneficiaries, the service is patient-initiated from any location, and most beneficiaries have supplemental insurance that shields them from cost sharing. As a result, the risk of misuse is greater. Policymakers may curb some of this risk by implementing visit caps or prior authorizations. Overall, DTC would increase convenience, but at a potentially high cost to the program. Because the costs of this service may outweigh the benefits, policymakers could consider testing the use of DTC within Medicare's Center for Medicare and Medicaid Innovation before implementing in the fee schedule.

The Commission has also discussed adopting the strategy used by commercial plans to more methodically test specific telehealth services, like DTC, within CMMI before

implementing them within the fee schedule. CMMI does some of this, but not on the scale that it could. Within our mailing materials, we identify examples of four telehealth services where their value is unclear. In addition to DTC, these examples include pharmacological management services, nursing home-based services, and remote patient monitoring for patients with chronic conditions.

Now, moving on from the physician fee schedule, the Commission has also discussed the coverage of telehealth under Medicare's other fee-for-service payment systems, such as hospital inpatient and skilled nursing facilities. To date, the Commission has discussed that these payment systems incorporate the flexibility for providers and patients to use telehealth services, and this flexibility stems from the fact that telehealth services are contemplated as a part of the fixed payments that providers receive.

The Commission has discussed expanding the flexibility of two types of entities that bear financial risk under the Medicare program to use telehealth services. While this issue goes beyond the specific questions of our mandate, it applies to the Commission's general principle

that when entities accept financial risk, greater flexibility is warranted. Therefore, it may be reasonable to delegate the principle-based evaluation of telehealth to the entities that bear financial risk such as two-sided ACOs and Medicare Advantage plans.

Two-sided ACOs bear risk by agreeing to reimburse the program if a beneficiary's annual spending exceeds a benchmark. Currently, two-sided ACOs have a waiver to cover telehealth services permitted by the Medicare physician fee schedule in urban areas and from the patient's home. However, in line with the Commission's principles about risk-bearing entities, policymakers could decide to expand the flexibility of two-sided ACOs to cover telehealth services that go beyond their current waiver and beyond current Medicare fee schedule coverage.

Andy will now talk to you about Medicare Advantage.

DR. JOHNSON: Under current policy in the Medicare Advantage program, plans must cover the same telehealth services covered in Parts A and B of fee-for-service Medicare. These services are included in the plan's bid. Plans also have the option to cover additional

telehealth services beyond the Part A and B benefit. These additional services, also called "supplemental services," are financed either by a rebate for plans bidding below their benchmark or by charging an additional premium.

Several Commissioners have voiced support for expanding telehealth coverage in the Medicare Advantage program beyond the current level of coverage and I'll now walk through two options for doing so.

The first policy option is to expand telehealth coverage in fee-for-service Medicare. This option would make no changes to the MA program or its payment policy, but it would expand telehealth coverage in Medicare Advantage to the same extent as it is expanded in fee-for-service Medicare. One issue to consider in expanding telehealth coverage is whether the basic Medicare benefit should be the same regardless of whether a beneficiary enrolls in fee-for-service Medicare or MA. The Commission has previously discussed this type of synchronization across fee-for-service Medicare, ACOs, and MA and generally favored consistency with respect to payments, quality measurement, and benefit design. Option 1, listed here, would favor maintaining the current level of consistency in

benefit design by having the MA benefit continue to track the fee-for-service benefit.

However, some Commissioners have also stated that in some circumstances risk-bearing organizations, and particularly MA plans, should be allowed greater flexibility in benefit design.

The second option would allow MA plans to include the cost of telehealth services in their annual bid. Under this policy, plans would bid on the basic fee-for-service benefit as well as any telehealth services they plan to offer. Therefore, Medicare payment for telehealth services would be included in the program's base payment to the plan and would not be financed by the rebate. Under this policy, we assume that the telehealth benefit included in the bid would be available to and mandatory for all plan members, meaning that all plan members would have access to the benefit and could not opt out of the telehealth portion in exchange for a lower premium.

This option would make the basic MA benefit offered by some plans different from the basic fee-for-service benefit. This difference may hinder our ability to evaluate market-level efficiency of MA and fee-for-service.

Therefore, to maintain an apples-to-apples comparison, plans would submit a bid that fully distinguishes the Part A and B benefit from the telehealth benefit. This separability of the benefit package exists in the current bidding process for supplemental services, so we think it should be feasible for plans.

Now I'll turn it back to Zach to wrap up.

MR. GAUMER: Over the course of this analysis, we have found that Medicare covers telehealth services in several areas of the program, commercial plan coverage is varied, and the differences between commercial plan coverage and the Medicare physician fee schedule reflect the payment incentives built into these systems.

Given the complexity of incorporating telehealth into the fee schedule, we identified three principles for evaluating telehealth. We provided several illustrative examples of how these principles might be used to evaluate individual services. In some cases, services demonstrate value and may be potential candidates for expansion. In other cases, the value of services is unclear, and testing through CMMI may be an option. Finally, we discussed entities that bear financial risk, and in these cases

Congress might consider expanding their flexibility to cover more telehealth services.

We would like to focus today's discussion on the structure of our report and solicit any questions or refinements you may have as we approach our landing spot.

To fully comply with our mandate, the structure of our report will mirror the materials provided to you in our three previous meetings. This will include background material, information on Medicare and commercial plan coverage, our principles, of course, and our examples that we have laid out. Following today's discussion, we will come back to you in January with a draft report, and you'll have an opportunity to provide comments at that time. We will then deliver this report to Congress in March.

Thank you for your time, and we're ready for your questions.

DR. CROSSON: Thank you, Zach, Amy, and Andy.

And we're now open for questions. I see Kathy.

MS. BUTO: So I was just wondering -- I've never been clear on this -- whether MA plans can substitute telehealth services for face-to-face without any -- even if they don't offer a supplemental benefit that's either paid

for through their savings or charging beneficiaries. Do they have that flexibility? is my question.

DR. JOHNSON: Not without adding or offering a supplemental package, and even in that case, the basic MA benefit must still be offered and available. It's just that in addition to in-person benefits, a telehealth visit could be available through the supplemental package.

MS. BUTO: So I guess I'm wondering can they -- do they have flexibility to substitute other kind of non-covered services for Medicare benefits or face-to-face meetings if they think that will avoid a face-to-face meeting, an e-mail message, any of that sort of thing? It's not allowed without a supplemental?

DR. JOHNSON: There are certain service that are considered adjunct to the Part A and B benefit, so email and phone call could be offered under the current A/B benefit. It would be considered as part of what's a normal physician office visit and subsequent to under the A/B benefit. So that would be acceptable.

MS. BUTO: Okay.

DR. MILLER: Can I just get -- both Jay and I, we wanted to make sure that we were following this.

So in your response and in your question -- well, I don't know if you used the language, but you used the language of you have to offer a supplemental with sort of the words?

DR. JOHNSON: If in understanding Kath's question, if there is a telehealth video visit, I think that would have to be offered through a supplemental package. It just couldn't happen without being formally offered through the benefit as submitted through the bid and the supplemental package.

DR. MILLER: Right. But the financing for that -- and this is the clarification that I want to make sure that we get -- you can either finance that through a supplemental premium, or you could finance that through your rebate dollars.

DR. JOHNSON: Correct.

DR. CROSSON: Right. And that's the thing I wanted Kathy to be sure. That in exchange, when he said it had to be offered through a supplemental, it means -- I'm going to use different vocabulary. I'm sure everybody in the managed care industry is going to freak out. You have your basic A/B. You can offer these other services, and

you can finance them in one of two ways. You can charge a premium for them, or you can finance them through a rebate dollar.

And I think the distinction in saying it has to be supplemental is you were mainly driving at the fact that it's different than A/B, and you have to offer it as a different service than A/B.

MS. BUTO: And that's really what I was trying to get at, Mark, because to my mind, it's not different from A/B. If you can do a phone call or an email, why can't you do like a Skype? Where do you start considering it kind of a supplemental benefit that either has to be financed through the rebate or --

DR. MILLER: Right. And the main thing I didn't want people to miss is sometimes when people use the word "supplemental," a lot of people automatically mean, "Oh, so they have to charge a supplemental premium." I want to make sure that people understood you could do this.

Now, the reasoning -- and as I understand it, there is some bleed-over here. That people do include in the plans, they do include in basic A/B, some overlap, things like phone calls and that type of thing. But I

believe Andrew's answer is correct if you want to say, "I am offering you the Skype option of initiating a visit with your doctor," because that's not allowable in urban areas in Medicare. You have to treat that as a new -- you have to treat that as a separate benefit.

I mean, what we're talking about here is saying maybe there's different ways to think about that.

DR. CROSSON: Alice --

DR. MILLER: Is that all right, Andrew?

DR. JOHNSON: Yeah. Sure.

DR. CROSSON: Did I see you, Alice?

DR. COOMBS: Yes. I just wanted to clarify, but if an MA plan has as a part of its protocol that they don't have enough mental health providers, they can offer that. They just don't bill for it, right?

DR. JOHNSON: The MA plan still has to have adequate network coverage without telehealth.

DR. COOMBS: Well, true, true, true. But I'm just saying if that's something that's a part of their -- that's just a part of their process in terms of patient care, they can offer it. They just can't bill for it under a -- say, for instance, you happen to be in an MA plan, and

they may be short on site providers or whatever, and they do a psych -- an E&M code. They can still offer that but that's under their whole cost of care for that beneficiary.

DR. JOHNSON: So the first part, I just want to make clear that when they say if a plan is short on providers, it still has to meet some basic adequate --

DR. COOMBS: Right, right.

DR. JOHNSON: But they could do better by offering --

DR. COOMBS: Right.

DR. JOHNSON: -- more -- increased access. So they could do that, but it would be financed through the rebate or through an additional premium.

DR. CROSSON: Pat, did you want to make a comment on that?

MS. WANG: It's a little bit confusing because people are using common sense to say, "Really?"

[Laughter.]

MS. WANG: But I think the distinction is the -- like when a plan goes out during open enrollment and says I have a Skype option or I have -- you know, I'm using Tele-Doc, and you can use this. That's considered like a

supplemental benefit. The kinds of things that you guys are asking about, I'm aware of plans that may -- if they have members who have difficulty accessing mental health services may use what we're calling telehealth to increase access in lieu of kind of trying to find a psychiatrist who's like 20 miles away or something that's not convenient. I think that's the difference.

I didn't hear anything that you said, Andy, that there is a prohibition on plans or even ACOs using those, you know. I mean, sometimes -- and it's all within the budget that you have.

DR. JOHNSON: Right.

MS. WANG: I mean, some plans try to get housing for their members. It's not an extra benefit. It's kind of in the course of what they're trying to do for overall health, if it looks like that's going to be more valuable than paying for a hospital emergency room admission, is to find a supportive housing bed. So I think that's the distinction, is whether you -- I think. Right? Is that correct?

It's sort of like publicizing it like here's the benefits that I offer potential enrollees, like we offer

Tele-Doc or something like that. That sounds like a supplemental benefit as opposed to using a variety of different techniques in the course of taking care of your members.

DR. GINSBURG: Yeah. So, Pat, they're just talking about the distinction between a benefit for all enrollees or an accommodation for particular patients.

DR. MILLER: And this is what I meant by -- and I think Andrew is getting uncomfortable, but I'm going to still say some more things and then let him get fully uncomfortable.

I mean, this is what I meant, to some extent, by bleed-over. A physician could decide, "Well, I'm going to deal with this through email," and just sort of deal with it within the context of the larger budget, as you said, as part of their payment as opposed to saying, "Okay. We're going to create an entire new benefit and offer it in this way." That's what I meant.

But I don't know if now we've crossed a bunch of lines that Andrew wants to redraw.

DR. JOHNSON: I don't need to redraw anything. I think we're all on, generally, the same page.

[Laughter.]

DR. CROSSON: Okay. David.

DR. GRABOWSKI: Great. Thanks for this presentation.

So you took us through four examples of how we could expand telehealth under the physician fee schedule, and if I had to sort of summarize, I'll have the potential to improve access and quality, but I'll also have the potential to increase cost as well.

Two questions on that. One, you mentioned, Zach, in the first example of Telestroke, the potential for an offset and that maybe we would see a decrease in long-term spending on disability. I could imagine other potential offsets with hospitalizations. I don't think those are going to pay for the program. I wanted to encourage you to think broadly about sort of these spending offsets.

Then as sort of a second question, are there other examples where those spending offsets are more direct and might even pay for the program? I don't see that potential with any of these four examples, but later, you mentioned the nursing home setting where maybe we could offer services there, and that may -- it's a chronically

ill population with great medical need. Is there a potential there to offer services and potentially lower hospitalization?

So those two questions. Thanks.

MR. GAUMER: Yeah. So I think in the Telestroke example, that is the only one where we offer some kind of an idea about an offsetting long-term kind of spending decrease, and that came from some research that we found the CBO in scoring bills, you know, had released some information publicly that said that Telestroke could generate long-term savings due to the reduction in disability, patient disability long term.

So that is something that we don't include. In the other examples, we could do a little bit more research and put some other ideas in there to consider what else is out there, but the only reason we did that for Telestroke is because it was right there in our faces and had been thought about by researchers recently.

Did I at all answer your question?

DR. GRABOWSKI: I think you did, and I think just to move to the second question, are there other examples -- and maybe this is pushing towards a Round 2 comment, but I

think there may be other examples in the program where we could think about a better alignment between kind of the application and potential savings elsewhere, so that we're targeting areas where we know there's a lot of hospitals, for example, and there's potential for telehealth to pay for -- or at least kind of largely pay for itself by generating savings elsewhere. I find those areas very, very productive and encouraging. Thanks.

MR. GAUMER: So the source of the examples that we have in the mailing material -- and I guess they're all here as well -- are things that we picked up in our search or in our site visits and interviews and also ideas that have come out of you guys. So if there are others out there that come to mind immediately, I think today is kind of the day to let us know, and we'll get cracking on it really fast.

[Laughter.]

DR. CROSSON: And I'm going to take that as a transition statement to Round 2. I see no further -- oh, more questions. Oh, sorry. Jack and Paul.

Go ahead, Jack. Sorry.

DR. HOADLEY: Mine is really sort of a process.

I think it's bene made clear that nothing that you're talking about here would be in the form of formal recommendations in this report, the formal recommendations that we vote on; is that right?

MR. GAUMER: So the plan here is to deal with this mandated report as we've dealt with the PAC-mandated report in previous meetings, where we would be -- you would be essentially voting for the entirety of the report and its contents as opposed to individual examples.

Have I described that accurately?

DR. MILLER: You have.

MR. GAUMER: Okay.

DR. HOADLEY: And sort of following that, for example, on the MA where you've got a couple of options, that's just part of that process of saying here's a couple of ways we can do things, or in the examples of these four clinical areas -- I mean, some people will quite likely read that as kind of a soft recommendation that we're sort of saying these are four potential areas for expansion.

I guess what the question is, if we're comfortable with that, or do we want a stronger sort of disclaimer language to say -- and you've used some of those

words, I think, but it seems like looking carefully at the wording around how we characterize those and then our comfort level with saying, "Yeah. This is kind of" -- vaguely if this is a soft recommendation, that's fine, or language that says, "Yeah. We're not going that far. These are just examples with pros and cons associated." And whoever reads this can make sense of it. I'm just trying to get a little sense of where we want to --

DR. CROSSON: Right. I'd only point out that that sort of distinction, I think, may be derived from the next part of our discussion, which is where do we have support for the principles and where we have support for the examples, and that might then influence the relative strength or neutrality of what's in that final report.

I saw Paul, and then I saw another hand. No?

Paul.

DR. GINSBURG: On two of the services, Zach -- I think it was Telestroke and Telemental Health, you mentioned that they would expand access, but that supply is very tight in those areas. And I just wanted to push you to think a little deeper about what does that mean. Does it mean, well, they may not expand access because supply is

tight, or it may expand access by having a reduction of other services that those short supplies, professionals provide, and thus, it won't cost much, if anything?

I know you don't know the answer, but it's just worthwhile making it clear what you were getting at.

DR. CROSSON: Okay. So I don't see any more questions.

Let's now turn to Round 2. Maybe you could throw up slide 17. Good.

The last two bullet points kind of, at least to me, summarize kind of the essence of the discussion here because it's kind of like, well, we have some principles here in the context of evaluating the incorporation of telehealth services into Medicare Advantage. Are these the right principles?

Then there are some examples created. I think maybe we're going to hear some more examples. Are they the right examples?

To what level do we have concern about -- well, let me put it this way. Let's take coverage of mental health services. What's the strength of feeling in terms of dealing with what we know are access problems that need

to be addressed versus the potential for abuse of mental health services?

So discussion around that, and then the second part of that is those sorts of things which are concerning enough, for which the value is not compelling enough, that we think they should be tested. We have some examples of that.

And then, finally, sort of adding on to the mandate, the question of whether or not we want to make some recommendations with respect to the Medicare Advantage program.

So thoughts about those issues that will help inform us, and to get back to Jack's question, how strong are the feelings in these different areas?

So let's open it up for discussion. I see Paul first.

DR. GINSBURG: Yeah. I'm comfortable with these principles. There's something missing, though.

After we're saying some services may add value greater than their potential cost, I think there's a need to say some services -- the value of some services may be less than the potential cost, and that's why we need to do

-- in many cases, we need to do testing rather than proceed to cover them.

DR. CROSSON: David. David, Kathy.

DR. NERENZ: This is generally fine, but there's a distinction that I think we touched on perhaps at one of the prior meetings, I just wanted to reinforce here.

Some telehealth services do seem, indeed, to be a different type of thing. They're new, and so it makes sense to think of them as a benefit. Either it's covered or it's not covered, but it's different.

But a lot of the things we're talking about strike me as just a different means to get to the same fundamental thing. Telepsych is an example. If you're a psychiatrist, I can go to your office, and we can spent an hour. And we can do an hour of one-on-one therapy, or I can appear by Skype in your office. And we do the exact same thing, and some other services are like that.

So it seems to me as we think about this issue of coverage, it may be worth at least trying to think about what's really a different service or, therefore, needs to be considered a separate benefit, and what's simply a different means or a different site, if we want to use that

terminology, to do something that's already a covered benefit? Maybe the path is easier at least down that second part if we can identify things that look like that.

DR. CROSSON: Let me just add onto that a little bit, David. I think we talked about this once before, but there's yet another set of values here that are really not on our table but are very important in considering the example that you just put forward, which is the sort of secondary value to the beneficiary whom might in fact be working or -- and in that case, the value to the employer of providing those same services but in a much more efficient way for those individuals and potentially for the employer if the beneficiary is still employed. And that's of substantive value.

From my own experience in the organization I used to work for, it's very cherished by the patients, the beneficiaries, but it's not necessarily a value that we're considering in these tradeoffs that we're taking into consideration. So that's an important point.

DR. GINSBURG: If I could add one more thing, you're right, David, that the telehealth mental health really is the same thing, roughly, as the in-person one.

But the change is that it's at dramatically lower cost to the patients by eliminating the time cost to the patient of scheduling the appointment, getting there, which really brings up the situation, you know, are these services that we're contemplating substantially reducing the price of, are they already overused or are they underused? And I think that's where the testing comes in.

DR. NERENZ: Oh, I agree absolutely, but I chose that example because we probably would tend to think of that as underuse, or if we're thinking, you know, off into the opioid territory, are we offering sufficient substance abuse services. So I'd be happy to add that concept as an overlay that we'd want to think down this line, particularly if it's an underuse area, rather than either known overuse or risk overuse.

DR. GINSBURG: We could even say that if this is an underuse area, we're not so concerned about the volume increases because they'd be more difficult, and it may be that we just have a win for the patients without a significant loss for the program.

DR. MILLER: Can I just -- in all this exchange, there's just one thing I didn't follow. I felt like

particularly on your last exchange there you might do something because you viewed it as under -- you know, a lack of need being met, like your psych example in your work. That's definitely what we were trying to do with, I think, number 3. We were trying to do that. We were trying to say, for example, in number 1, let's just -- and now let's just do pretend on everything, okay?

The first example, the outcome here is so positive, you might want to incur the cost, that it's this notion of cost -- or value exceeds cost.

Then there was the example of saying that there might be a value to a specific set of patients, and it's a closed enough group that the size of the cost, you know, you're kind of going, yeah, this is worth it. So a Parkinson's patient with mobility issues, you say I'm going to do this because, you know, people are trying to be Parkinson's, just to be very blunt about it.

And then number 3 became this issue that you're talking about, it's like there is an underservice here in the country, and the program may want to incur the cost in order to do that.

And then the fourth category -- although there

was a real question there of, you know, to take on. And then the fourth is it's unclear whether from an access or a quality point of view that value exceeds the cost, and so that you want to park into demo space.

So the only thing -- I was agreeing with everything you're saying, but perhaps we just didn't get that third point across well to you, and so I wanted to say that is one of the very principles.

DR. NERENZ: And I don't think there's any disagreement here at all. I was just pointing out that rather than always using the phrasing and the vocabulary to say, well, this is a new benefit, there may be reasons to say this is a different way to get an existing benefit, and we should think of it that way.

DR. CROSSON: On this point, Jack?

DR. HOADLEY: Yeah, on Mark's point, I actually kind of like that notion, and it changes a little bit of the tone of how those examples get read. So the way you just framed it to say the four examples are in a sense four prototypes or genotypes or whatever --

DR. MILLER: Illustration.

DR. HOADLEY: -- as opposed to, okay, we just

thought of four things that we've seen out there that happened to work and they're just sort of happening, and maybe this was there in the way it was written and I missed it. But I like that because it says we're not so much saying, oh, go pick out stroke, you know, mental health and so forth as things you might tick off in a piece of legislation. And we still might be okay if somebody did that, but what we're really framing is saying there's kind of these four genotypes of kinds of situations that we're now applying our principles to and using an example to play it through. I think that actually frames it really nicely.

DR. MILLER: That's what we were trying to do.

DR. HOADLEY: Yeah. Obviously, didn't quite get it all, but now I'm getting it.

DR. MILLER: I think it was Andrew.

[Laughter.]

DR. CROSSON: I've got Kathy, David G., Dana, and then Bruce.

MS. BUTO: I'm trying to sharpen what Jack is saying because I got the impression in reading the paper -- tell me if this is right -- that these examples, especially the first three, were examples where partly based on what

Congress asked us to do, which is look at where this is being used commercially as well as in Medicare and where might there be some areas of opportunity to expand which are good for the program and beneficiaries, that these examples rose to the top. In other words, these aren't just examples. These are the ones that we're kind of struck based on experience as there could be real value. So I want to make sure we know where we are on this. Are we going to -- because I think some concern we have is that they don't just take these examples and say, oh, yeah, we'll add all these other categories that might meet one of your three criteria. I don't think that's the intention.

So I like the way it was framed, and I thought it went to the charge we were given to look at what the experience has been and where we think there's real value.

I would actually characterize these more -- rather than as an expansion of benefit, more like flexibility in the way the benefit's delivered, back to David's point, for these areas, because there is a benefit behind each of these that we're allowing greater flexibility in the way that it's actually delivered by the provider.

And then on the fourth one, direct-to-consumer telehealth, I wondered if we could also consider mentioning greater flexibility in relation to the per beneficiary primary care management. Did we do that already in our primary care per beneficiary payment? Because this strikes me as one where, if that ever came to pass, this would be a terrific additional tool for primary care physicians who would like to be in touch but don't have enough office hours to accommodate everybody.

DR. MILLER: To try and answer your question directly, my recollection is when we did talk about the per person primary care payment, we said the dollars could be used for these coordination activities, and I thought we rattled this off as part of it.

MR. WINTER: Yes [off microphone].

MS. BUTO: We did? Okay.

DR. MILLER: It is, and so there's no --

MS. BUTO: So you might reinforce that here.

DR. MILLER: -- problem bringing it -- we could bring it back into this discussion.

MS. BUTO: Great. And then my last point is back to the MA issue. I would really -- I think it would help a

lot to differentiate when something's a supplemental benefit versus either delivery by a different way or just the service that Pat was talking about, where you're making an accommodation to help a beneficiary, and that's totally within the plan's purview. So we're not confusing about how rigid the rules are around MA plans.

DR. CROSSON: Okay. David.

DR. GRABOWSKI: Great. Thanks. First, I'll start with the bottom bullet there. I'm very much in favor of consistent, I think, with MedPAC philosophy that entities bearing financial risk under Medicare should have more flexibility and be allowed to cover telehealth. So I'm very favorable towards that idea.

Second, I sort of struggled similar to Jack with kind of the examples versus the principles, and I like kind of working from principles and using these examples to play that out. And I was trying to think of telestroke and these different examples, and I think flipping that and thinking the principles and then trying to use these different examples, I like that approach, Mark. So thanks for that.

Then, finally, similar to Paul, I'm very much in

favor of using CMMI to sort of test a lot of this, and I think all of these ideas we can think through sort of the potential quality and access impacts and the cost impacts, but actually testing this is quite important. So I would very much encourage us to put that as a recommendation to have CMMI test this.

Thanks.

DR. CROSSON: Thank you. Dana.

DR. SAFRAN: Yes, I also really like how this is taking shape and, in particular, feel like the flexibility for the MA plans and the ACOs is the right place to start. I am concerned that the traditional fee-for-service system that we'll see this being inflationary. And I hear us saying, well, maybe that's okay for some things. And maybe it is okay for some things, but I think there are some good reasons to begin with this being implemented and studied in the MA and ACO environments. And I might even go so far as to ask that as they are implementing, that they are indicating how it will meet the principles that you said. So how will it improve access if improving access is part of what they're doing? How will it improve safety or other outcomes? And how will it help to manage cost? In

particular, I'm really interested in our learning and having these organizations think about how it allows them to take cost out of their existing cost structure and move away -- as we started talking about last time, move away from building-centered care. And if we can get them thinking about that, you know, for example, some of the offsets of even by improving access to mental health, which might increase costs, because there are these offsets and because it allows them to provide care in a less expensive way, you know, I think you need these organizations that are rowing in the same direction as we're trying to row in terms of managing overall costs, to be the ones where this gets tested first would be my thinking. And I'd go so far as to ask them to help us understand how their implementation plans are going to support your principles.

DR. CROSSON: Bruce.

MR. PYENSON: I'd like to pick up on Dana's comment and also Paul's comment. Paul commented that telehealth could be very valuable for the beneficiary in terms of savings of travel time and so forth. And, Jay, you had a similar comment for the employer perspective. But then Dana was talking about the infrastructure cost

moving away from facility.

Now, if we think about a hypothetical situation where we had a doctor whose entire practice was telehealth, think about what that would do to the factors within RBRVS. So within RBRVS there's, you know, work expense, practice expense, and malpractice expense. The work component would stay the same. The practice component could go down to zero. There's no need for an office and any of the supplies and all the other kinds of things there. But under the current structure, that would be a very -- such a telehealth specialist would be getting a lot of money from Medicare without having the expense. It would be very profitable. Now, that's part of how telehealth companies do their thing, right? If a physician doesn't have an office, they don't need as much income.

So I see that heading in the direction of what we saw yesterday with the off-campus emergency rooms where, you know, you have a different kind of enterprise getting different kinds of patients, different kinds of questions. So I think if -- a consequence of broader coverage of telehealth by Medicare would need -- would require reconsidering the E&M codes, and we have an RBRVS structure

to think about that.

Now, that perhaps doesn't make sense if, you know, if a physician gets one or two telehealth calls a week. You know, the practice expense is still there. They can't shut down one of their -- you know, pay less rent or something like that. But if this takes off, we have actually an interesting potential to reduce that component of Medicare spending appropriately.

So what I would ask is some consideration that Medicare not overpay for the practice expense at telehealth grows.

DR. CROSSON: Good point. Alice and Jack.

DR. COOMBS: So I was looking at the bullets, and in the context of what Mark has said, the last bullet I actually have problems with in the sense that that's something that maybe I would say needs to be studied under CMMI, and I would include the MSSPs with that as well.

In terms of, I think, the greatest value, I would say it would probably be telestroke, and there's one other entity that I think you guys mentioned, or maybe I saw it in a former chapter, was Parkinson's disease, and so Parkinson's disease and telestroke. And just to let you

know, Paul, you asked a question about how are resources constrained, and I work at two different hospitals, and one is a very busy stroke center. And so someone in neurology gets the call that a stroke patient has arrived to a community hospital 10 minute, 15 minutes away. It's in the middle of the night, and they will telegraph the CT scan and they will actually read it, they will do everything necessary and say, okay, drop the tPA. And so sometimes they transfer them to us from the community setting, but whatever is done, it's done in such a way that you can have total resolution of a patient who's totally cadaveric on one side, cannot move anything. You drop the tPA, and hours later you see them moving, and it is dramatic. And you consider what would have happened 20 years ago. That patient would have gone to the hospital, stabilized, blood pressure control, and that patient would be your SNF or LTCH or IRF patient. And that hospitalization would have taken a long time. So I think the value of that is absolutely incredible, and also the cost savings that's accrued.

And just to let you know, it is the fifth leading cause of death. Every 40 seconds someone's having a

stroke, and every four minutes someone's dying of a stroke. So this is like one of those areas I don't expect for things to change in terms of population health measure immediately. It's going to be someplace where we need to be throughout the country.

DR. GINSBURG: Alice, I didn't imply that telestroke did not have value --

DR. COOMBS: No, no. I was just saying about constrained resources, and it may be that the neurologists are not available at wherever the patient is at St. Elsewhere. And so it doesn't mean that they necessarily don't have all the FTEs working there, but it may be that specialty in and of itself may be deficient in that region.

DR. GINSBURG: So actually, when I was listening to you, there may be examples where neurologists are in short supply. If they don't have to come down to the hospital, they can do more. They can provide that wisdom on a telehealth basis, and in a sense nobody else misses out on neurologist services because they're spending time consulting on stroke patients.

DR. COOMBS: And that very reason, my brother actually had a stroke, and I called from Boston and asked

if a neurologist could see him in Los Angeles. And I was actually able to fly from Providence, Rhode Island, to California and see him before a neurologist came in his room. Needless to say, he had permanent sequelae because of the stroke. So just that piece alone is huge in terms of having someone available.

And then mental health services, I think mental health services are really important. I don't know, MA plans -- Pat, you were very helpful in kind of elucidating how the process works. But I think that mental health services are probably another high priority area, as has been mentioned already. And probably because patients -- it's a stigma sometimes going to see a mental health -- a psychiatrist or a psychologist. And having telemedicine is an easy way for them to actually see someone without the stigma, and patients feel a little bit more comfortable because of confidentiality. So I just would like to say that that last bullet is one that I'm not very comfortable with, granting greater flexibility without further study.

DR. CROSSON: Okay. Jack, Warner, Pat. Let's go up this whole row here. Jack.

DR. HOADLEY: So, thank you for all this work and

I know you guys have done a lot of work on this on a pretty abbreviated schedule and it's impressive. And I think we're ending up in a pretty good place overall.

Just a variety of little comments. I'm struck that -- and I think this is there, but on the MA options, you know, the discussion we were having about trying to tease out the details, the extent to which the option -- either of the options you've laid out sort of fix those problems, or how they address that sort of ambiguity, just make sure we've made real clear sort of the linkage between this -- maybe we can tease out a little more from this discussion of the circumstances that telehealth gets used or doesn't get used in MA, and whether -- and the whole complexity of paying for it gets fixed by this. I mean, I think that was the -- I mean, it's clear that was the intent.

Second, sort of going to this whole discussion of how we think about the tradeoffs and the whole notion, and one of the early slides of exercising caution, you know, I think we're teasing that out really well, both in what you've written and in how we've talked about it, and it does strike me that there significant areas where improved

access is worth some investment of additional costs. The one I think, on the other side, the one that struck me, is some of the potential roles for some of these vendors. You know, we've seen, in so many areas, you know, you start out designing something that makes a lot of sense, the way it's being done, the way it's initially done just works and is sensible, and then certain kinds of vendors or companies get a hold of it and they say, "Okay, boy, we've got this thing. Now we can just push these services into people."

I think we got some of that out of the commercial insurance experience, and that may be something where we can sort of pull out that notion as one of the potential pitfalls, and that goes, again, to some of the potential for testing some of these things in a CMMI context, although I suspect that through a controlled demonstration is not where you get the playout of that exploitation of something. That comes later. Okay, you test it, it's all very clean and controlled, and it works in that controlled situation. And any insights, whether from private insurance or elsewhere, of how to sort of prevent the exploitation, again, often driven by certain kinds of vendors that we can put in there, seems like a useful

point.

But it does go back to saying -- that caution of trying to figure out the tradeoffs and that framing of these different examples and where the tradeoffs -- where the risks of those exploitations seem less, or how we think of them in those different examples. I think that's a nice way to frame all of this up.

The last comment is simply that it struck me, and it was on your Slide 3 or something, where you talked about the comparisons of what you learned in the commercial, that in the commercial sector generally was not making the distinctions of rural versus urban in the way that Medicare -- and I was somewhat expecting that we might have more of a stronger observation around that point, that maybe the distinction about focusing this strictly on rural areas is not the most useful way to -- and maybe one way to think about that is that some of these other thoughts we're building in these four scenarios are a better way to think about, you know, a service that has an unmet need as opposed to, you know, it's just a rural thing. So we can have shortages of neurologists in any particular community, temporary perhaps, you know, longer term, whatever, as

opposed to sort of making the blanket assumption that rural and general has shortages and urban doesn't. And so, you know, maybe there's a statement -- again, we're not framing any of these as, you know, bold-faced recommendations, that the urban-rural distinction that we've used to date isn't capturing some of the things that we're thinking of.

DR. CROSSON: Thank you. Jack, I just want to emphasize, I have the similar concerns that you do, particular about the extension of telehealth mental health services, and I can see the need here, which we've all expressed. I can also see, you know, the potential that you've described. And I just wonder, in terms of thinking about ways that, you know, we might suggest something could be done about that, and I'm not sure I know what that is, exactly. I'm not a particular fan of preauthorization, but something -- you know, or even limits. But there may be some notions that we could conceive of where we could at least caution in that regard, or perhaps make some suggestions about how that could be forestalled.

DR. HOADLEY: Yeah. I think that's right, and prior authorization doesn't really feel -- I mean, it seems like that's a hard way because it creates a lot of barriers

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DR. CROSSON: Right.

DR. HOADLEY: -- a lot of burden. Again, we've seen this in so many other areas and we've talked about different parts of an industry that come in. We talked about it yesterday with some of the freestanding ERs, you know, ones that simply come in to say, okay, there's a profitable area to move into. It's nothing about the need of a community, and how do we draw distinctions.

Now there we've got mileages and things we try to play with. It's a lot harder to think about how you would do it here.

DR. CROSSON: Right. I'm sorry, Kathy, on this point.

MS. BUTO: On Jack's point, my impression, when I was reading this, was that actually most of our expansions are into urban areas, from a benefit that is largely available to rural. But I agree with Jack. I think that doesn't -- that shift in our thinking, based on the analysis of what commercial plans do, doesn't come through as strongly as it should.

And just on the point of the two options for MA

plans, isn't the first option just status quo? It's essentially whenever Medicare expands a benefit, MA plans expand a benefit?

DR. JOHNSON: It would be status quo, but just pointing out that if there some expansion under fee for service, given a renewed effort as a result of our report perhaps.

DR. HAYES: Yeah. It just didn't feel like a real option to me, because I know that that's what we do now. Then I wondered, did we really just have the one option, although I guess the other aspect would be you can always continue the supplemental premium and rebate approach, right?

DR. HOADLEY: That would be the point, then, to emphasize. I didn't think that all the way through. But to emphasize the point that Option 2 accomplishes some of these things in a way that Option 1 doesn't. Option 1 does this much, in terms of if we make other adjustments, but Option 2 would take -- would go ahead.

DR. CROSSON: Okay. Rita.

DR. REDBERG: Thanks. And I think I like -- I agree with a lot of the Commissioners' statements and the

principles and the plan you've set out going forward, because I think there is certainly a lot of potential to do good in telehealth, but I think it makes sense to start in risk-bearing MA and ACO entities. I do worry about the volume incentives in physician fee for service, particular before we have a lot of evidence. I think, like a lot of new things, but this is clearly a new thing.

We really want to see evidence that it does adhere to the principles, and, in particular, improve outcomes, because, you know, there's all kinds of things, as we've said, that can be telehealth. There's, you know, tons of now health analytics, and blood pressure things, and we don't even know if they work. I mean, if the put outcomes just on a quality level -- you know, the FDA is still trying to figure out what has to be regulated, what isn't. But we know there are a lot of things on the market that purport to tell consumers things about their health that we have no idea if they actually do or not. And so I think it's good to kind of go slow and look for the evidence, and involve CMMI, too, in some of the innovation projects.

So I like the potential and I think the examples

you chose are good ones, the Telestroke, and certainly the mental health. I've had patients that have tried that and really like it, because of the privacy issues. And also some patients have used it when they're not native English speakers, to have someone who they can -- done internationally, so that they have someone that they feel more comfortable talking to in their own language. So I think it's a great summary.

DR. CROSSON: Warner.

MR. THOMAS: So I would just want to echo Alice's comments around especially stroke and mental health, and I think the more that we can provide flexibility into rural areas, I think this is a huge opportunity to continue to expand capabilities of rural facilities. We were talking about, you know, critical access hospitals yesterday, that they are declining utilization, because they don't have the folks that kind of keep people local, so they ship everybody out. Stroke telemedicine is one way. We actually have about 60 hospitals on stroke telemedicine, and we have about a 90 percent retention at those hospitals of patients versus before it was probably, you know, 40 to 50 percent of patients would be retained locally.

So I think there's more opportunities, with certain conditions, that can be treated locally with the right telemedicine and clinical capability being connected to them.

I'm a little different than where a lot of other folks are on this. If I was going to bet on an innovation, this would be one I would bet on, because it is relatively low cost, frankly. I think you could price it so it was low cost, and I think the impact is potentially pretty substantial. Right now we don't control, you know, when people go to the doctor or go to an ER, and we were talking yesterday about ER utilization. This is a potential to potentially avoid ER utilization, frankly. If you get the right telemedicine consult and you're told, you know, how to handle your medical condition, you're less likely to go to an ER, especially if you have to wait four, five, or six hours.

So, you know, I think we should do more things through CMMI. I think those are great places to test. But I would be more inclined to give more flexibility, and I know the direct-to-consumer component is a little sensitive, but today people can access services whenever

they want anyway. So I don't think it's like someone is going to get a telemedicine consult and then go get, you know, an office visit if they don't have to. So I just would ask us to think about that.

But I would encourage us to -- I would actually say, on the stroke side and on the mental health side, let's make sure we set the adequate reimbursement, to get more people to do it, because it is life-saving and life-changing in those services.

DR. CROSSON: Yes, Pat.

MS. WANG: So I actually generally think that Option 1 is the correct way of sort of thinking about this. I definitely think it's like a no-brainer, based on what everybody has said and what the literature has shown and what you wrote about. The Telestroke is a benefit that should be made available to beneficiaries who live in urban areas as well as rural areas, so expand that out.

Tele mental health, I have to say it sounds really good. The thing that's a little different about, you know, the flexibility to use it when you're an ACO or an MA plan, you know, on a person-specific basis, to declaring it part of the Medicare A/B benefit is -- you

know, I just want to take a pause there, because that has its own implications, at least to me, and I'm not sure that I feel that enough is known about how that would actually work. I think it's definitely beneficial for many people, but unlike Telestroke, which is going to be beneficial to anybody, everybody, tele mental health is still a little bit young in the development of the service. I'm just a little concerned about sort of saying, you know, put it into the A/B benefit, you know, for the whole country. I'm just a little hesitant to do that.

The other thing that I just want to make sure that I understand is the final bullet here about flexibility given to MA plans and two-sided ACOs, you know, as a general principle, of course, you know, I think that's right. I just want to make sure that the way that I interpret that is, so, under Option 1, something goes into fee for service. It does become sort of like a mandatory benefit that everybody offers. This has to do with the things that we described that think entities at risk do now, which is on a person-specific basis, try different approaches. That flexibility remains.

I'm not sure that I would agree that that

flexibility should extend to I am now going to advertise and offer a direct-to-consumer telehealth benefit to all of my MA enrollees. It's not a supplemental benefit. I'm going to pay for it within the premium, but it is a different benefit. Again, it does that step-up. It's sort of like part of the A/B package now, as opposed to what plans are doing now, which I think is flexible enough. Do you know what I mean?

So I just want to kind of just draw that distinction a little bit. I think you do -- I don't think it's a great idea to start -- for Medicare to start going down two different tracks. Entities at risk can kind of put any benefits that they want to in there, and fee for service is still wanting to experiment, to see whether it's -- it just feels a little funny. So I feel like Option 1, with the current flexibility that risk entities now have to use telehealth, is kind of the right thing.

DR. CROSSON: Brian.

DR. DeBUSK: Talk about terrible timing of comments, because I'm about to advocate for mental health --

[Laughter.]

DR. DeBUSK: -- and for Option 2. So I'm sitting here thinking, did she read my notes and just go with the opposite?

MS. WANG: No, I read your mind.

DR. DeBUSK: Yeah, read my mind. That's even scarier. Thank you.

I want to advocate for going ahead, going forward with mental health. I will tell you I like the way that it made it as one of our four illustrations. I hope we can find a way to maybe even lift it above just an illustrative example in this report and maybe even set it aside as its own case study, area, whatever. And here's my rationale. I think we're missing an opportunity in this congressionally mandated report to send a message that says when you have 50 percent participation rates by psychiatrists, when you have a particular discipline that's somewhat checked out of a payment area, that the program is prepared to respond aggressively to fill that void.

And you can imagine what opening this up to telehealth means. I mean, what it really means is that any psychiatrist, anywhere, could provide this mental health benefit. I mean, you're breaking down all these geographic

barrier. I would see that as a pretty aggressive response, but I would also see that we would be doing this in an area where the providers aren't participating at rates that are -- that we typically see for other categories of providers in the program.

So I hope we don't miss that opportunity to say, you know, if you don't participate, we're going to do some pretty aggressive things to make sure that our beneficiaries are taken care of.

The second thing I want to talk about is this Option 2 on Chart 16. I really like Option 2, and I completely get it in that you wouldn't just want to let fee for service start billing telehealth. I mean, it would be inductive. We'd get a lot of new spending. And I also get it if you're in a fully capitated, let's say an ACO, a Next Gen, per-member, per-month, you'd really want to be very lenient there, because they have a lot of incentives.

MA is a little bit of a gray area, because they are fully capitated but their benchmark, or their bid is a function of anticipated spending. So it sort of falls in that gray area of it's not truly, truly capitated. It's capitated and comingled with a benchmark that has

anticipated spending.

But consider this. Let's say that I'm at my full rebate, my 70 percent rebate on an MA plan. When I bid, if I were to bid below the benchmark and not incorporate that spending, I'm going to get 70 percent of those dollars back. So, really, I want us to hope we can look at this way. Really, for only a 30 percent incremental cost, we're going to have the opportunity to let MA plans just basically go unfettered in this telehealth space.

To me, it seems like if we're only putting 30 cents on the dollar truly at risk -- and I don't know what the average blended rebate is. It's probably closer to 50 percent or so, maybe -- but we're getting to work with telemedicine at a discounted rate, because we're using dollars that presumably would be coming back to these plans as rebates anyway. To me, my inclination -- Bruce, is it lower than 50 percent?

MR. PYENSON: They have to use the rebates for benefits.

DR. DeBUSK: That's what I'm saying. Let's say that I allow them to incorporate in the benchmark now, so their bid is going to be a little bit higher, right?

DR. MILLER: Well, that's the $64,000 question.

DR. DeBUSK: Well, let's assume their bid is a little bit higher. They're going to -- either way, a portion of that money -- let me just sort of step back in in a more general way. Either way, a portion of that money would find its way back to them, that they could then presumably use on extra benefits. Like if they wanted to incorporate telehealth, and we stuck them with just Option 1, they could also just bid below the benchmark, get a 70 percent, 50 percent, 60 percent rebate, and then apply that rebate, right, toward extra benefits. There's nothing that would stop them from adding the telehealth benefit through funding it through the rebate. Correct?

DR. MILLER: Including right now.

DR. DeBUSK: Yes, right now. Including today, right? So the point is, if we go to Option 2, where we allow them incorporate really as much telehealth as they want, but they get to build that into their bid, their bid, I guess, worst case would go up.

DR. MILLER: Let's say it goes up. I mean, you know, what everybody says is this saves mountains of money --

DR. DeBUSK: Right.

DR. MILLER: -- and then the argument is, I want to build it into my bid, and the assumption is that the bid will go up, which is a little counterintuitive, but go on.

DR. DeBUSK: Well, but that's the point. Even if the bid goes up and they are participating in this plan, let's take the delta of how much the bid would have gone up anyway. If they had subtracted that delta in their original plan -- let's say they said, okay, we're not going to build this into our plan. Let's say we stuck them with Option 1. So, presumably, their bid would go down by that delta. That differential between their bid and their benchmark, they're going to get 50, 60, 70 percent of that back in rebate dollars anyway.

The argument I'm trying to make is --

DR. MILLER: And in this instance, to the extent -- I think I'm following you now. It took me a little while to catch up. But I think the distinction is whether it's a 100-cent dollar or a 70-cent dollar.

DR. DeBUSK: Yes.

DR. MILLER: Right?

DR. DeBUSK: I'm making -- and I probably should

have said this at the first -- I'm making an incremental cost argument, is what I'm making, and what I'm saying is that granted that MA plans aren't true, true capitation in that they get this bid benchmark mechanism, but when you consider the incremental cost of 30, 40, 50 percent -- I mean, we would be buying that telehealth, in theory, at a discount of sorts. To me, the opportunity to turn these guys loose and really see what they can do with telehealth and study it closely, knowing that we get to buy it at somewhat of a discount, to me seems like a pretty good bargain.

So those were my two points, telehealth and Option 2 on Chart 16.

DR. CROSSON: So, Brian, can I just -- I just want to clarify a little on your first point, because I thought I heard potentially two things that were a little bit disparate. Your first point was that because of a shortage of mental health services available to Medicare beneficiaries, and partly as a consequence of mental health providers not taking care of Medicare beneficiaries or not doing it through the Medicare program, that you would favor expansion of fee for service -- in the fee for service Part

A, Part B expansion of telehealth for mental health services.

But then I thought I heard you say, towards the end, that you were concerned about induction of services if we expanded --

DR. DeBUSK: Sorry.

DR. CROSSON: You're saying --

DR. DeBUSK: Let me clarify.

DR. CROSSON: -- you're saying that's your general principle --

DR. DeBUSK: Yes.

DR. CROSSON: -- but with respect to mental health services you're making a special case.

DR. DeBUSK: Yes. Mental health would be a special case. In general, I think just turning fee for service loose with telehealth could be -- could have serious spending ramifications. And then back to the other comment about Option 2 on Chart 16, again, I just see the opportunity to purchase telemedicine services in MA plans at a somewhat of a discount or a marginal discount --

DR. CROSSON: I got you.

DR. DeBUSK: -- and I hope we take advantage of

that.

DR. CROSSON: I got that. Okay, Paul.

DR. GINSBURG: Just two things. You know, first of all, I wanted to say that I'm very enthusiastic when the staff uses site visits as part of its projects, and I think it really came through on this project. I think that's been a significant part of the value that this report will have, is really what you learned through the site visits. So I just wanted to say that as a general thing.

In this debate about Option 1 or Option 2 for Medicare Advantage, it appears to me that, for at least several years, the MA plans or their actuaries won't really know whether, you know, providing a telehealth benefit is going to increase or decrease costs. And so we probably shouldn't take this too serious, and we probably should acknowledge that this is going to be a great area of uncertainty, rather than just assuming, oh, you know, there must be an answer and actuaries will find it.

[Laughter.]

MR. PYENSON: Nobody listens to my answers anyway.

DR. GINSBURG: But obviously they'll be doing

their best but they won't be that precise. So I think we should acknowledge that this is going to be a very vague area.

But I do think that Option 2 is the way to go.

DR. CROSSON: Warner and then Bruce.

MR. THOMAS: Just real briefly, I think the other thing that is not covered in the report that could be helpful is just the whole issue around licensing, and, you know, that there are some states that are still dragging their feet around the whole licensing issue, and it is a limitation, frankly, for some states. I don't understand all the issues around that besides parochialism, but perhaps there could be a comment in here about that that's an important consideration to the implementation and the effectiveness of this service.

MR. PYENSON: I may have missed this in the material, but having an option that would allow MA plans to include telehealth services in their bid as a voluntary option, as opposed to a new mandatory --

DR. JOHNSON: Meaning voluntary for the beneficiary or voluntary for the plan to offer?

MR. PYENSON: For the plan.

DR. JOHNSON: I think the way we were envisioning it would be that if a plan wanted to offer particular telehealth services they could include that in the bid, and any telehealth services that they would offer would be in the bid and funded through the program's base payment rate.

MR. PYENSON: So the last bullet on page 16, that would apply to just the MA plans that --

DR. JOHNSON: Correct.

MR. PYENSON: Okay. Thank you.

DR. CROSSON: Okay. This has been an excellent presentation, an excellent discussion. We will be incorporating the range of ideas here. There are some disagreements. They can be constructed, I think, as options in the final report. We will be seeing it again in January for a final vote.

Before we proceed with the public comment period, I cannot end today's discussion without an acknowledgement of the fact that this is the last meeting for Mark Miller, after 15 years of exemplary leadership of MedPAC. I have enjoyed 10 of those years myself, both professionally, as a member and later Chairman of this Commission. I think the Medicare program and the public at large have benefitted

dramatically from the intelligence and leadership and sensitivity and occasional sense of humor manifested by Mark, and I just want to publicly acknowledge his work.

[Standing ovation.]

DR. MILLER: Thank you.

DR. CROSSON: So we will proceed with the public comment period. If there are any members of the public who would like to comment on issues that we have discussed today, please come to the microphone so I can see -- it looks like we have a substantial line there. Let me just wait a second for the clearing-out process.

I would like to remind you and others in the audience that there are a number of ways to provide input to MedPAC and the staff -- directly through e-mail, through written correspondence. Public comment period is one of those, not necessarily the best because it occurs after the discussion has taken place.

For those of you who are going to make comments I would ask you to identify yourselves and any organizations that you are representing or are associated with. And I would ask you to keep your comments to two minutes. When this red light goes out, that will indicate that the two

minutes have expired. Thanks very much.

MS. TRUJILLO: Thank you. It will be brief. Sylvia Trujillo with the American Medical Association, and I am actually commenting on both sessions.

So with regard to the discussion around the Part D program and biosimilars, just an observation during the time that the ACA was being debated and the biosimilar provision conferring the FDA with authority for approval of interchangeable biosimilars, interchangeable products to an innovator versus the biosimilar. A lot of our physicians made clear that this new regulatory regime could create a lot of confusion about whether or not the products were truly interchangeable. So the only observation I have with regard to that is the one thing that we strongly support is your effort to remove perverse incentives that would encourage people to use the innovator when a biosimilar would be equally appropriate, but caution that any changes that would force switching between either biosimilars or the innovator, if it's not truly interchangeable, we encourage you to be mindful of. So that's on the first session.

On the second session, just very quickly, first,

we applaud the structure that was outlined today with regard to the three criteria and our categories for evaluating expansion of telehealth. I do want to flag that there is a distinction between telehealth and remote patient monitoring, and in the Medicare program the AMA supports the definition of telehealth as a two-way audio-visual exchange. And we do caution that we don't consider, nor does the program consider telephony to be telehealth.

And with regard to the licensure issue, we do have an interstate compact that the AMA and many in the Federation of Medicine and the Federation of State Medical Boards have been strongly advocating for, and we already have 22 states that are adopting it to facilitate things like telehealth. And I would note that a lot of telehealth and remote patient monitoring doesn't necessarily go across state lines. It's normally a hub intrastate of a medical center and out to rural areas or urban areas.

So our understanding and belief that for physicians the big questions are, will I get sued, so addressing liability issues, and will I get paid. But even before that, their question is, does it work? And to that end, we have submitted previously and we strongly support

the three examples you all used in Options 1, 2, and 3, with regard to telemental health, individuals with physical limitations or complex chronic conditions that make it difficult for them to receive care, as well as specialty areas that are underserved currently, such as neurology, when you have a Telestroke scenario.

DR. CROSSON: Please conclude.

MS. TRUJILLO: Thank you very much.

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

MS. DROBAC: Hi. I'm Krista Drobac. I'm with the Alliance for Connected Care. It includes stakeholders like Stanford Health Care.

I have three -- or two comments, separating remote monitoring and telehealth. Remote monitoring is not subject to the 1834(m) restrictions that telehealth is. So the first thing is I would encourage you to reexamine the definition of remote monitoring, on page four. It is widely considered to be remote monitoring of biometric data that is asynchronous, not necessarily a two-way video exchange.

Also, there is coverage of remote monitoring in Medicare today. We have implantable devices that are paid

remotely. Just yesterday, in the physician fee schedule, CMS unbundled the code 99091, which is the remote biometric monitoring of a patient.

Then, also, I would like to just say that on Slide 12, on remote patient monitoring value not being tested, there is voluminous amounts of data around the value of remote patient monitoring, even in the Medicare program, because a lot of hospitals are paying for this out of their operational budget, which has created a lot of evidence.

And then on telehealth, I was hoping that you might consider including another example, which is post-acute care. There is evidence that telehealth is very advantageous in post-acute care. For example, the Obama Administration created eight new codes under the CCJR Demo and the Cardiac Care Demo, in part because they believed that there was a lot of value in having telehealth visits once a patient leaves the hospital.

And then the other thing is, last thing, is I would love to encourage you to acknowledge the data coming out of the Veterans Administration around both direct-to-consumer care and telemental health, because there is

significant evidence in VA, and TRICARE just added telehealth, and there's also DoD telehealth, so the other parts of the government that have shown a lot of cost savings, actual cost savings, so I would love to see that acknowledged.

Thank you.

DR. CROSSON: Thank you so much.

DR. FLANNER: I'm only slightly nervous here. I'm David Flannery, Medical Director of the American College of Medical Genetics and Genomics, which is a specialty society representing clinical genetics specialists. Every specialty has its own organ system. Ours is the human genome. Consequently, we see patients from infancy through mature adulthood.

With increasing rise of precision medicine there is increasing need for patients to see medical geneticists. We are a small but mighty band of specialists. There are currently 1,600 active M.D. geneticists in the U.S.

In addition, we are not well dispersed, primarily being in academic medical centers. ACMG recognizes that telemedicine increases access to quality medical genetic services, as documented in many publications, which I will

be happy to share with you -- I have a multi-page bibliography of that for you -- and we promote the use of telemedicine for genetic services.

I can speak from personal experience. Prior to my position, I was on the faculty of Medical College of Georgia for 29 years. I started using telemedicine to see genetic patients in 1995, and by 2014, I had three half-day genetic clinic by telemedicine, seeing patients all around the state.

It is ironic that if geographic limits persist for Medicare beneficiaries in cities like Macon, Savannah, and Columbus, Georgia, they would have to travel to see a geneticist in the only two locations, which are Augusta or Atlanta, and this is something that should certainly be fixed.

Thank you.

DR. CROSSON: Thank you.

MS. BOYLE: Hi. My name is Lynne Boyle and I am representing University of Virginia Health System. I just want to say thank you to the MedPAC staff for coming to visit us. We really appreciate the opportunity to share our information with you. We are -- the UVA Health System

is working with -- in 153 sites across the commonwealth in over 60 subspecialties.

I just want to express my appreciation for the comments around the examples that were used around Telestroke, telemental health. Obviously those are service that we provide. I just also want to make a distinction or a comment around substance abuse. So it's a really opportune time right now, and we provide those services as well.

Just as a follow-up to some of the comments around remote patient monitoring, it is an area that we do provide, and we have seen exceptional savings in that, in terms of sending home our cardiac patients with remote patient monitoring, and we've seen a reduction in about 40 percent of hospital readmissions there. So that is definitely one area that we see savings to the Medicare program.

And, last, in vis-à-vis the discussion around Medicare Advantage, in Charlottesville there is not a lot of Medicare Advantage. We are still fee for service quite a bit. And I just think that is just a basic understanding that needs to be reiterated in the report.

Thank you very much.

DR. CROSSON: Thank you. Seeing no one else at the microphone, we are now adjourned until our December meeting. Safe travels, everyone.

[Whereupon at 11:34 a.m. the meeting was adjourned.]