MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Thursday, October 5, 2017
9:25 a.m.

COMMISSIONERS PRESENT:

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JON B. CHRISTIANSON, PhD, Vice Chair
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KATHY BUTO, MPA
ALICE COOMBS, MD
BRIAN DeBUSK, PhD
PAUL GINSBURG, PhD
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AGENDA PAGE

P R O C E E D I N G S

[9:25 a.m.]

DR. CROSSON: We're going to reassemble and begin the meeting. We are going to open the meeting in a minute.

Before we begin our work, I'm going to ask for a moment of silence in recognition of the tragedies that have hit our nation in the last number of weeks.

[Moment of silence.]

DR. CROSSON: Okay. We are going to start off with a discussion of the Merit-based Incentive Payment System, MIPS, and Kate and David are here. David is starting? David is starting.

MR. GLASS: Good morning. Today we are going to present a policy alternative to the merit-based incentive payment system, or MIPS, one of the paths for clinicians under the Medicare Access and CHIP Reauthorization Act, MACRA.

Today's presentation is the next step in our work on MACRA and its related policies: the merit-based incentive payment system and advanced alternative payment models. We have presented on this topic five times over the past two years and developed the Commission's positions

in the last two June Reports to the Congress. We have also provided guidance to CMS on their implementation of MACRA in three comment letters.

Today we would like to get your feedback on an alternative policy option to MIPS. And for clarification, this session only covers MIPS -- not other issues in MACRA, such as A-APMs, nor issues in the fee schedule more broadly, such as the balance for primary care.

I'll go through a brief description of MIPS and highlight some of the Commission's key concerns. Then Kate will present a policy alternative. As she will discuss, time is of the essence in pursuing an alternative to MIPS, and, therefore, she will ask you to discuss if we should develop the policy alternative into a draft recommendation for the December meeting.

MIPS is an individual-level clinician payment adjustment that Medicare will use to start adjusting payments to clinicians up and down in 2019. It builds on prior efforts by Medicare to adjust payments based on quality and EHR use, and uses many of the same measures and processes.

MIPS applies to clinicians in most specialties,

those who are above a low-volume threshold, and who do not participate in Advanced Alternative Payment Models (or A-APMs) at a level sufficient for the incentive payment.

Clinicians are reporting their MIPS data now, and that's based on their participation in the program during 2017. They will get the payment adjustments in 2019.

The basic MIPS adjustments are budget neutral, and there is also an additional $500 million appropriated each year from 2019 to 2024 for exceptional performance.

This slide lists the four areas in which MIPS will assess clinician performance and the respective weights for each category in 2019.

For quality, clinicians must choose to report six quality measures from a measure set of around 300. Large group practices must also administer a patient experience survey. Quality counts for 60 percent of the score in 2019.

The Advancing Care Information area is the latest iteration of EHR meaningful use, and clinicians will attest to their performance in 11 to 15 activities such as e-prescribing or immunization registry reporting. This counts for 25 percent.

CPIA is a new category. Clinicians will attest that they undertake practice improvement activities like 24/7 access or participating in a medical home, and this is 15 percent.

The cost area performance will be calculated from claims, but note it is weighted at zero for the first two years of the program. CMS had some leeway in what weights to use in the first two years.

The next three slides outline some of the Commission's concerns with MIPS. All of these points are elaborated in more detail in our comment letters and reports. So first we look at burden and complexity.

MIPS requires a significant amount of clinician burden to extract and report quality, ACI, and CPIA information. CMS estimates that the clinician cost to comply with MIPS in the first year of the program is over $1 billion.

Second, MIPS is extremely complex, as we have brought up in our comment letters. And CMS, in trying to give clinicians more flexibility and options, has actually increased MIPS inherent complexity. For example, there are many exemptions; in fact, in 2018 CMS estimates there will

be more clinicians exempt from MIPS (800,000) than participating (600,000).

There is special scoring and rules for facility-based clinicians, clinicians in certain models, clinicians in certain areas.

There are multiple reporting options, such as EHRs, web interfaces, and registries. In addition, clinician's performance score for quality is dependent on the actual reporting method they use.

Because of all this complexity, it is extremely unlikely that clinicians will understand their score or what they need to do to improve it.

What is more, we have concerns with the measure themselves and the scoring system.

Our most basic concern is that the measures used in MIPS have not been proven to be associated with high-value care. Many of the MIPS quality measures are process measures, assessing only the care a provider delivers within their four walls. Many of the remaining measures are attestation only, "check the box" sort of measures. The fact that after ten years of collecting many of these measures, there is minimal information for patients on

Physician Compare, which highlights the low value of the information.

Part of the problem is there are overall challenges in developing any individual clinician-level performance adjustment. Key among them are the statistical limitations caused by relatively small case sizes for any given clinician.

Another concern is that MIPS is structured to maximize clinician scores, which seems like a good thing, but it leads to score compression, that is, everyone will seem to have high performance. And, in fact, many of the measures are topped out or appear to be topped out given who reports them. And that will limit Medicare's ability to detect meaningful differences in clinician performance.

In the first two years, the high scores coupled with the very low performance thresholds, (3 points and then 15 points out of 100) will mean minimal rewards because everyone will be a winner and it is a budget-neutral system for the base adjustments.

In later years, Medicare will have the opposite problem. Minimal differences in apparent performance could result in large differences in payments.

Finally, clinicians choose what six measures they want to be evaluated on. Thus, each clinician's composite MIPS scores will be comprised of performance on different measures. But clinicians will nonetheless be compared to each other to derive payment adjustments. And this is inequitable.

Because of these many concerns with MIPS, we conclude a new approach is needed.

MIPS will not achieve the goal of identifying and rewarding high-value clinicians. Yet there is agreement that there should be a value component in Medicare fee-for-service.

In addition, the statute requires that quality measures should be comparable between MIPS and A-APMs. But the silo-based measures in MIPS are not working for fee-for-service and are unsuitable for A-APMs that are designed to drive care coordination across silos. An alternative would be to use population-based measures that would be suitable for A-APMs and would help drive delivery system reform. But they would need to work in fee-for-service as well.

Kate will now describe a policy option to address

this dilemma. It uses population-based measures and is designed to be compatible with A-APMs and yet also work in fee-for-service.

MS. BLONIARZ: In putting together the policy option for MIPS, we have the following goals in mind:

First is to align the quality and value signals across the health care delivery system. And those signals are towards a delivery system that is patient-oriented, coordinated across silos, and focused on improving population outcomes.

Second, to equitably assess clinician performance using the same set of measures.

Third, that a redesigned value program should minimize the upside from remaining in traditional fee-for-service.

And, fourth, to reduce or eliminate a real, quantifiable clinician burden.

So the policy option is as follows: It contains two elements. First, it would eliminate MIPS and all of its related reporting requirements. This would mean no more clinician reporting of quality measures, Advancing Care Information, and Clinical Practice Improvement

Activities. CMS would no longer support EHR reporting of measures, the web interface, or the CPIA or ACI data collection.

The second component is a new voluntary value program, along the lines of what we described in our 2017 June report to Congress. I'll describe this on the next slide.

Here's how the voluntary value program would work.

All clinicians would have a portion of their fee schedule payments withheld -- for example, 2 percent -- to go into a value pool.

Then clinicians would make one of three choices. They could elect to be measured with a sufficiently large entity of clinicians (and potentially be eligible for a value payment). They could join an advanced alternative payment model and receive their value withhold back. Or they could make no election and lose their withhold.

Let me talk about the first option for a second. So these entities could be a group of clinicians all affiliated with a hospital or in a local area. And the entity's performance would then be collectively measured

using a set of population-based measures, which I describe on the next slide.

The limiting factor for these entities is that they need to be sufficiently large to have statistically detectable performance on the population-based measures. But, otherwise, it would be left up to the clinicians themselves to determine how to organize into entities.

The population-based measures could be in three categories: clinical quality, patient experience, and value. There are a couple of examples on the top of each slide. The benefits to using these measures is that they can be extracted from claims or centrally conducted surveys, eliminating the clinician measure reporting burden. And, second, using all the measures in combination would help to balance incentives from overuse or underuse of services.

Let me take a step back here and make a few points about the policy option. It is important to recall the current status quo of MIPS. It's extremely complex and imposes a significant burden. We believe that it will not succeed as a quality improvement process and sends the wrong signals to clinicians and the delivery system in

total.

Clinicians are starting now to report their 2017 activities for the 2019 payment year. Time is of the essence if the Commission wishes to make substantive changes to the program.

The intent of the policy option that we present here is to encourage clinicians in fee-for-service to join with other clinicians to assume responsibility for the outcomes of their patients. This option would be for the purposes of allocating Medicare dollars. It would not preclude intermediate entities like ACOs or specialty societies from collecting or reporting individual clinician performance.

So here is the illustrative policy option I have been describing. It would eliminate MIPS, doing away with individual-level clinician payment adjustments and all of the reporting requirements. In its place would be a new voluntary value program that would allow clinicians who elect to be measured with others to be eligible for a value payment based on the population-based outcomes of their patients.

The question for your discussion is whether we

should move towards formalizing this as a draft recommendation in December. So we're happy to answer questions and look forward to the discussion.

DR. CROSSON: Thank you, Kate and David.

Let me see hands for clarifying questions. Okay, let us start with Warner today.

MR. THOMAS: Thanks for the report. On the policy option, the proposal, so for folks that do not opt into the program, what would be their situation? Would they have a withhold, then --

MR. GLASS: They'd lose the 2 percent withhold.

MR. THOMAS: So they'd just lose the 2 percent with no potential option, okay. And what about -- and just for clarification, folks that are already in an A-APM, how is that going to be handled?

MS. BLONIARZ: So you can think about it -- people who are in an advanced alternative payment model just get their withhold back. They're not in the program at all. That way they're only facing one set of incentives for their A-APM. For groups that might be in another model that's not an advanced model, say Track 1 ACOs, you could envision that being, you know, the entity that elects to,

you know, participate in the new voluntary value program.

MR. THOMAS: So basically if you're in a Track 1, that entity could participate with whatever the measures are that are outlined, and then anybody that is in that ACO -- or, excuse me, in that Track 1 -- yeah, I guess in that Track 1 ACO would essentially be eligible for the additional payment?

MR. GLASS: Right. Any clinician who's a participant in that ACO would be measured as part of that ACO and could get their 2 percent back or even above that, depending on how it worked.

MS. BLONIARZ: But in a Track 1 ACO, I think the way we were thinking about it, they would not use their ACO reporting measures. They would still be assessed with the same set of measures that's used in this value program.

MR. GLASS: But the idea is that the two sets would probably be about the same. That's the idea of --

MR. THOMAS: I think that's a question. Are those going to be aligned or is it going to be --

MR. GLASS: Right. No, that's the idea of moving to the outcome-based, population-based measures, is that the A-APMs would start being measured on that. These guys

would start being measured on that, and there would be a lot less burden for everyone.

MR. THOMAS: And physicians in an advanced payment model are handled how?

MS. BLONIARZ: They just get their withhold back, and they're not part of the program.

MR. THOMAS: All right. Thank you.

DR. CROSSON: Bruce.

MR. PYENSON: Thank you very much. A question on page 4. The cost item there, the MSPB, Medicare spending per beneficiary, is this a rare event where that's the same measure that's being used for hospitals?

MS. BLONIARZ: Basically it is. I think the attribution is slightly different, but I believe it's basically the same measure as in hospital VBP.

MR. PYENSON: Thank you.

DR. CROSSON: Kathy.

MS. BUTO: Thank you again for this work. It's tremendous. A question about the timing. I'm assuming from the report that MIPS could be repealed immediately under this scenario, but that it would take at least a couple more years to implement the alternative approach, so

2020, 2021 at the earliest probably to structure this.

MS. BLONIARZ: You would probably need to have a notice and comment period kind of telling clinicians what they would be assessed on. There would need to be a process that CMS would establish to have voluntary election into groups. But I think as we said earlier, we're hoping that CMS has already built a lot of that infrastructure from two policies they're implementing now. One is the virtual groups policy in 2018 quality payment program, and the second is the opportunity for MIPS-eligible clinicians to use their hospital VBP score for their MIPS score, which is also happening in 2018.

So we think some of the infrastructure is already there. It could probably move much more quickly.

MS. BUTO: Okay, so you could phase in the population-based measures and so on.

MS. BLONIARZ: One other point I wanted to make on that. I think if you have a measure set that is calculated from claims or from surveys that, you know, let's say CMS administers, you can also modify the measures over time if, you know, there's some measure that then is no longer consistent with clinical practice. There's some

flexibility. It's a little more nimble than if clinicians have to report measures and there's a kind of -- you know, they're used to reporting measures. It's a burden to kind of change that.

MS. BUTO: Right, right. And my second question is: Since this approach would largely -- I think it would eliminate all the exceptions, right, of the current MIPS system?

MS. BLONIARZ: That's right.

MS. BUTO: Have we looked at, thought about the impact on isolated providers? Even though they're virtual groups, just the idea that a physician, say, in an extremely rural area, a Frontier area is going to be able to go in with a group and have an impact on some of the population measures. I'd just be curious whether you looked at that.

MR. GLASS: I think Sue might be able to address some of this, bringing in physicians in rural areas into a larger group. And they would -- because the groups are kind of virtual in some sense, they could choose to do that. They could align with a larger hospital area, a hospital group, for example, or some other group.

MS. BUTO: Right, it wasn't so much whether they could find a group as much as what impact -- they'd have the withhold, but the question is whether they'd be able to meet the population standards, the population-based --

MR. GLASS: But that would be true -- yeah, I mean, they'd have to join -- that's the one requirement, is that they join a group that's big enough to be measured. And any individual physician, whether they're in rural or urban areas, will -- you know, how much influence do I have on the total? That'll be true for anyone.

DR. CROSSON: Okay. I had Pat on this point or -- no, separate. Okay.

David.

DR. NERENZ: Thanks.

Slide 10, please. Is there a ball-park number we should think about for this phrase "sufficiently large entity"? Obviously, this links to the measurement properties and how big denominators need to be. What kind of numbers should we be thinking about?

MS. BLONIARZ: So we actually talked about this a fair bit, and Ledia has been helping us think through this.

So it is going to vary by measure. I think some kind of reference points you could have are -- some of the measures, the avoidable hospitalization, avoidable ED measures, seem to be -- show some reliability at about 1,000 attributed clinicians.

You could look at something else like total cost of care, the pioneer ACOs, next-gen. That's about 10,000 attributed beneficiaries, and it's also going to kind of matter based on the attribution rules. You know, you might use multiple attribution, which might increase the sample size. Those are kind of the numbers we're thinking about.

DR. NERENZ: First, you said attribute physicians, then you said beneficiaries.

MS. BLONIARZ: Attributed beneficiaries. I'm sorry. That was all in the context.

DR. MILLER: Benes. She meant benes in both.

MS. BLONIARZ: Benes, yeah. Attributes, benes.

DR. NERENZ: And these would be largely sort of at the primary care level? I mean, let's say you were a single specialty group and you choose to do this --

MS. BLONIARZ: You probably would not --

DR. NERENZ: -- and these dynamics change

radically.

MS. BLONIARZ: You probably would not -- so one thing we will say, you probably would not have enough power if you were a single specialty group, no matter how large. You would need to have some kind of diversity of clinician specialties. What I don't know is whether a large primary care practice would have enough diversity and specialty kind of -- you know, some of the measure are -- you know, especially the episode cost measures would be attributed more to specialists versus primary care.

DR. NERENZ: Okay. But the group configuration won't change measure by measure, so that whatever the group --

MS. BLONIARZ: No, that's right.

DR. NERENZ: Okay. And that leads to my second question --

MS. BLONIARZ: That's right.

DR. NERENZ: -- Slide 11. I may have already implied it. The groups participating in this would be subject to all of these measures as a set, right? You don't pick and choose?

MS. BLONIARZ: That's right.

DR. NERENZ: Okay. So whatever your configuration is, it has to be the right mix and big enough so that all of these measures can be calculated. Okay.

And, again, do you want to give us any ball park? Because we're not talking about two or three docs getting together. We're talking about how many?

MR. GLASS: Well, you can't say how many docs. I mean, if it is 10,000 beneficiaries, how many doctors is that? I don't know. How many clinicians? It's hard to say.

DR. NERENZ: Well, okay. I'm just trying to -- again, this is Round 1. I'm just trying to get an idea --

MR. GLASS: Yeah. That can be fairly small --

DR. NERENZ: -- of what we're talking about.

MR. GLASS: -- if you're doing primary care.

DR. NERENZ: Okay. Last question. You didn't mention this. Is there any thought you want us to have in mind about the weighting of any of this, or is that to be determined later?

MS. BLONIARZ: I think, again, this is -- you know, this is a little bit more exploratory maybe than other things. I think that would be a question in the

design of how the -- how the composite score is weighted.

DR. CROSSON: Pat.

DR. GINSBURG: I can clarify something on David's first question, and Kate had mentioned that this would not work for a large single-specialty group. And I think the reasoning is that even though they may have plenty of attributed beneficiaries, they are not controlling most of what happens to those beneficiaries, which would be primary care and other specialists. It might work for a much smaller group if it was multispecialty or even primary care, to the degree that primary care has some control over the -- you know, the broad population. So I think that's how we need to think about it.

DR. CROSSON: Pat.

MS. WANG: I think you answered some of these questions with David's section. Can you say more, Kate, about CMS is undertaking? There's some infrastructure work going on around virtual groups and sort of what those look like, and related to that, is there also work under way about different attribution methodologies?

I assumed that attribution in this case would be retrospective, but is there work that goes beyond like

looking at sort of the primary care linkage? I was just curious whether there's foundation there.

MS. BLONIARZ: Right. So part of the MACRA statute had a provision to allow clinicians to join in virtual groups and basically be treated as if they were a group practice under MIPS. Currently, clinicians in MIPS can either report individually or as a group practice, which is basically the TIN, at the TIN level.

So CMS kind of deferred it for the first year of the program and is now starting to roll it out, allowing entities, physicians -- I believe where the TIN has ten or fewer clinicians to join with other clinicians in virtual groups. And I think the minimum size for a virtual group is two clinicians, and then the maximum, it could be much larger. So they are kind of undertaking that. It is going to be an attestation kind of policy where clinicians say, "Yes, I want to be measured with David," and then they would be kind of treated as if they were a clinician group and for any other purposes in MIPS.

Your second question?

DR. CROSSON: Prospective versus retrospective.

MS. BLONIARZ: Oh, attribution.

MR. GLASS: I don't think we have weighed in on the retrospective versus prospective attribution.

DR. CROSSON: Well, I --

MR. GLASS: I don't think that's a --

DR. MILLER: I don't think we had a reaction to that.

MS. BLONIARZ: So kind of the state of the kind of research on attribution, there's a number of different ways to do attribution. There's single, multiple, based on E&M, other types of measures.

CMS has a lot of experience with this, even in fee-for-service. Under the predecessor Value Modifier Program, there were a number of claims-based measures that they attributed, so they had a set of rules about how that worked.

One thing we've been thinking about is whether multiple attribution might increase the number of attributed beneficiaries, you know, if you're not just attributed based on the plurality of E&M visits, but, you know, cost or quality outcome is attributed to every provider that treated you through an episode. So there's some research there.

DR. CROSSON: Just to clarify, I think part of our reaction was we -- at least I was a little bit confused about whether we are talking about what physicians would be counted in the group, which would be prospective by its nature, voluntary, right? And then what beneficiaries, and that could be prospective possibly or retrospective.

And maybe I'm just clarifying that for myself.

DR. MILLER: And then I would say we've generally taken the notion, particularly when we've done all our ACO work, as trying to give the group a prospective sense of who they're responsible for, and I suspect Sue probably has feelings about that.

DR. CROSSON: And it's your turn.

MS. THOMPSON: It's my turn? Thank you.

And, Kate and David, great job there, great work, very clear, and very timely.

On page 10, to the question on the withhold, you used 2 percent as an example. Any other thought about the withhold? I mean, is there anything that we have to look back to in terms of impact withholds have made? Other programs where that concept has been used?

MR. GLASS: Well, I think one notion is that you

want to keep it kind of less than what would happen if you were in an A-APM.

MS. THOMPSON: Okay.

MR. GLASS: So that's kind of -- I guess, do we have any deeper thoughts than that? But that was kind of what we started out with, and then, you know, someone has to choose --

MS. THOMPSON: And what connection?

Yeah, to get started.

MR. GLASS: Yeah.

MS. BLONIARZ: I guess, I mean, I think there's a lot of discussion people could have about what kind of reduction do you need to motivate clinician behavior. I think it's generally larger than this, but I think, in this sense, it's a little bit less about maybe motivating significant practice transformation and more about just kind of sending a signal that remaining in fee-for-service without getting organized might not be quite as attractive.

MS. THOMPSON: So 2 percent this year, maybe going 3 percent? I mean some sort of an --

DR. MILLER: And I'm just going to make this comment because we're -- just because. This is a

clarification because I think this has come up in a couple of questions. So, fundamentally -- or in a couple of conversations -- what we're talking about is taking the block of payments that are going to the physicians, taking 2 percent, and then reallocating that on the basis of these population-based measures.

As you know, as part of MIPS, there's also the extraordinary performance, $500 million for a set of years. That, the Commission has talked about in separate conversations, retargeting that money for other purposes. That money is still being in our thought process here, held to the side to be retargeted. And so when we say budget neutral, we're talking about the basic transaction of funding. That $500 million still sits off to the side for the Commission to have a retargeting conversation on that.

So just since you brought up the 2 percent, I thought I'd tag it on there.

DR. CROSSON: David.

DR. GRABOWSKI: Great. Thanks, Kate and David. This was great.

Given the voluntary nature of the program, are you worried that certain clinicians, whether they be rural,

those largely caring for dually eligible beneficiaries, are going to lack access to a potential virtual group? And if so, what are those barriers, and how might we think about addressing those?

Thanks.

MS. BLONIARZ: Yeah. I think, I mean, one thing we've talked about a little bit is what happens if only those that expect to do well come back into the VBP.

I think we've thought about it. I don't know that we have a great answer yet.

I think for the measures, there would be risk adjustment or whatever kind of adjustment is necessary, kind of comparable with what Ledia has laid out for kind of the quality principles that the Commission has.

But, yeah, this is definitely something we've kind of thought about and haven't totally nailed yet.

MR. GLASS: But I do think that if you look out in the ACO world, they are making --

DR. MILLER: Yeah.

MS. BLONIARZ: Right.

MR. GLASS: -- efforts to reach out to the rural areas, set up ACOs in rural areas. It can be done.

MS. BLONIARZ: Right.

DR. MILLER: Yeah. And Kathy implicated this too, and just to kind of knit some of this back together, I think of it as three ways. There's sort of the -- and you were referring to Sue. There's sort of this notion of urban hospital systems and then reaching out to their rural partners, and you could create it that way, which is not unlike what Sue has done in her ACO world.

There is an ACO organization that is actually knitting together rural practices, even though they're not next to each other, and you could imagine an organization like that just entering the rural world and starting to knit these people together.

And then I would leave at the end of the train. I suppose you could contemplate exceptions, but I think the notion would be you'd want to be pretty narrow about it and not replicate half of the people being out, like we have now.

MR. GLASS: And practices that simply didn't treat many Medicare beneficiaries would just opt out, probably.

DR. CROSSON: Jon.

I'm sorry.

DR. GRABOWSKI: I was going to follow up with that.

DR. CROSSON: Sorry.

DR. GRABOWSKI: And this would probably be true of any part of the program, but here's a particular example, where if you don't get the risk adjustment correct or at least largely correct, you're going to magnify disparities. You're going to kind of widen that gulf between the haves and the have-nots. So that's a really important point as we think about this going forward.

Thanks.

DR. CROSSON: Jon.

DR. CHRISTIANSON: So I think it's kind of hard to think about, in some ways, as the clarifying question suggested, how much of this the clinician needs to be -- specific recommendation on versus how much we say, and this should be determined by CMS as they see fit. So this probably falls in the other category.

But I could imagine some physicians who have tried hard to be part of a voluntary group. We talk about it as, okay, the voluntary groups will take them, as though

that will happen, and it may not. And it may not be because they're judged to be poor performers. Maybe inside a group will say, "No, we don't need more physicians in this area," or whatever for management purposes.

So you have a physician that says, "I tried to do the right thing. I tried to join a group. I wasn't able to, and now I'm losing my 2 percent withhold" -- have you contemplated sort of what you -- what you would respond there or whether there was a way to sort of -- I mean, you could imagine doing this over a 3-year period, "We'll give you 2 year or 3 years to try to be in a group," but that doesn't necessarily address those folks totally.

MS. BLONIARZ: I mean, completely off the cuff, you could think about something like CMS helping to create a fallback option, you know.

DR. CHRISTIANSON: Yeah. So this is one of the things that -- to my point, that you would see as a detail level that CMS would probably want to address and that we wouldn't necessarily weigh in on as a Commission.

MR. GLASS: Yes.

MS. BLONIARZ: Yes.

DR. MILLER: I mean, we can certainly talk about

it as CMS doing virtual groups based on what IDs -- beneficiary IDs given physicians who they touch and say that this is something that we would look for CMS to do if you wanted something a little more concrete than, "Oh, somebody should figure this out." And there are methodologies that they are aware of," that's sort of --

MR. GLASS: But I think what Jon was saying is what if the group doesn't want them in, and that's a different issue. I don't --

DR. MILLER: Yeah. Well, and I think what Kate was saying and I was trying to give it -- a little more concrete for your comfort is -- and, of course, we discussed this because, you know, there are people that might be not wanted in a group for reasons that have nothing to do with their practice patterns. The notion would be that CMS could offer a virtual group for them to be a part of.

DR. CHRISTIANSON: And they would have the choice of joining it or not joining the group. Yeah. So, I mean, that's something to think about going forward, is whether that's -- you see that as a roadblock that we would need to think about or whether we just want to raise the

possibility and --

DR. MILLER: Yeah. And we could do a medium concrete thing, you know, where we sort of talk about how they might go about doing that, but the specifics would be left to them.

DR. CROSSON: Clarifying questions?

Dana.

DR. SAFRAN: Three that I think are quick.

First one is back on the 2018 legislation that you've talked about and the infrastructure that's happening there, do we have -- or has CMS been able to provide us with any kind of view of the landscape of, you know, what -- how many physicians and in which specialties do we know that folks really do have a kind of obvious virtual group that they can be part of? So that's one question.

The second, sort of related to that, is, Does that 2018 legislation, either piece of it, already put in place kind of the administration infrastructure that CMS is going to have to have anyway to track all this? Because, you know, that seems like a complex task on a national scale.

And then my third question is -- and, David, you

started to get at this a little bit, but can you just talk to us about how you thought through a physician's motivation to go this route versus in A-APM? Because these start to feel like they're -- and I think you said this in the chapter -- kind of entities that might be on the road to A-APM but not quite there, so just any of your thinking about why they choose to be in this versus that.

MR. GLASS: All right. Well, I can start with the last one.

The tendency would presumably be people would want to be in the A-APM because of the 5 percent incentive they're getting on their payments, on their physician fee schedule payments, and because of any possible upside. The reason people seem to be hesitate to going to A-APMs are either they can't find one that fits them or they don't want to take any downside risk, and there is some downside risk associated with A-APMs right now, but -- or by statute.

Now, that is getting to be a very limited amount in the Track 1. Plus ACOs that are starting in 2018, it's going to be, for certain practices at least, 8 percent of their revenue, and then they are going to get 5 percent

back as an incentive payment. So they're at a very small level of risk.

So, anyway, I think that's the kind of calculus people would have to start working through.

DR. MILLER: And I realize this is really blunt, but the other thing is avoiding the 2 percent, right?

MS. BLONIARZ: So --

DR. CROSSON: But you had other parts of your question?

DR. SAFRAN: The first two parts.

MS. BLONIARZ: Yeah.

So on the virtual group stuff, so CMS is putting in place the infrastructure kind of through this year. It's going to start in 2018, January, and so they will have some process for kind of identifying clinicians who have elected this option and will want to be measured. I'm sure it's extremely complex to kind of back that out of other clinician performance and make sure all the quality measures travel and everything like that.

I think the kinds of entities that could find it appealing are ones that are reporting to commercial contracts for quality measures, and maybe it's something

that doesn't line up exactly with the TIN, you know, how the group is billing Medicare.

The other idea would be Track 1 ACOs that say we want to all report for all of our clinicians, but we don't -- you know, we're not all under the same tax ID or it doesn't kind of line up with the organizational entity.

MR. GLASS: So there's the, what, NPI? That's the individual identifier, and then there is the TIN, which is the taxpayer identifier number. So a group might have one TIN for everyone. On the other hand, they might have separate ones. So that gets all very messy and complex, and CMS has to sort it out. And they've taken different routes on different -- like, for instance, MSSP tends to go on TINs. Next-gen and pioneer tended to be on TIN/NPI combinations.

So those mechanisms are there. They're somewhat limited, but they're there.

DR. SAFRAN: Kate, maybe can you just speak to the first question, then, about what do we know about how many physicians have such an entity, or do we just not know?

MS. BLONIARZ: Yeah. I'm not sure I could say.

I don't know. I mean, since it hasn't started, I don't have a sense from CMS about how many have come in wanting to do this.

DR. CROSSON: Okay. Questions? I see Alice and Jack. Alice.

DR. COOMBS: Table 1 gives a breakdown of --

DR. CROSSON: Microphone.

DR. COOMBS: You give a breakdown of clinicians that are exempt in the paper, and my question is, I was adding them up, and, you know, we do our annual physician and other providers in December. So you know the question. You know where I'm going with this. Exactly. And I just read the OIG report, and what I'm going to ask you is important because we've talked about physician-led ACOs and hospital-led ACOs. What portion of those clinicians that are exempt in those categories, the first category being the volume and the second category, are non-physicians, are in the other clinician status?

MS. BLONIARZ: That second question I will have to get back to you about exempt. Yeah, so this is something that we've talked about at the office. So there's about 1.3 million clinicians that are subject to

MIPS, and that is far greater than what we normally report, which is about 900,000 clinicians together.

So the one big piece of that is we have a low-volume threshold that we basically apply to get to our 900,000 level. I believe it's 20 patients?

DR. HAYES: 15 [off microphone].

MS. BLONIARZ: 15 patients. So we have like a de minimis threshold. That gets you down a lot.

There's also non-physician, non-DO, non-NP and PA specialists, providers that are in those categories. So optometrists, podiatrists, you know, groups like that.

DR. COOMBS: So when David gives a slide of 800,000 providers or clinicians being exempt, it's kind of artificial in that it does not speak to physicians who are exempt from participating. That's my point, is that if we knew what percentage of that 800,000 were actual providers in a clinical setting that took care of patients, it might be helpful, and also the breakdown of that, because we're talking about predominantly physicians in the MIPS, and then we throw this data pool in there that gives you an artificially elevated number. It looks much more dramatic than what we might -- it might appear in reality.

DR. CROSSON: Jack.

DR. HOADLEY: You know, I strikes me as I'm hearing some of these other clarifying questions, there's a number of things here that would really be useful to give examples in the chapter, the kind of questions about how many doctors or how many beneficiaries corresponding to the doctors would make one of these groups typically.

It also occurred to me, one of my questions -- and this could just be done with an example in the chapter if you do not want to do it now -- is when we talk about the reporting burden -- and we've probably done this at some point in the past, but, you know, what's a real concrete example of a measure collection that creates that reporting burden? We talk about that's sort of the aggregate burden it creates. But it would be nice to have kind of a specific example, as well as anything on what's lost if we drop this whole array of measures, even if we think on balance that's a good decision, make sure we're fairly explicit about, okay, but the downside is we will lose the ability to know X and Y and Z. And it just seems like that would be part of making the case.

The question I'd like to ask right now, though,

is on Slide 10, where you talk about the withhold, and you use the example of 2 percent, you didn't kind of give an example of what the upside could look like, except to say that it would be less than under an A-APM. Can you say any more about what that might look like to help to get a sense of how this could play out?

MS. BLONIARZ: So, I mean, the simple answer is probably 5 percent.

DR. HOADLEY: Okay.

MS. BLONIARZ: You know, the bases are a little different, and this has come up in some of the press reports, but MIPS right now applies to items and services. The A-APM incentive payment only applies to services. But, you know, you'd think something less than 5 percent.

DR. HOADLEY: Okay. And would you anticipate that somebody -- you know, somebody who opts out would lose their 2 percent withhold. If somebody opts in, is there still a possibility at the very bottom of the measures that they could lose the entire 2 percent? Or would we want to set it up at a point where, well, they're guaranteed to at least get minus 15 or something like that?

MS. BLONIARZ: You could. I mean, we did kind of

think of an idea where nobody could be worse off for electing, so you couldn't lose more than percent.

DR. HOADLEY: 2 percent.

MS. BLONIARZ: But, yeah, there are other options.

DR. HOADLEY: Okay. Thank you.

DR. CROSSON: Okay. Another clarifying question? Bruce.

MR. PYENSON: The entities that are described, Kate, that you described, do you envision those as potentially including organizations like independent practice associations?

MS. BLONIARZ: That would be another example.

MR. PYENSON: An example. Do you envision whether organizations, the new organizations could be created on a for-profit basis? Is there enough money in this kind of entity to encourage new organizations?

MS. BLONIARZ: We haven't thought about that, whether there's a market. But there's a market for a lot of stuff, so --

[Laughter.]

DR. CROSSON: Okay. So I --

DR. MILLER: I would - I hadn't thought about this either, but there are organizations out there trying to help physicians get organized into APMs and ACOs. There are organizations out there knitting people together in the rural area. That one is not-for-profit, if I'm remembering correctly, but I'm not sure I do. It would seem like they could diversify out and say, by the way, I can help you, you know, get your ducks in a line for MIPS.

DR. CROSSON: But, you know, an additional question would be whether there's -- I think this is maybe behind this. Is there enough profit stream there for an organization on an ongoing basis to organize this in order to participate in that profit stream? Is that what you were asking?

MR. PYENSON: That's one question. I guess another question could be are there regulatory obstacles that someone needs to think about if an IPA -- you know, some private organization moves in this direction.

DR. CROSSON: So that would be potentially federal, but also state and maybe local regulations as well. That would be something to think about.

DR. GINSBURG: If I could add, I would think

that, you know, we shouldn't think of Medicare in a vacuum, and some of these organizations supporting physicians and others and moving into alternative payments, you know, may be doing work in commercial insurance and Medicaid programs. So in a sense, it may be adding in something in Medicare. It doesn't have much in the way of fixed costs. And even if the returns are not that large, it might still be worth doing. And, actually, you know, I think the clinicians might be in a better place having incentives for all the different payers more lined up with each other than very disparate.

DR. CROSSON: Okay. So now we're going to proceed to the discussion phase, Round 2, and Alice and Paul have asked to go first. Alice?

DR. COOMBS: Yes, thank you very much. I'm very encouraged, first of all, the chapter was excellent, and it generated a lot of questions. And I think that's a sign of a good place to be.

I speak as a practicing physician who takes care of patients in the hospital and outside as well. And so as I speak about MIPS, you know, one of the things that concerned me early on was obviously how you pick the

indicators that you wanted to choose, choose the best things. But then I've had a chance to actually just think about the whole process of process measures versus outcome measures and the subspecialty groups. And I think -- and I can talk about that in a minute, but I wanted to talk about the OIG's report.

What's really interesting about that report is that in year one you see the highly performing ACOs way at the top in terms of expense, you know, okay with quality, and it's 36 percent of them that actually by year three they move to a better place. So that's a good thing. It's a testimony to how, you know, you can change the conscious level and things happen that are good in terms of outputs.

The piece of it is that 38 percent of them didn't do better. As a matter of fact, their costs, spend went up to the tune that the delta was $1 billion saved, but there was a considerable increase in this bottom group -- speaking to the fact that it actually takes time for people to actually transition to a better place, even as a cohort collective group of same-minded individuals in an ACO.

So the reason why I say that is that MIPS has got a lot of problems with it, and to start off, it's the place

of many practicing physicians right now where they're getting used to it, they don't like -- some don't like it. Some of them complain about the measures being not applicable in the big picture. Some of them are.

The problem is that you have this heterogeneous group of physicians, and we're trying to cart them or herd them into one stall and say, "You guys all get in that stall and do population measures."

Our choices that we've given, the three choices, I just want to speak to virtual first. So ASA in anesthesia has future models of anesthesia, where we were talking about virtual groups. The reality was that at the time no one in the room had been involved in a virtual group. But we had to make recommendations to CMS that this is what things are important for a virtual group. To my knowledge, in both of the practicing areas that I practice in, I don't know of any virtual groups. And so it is something that is a really good discussion. It's a great discussion. But for the private specialists -- and maybe things are going to evolve differently, but we're talking about the 5 percenters, and I call them the R-A-P-E-R, the radiologists, anesthesiologists, pathologists, and ER docs.

They represent a large -- when you pull them together, they represent a large group that don't have the capacity or don't understand how they're going to manipulate this piece.

The next piece of it is that when we put the population measures out there, how well do those population measures relate to the specialists? For instance, if I was as primary care doc and I was going to run an ACO, I would want the anesthesiologists. They've got low mortality. They've got, you know, they're not attributed with a lot of problems. And it's 5 percent of the physician workforce that you could say those are good ones, I want them, let me grab them up.

However, if I was someone who was in that same group, am I going to go after the addiction medicine or the ones with a lot of patients that are resource intensive? And so when we talk about this virtual group, we've got to think about the heterogeneity that exists within the workforce. I'm sure that we want to get to a place where we consider population measures because I think that's really important, but the time factor and the time concept from the OIG's report dictates that it's going to take more

than three years. And even as we sit here and try to make spaghetti here, it's going to take a lot more time to get the nuances. I listened to Kate, who has done a fabulous job, and there were a lot of, well, we haven't figured that out, we need to get back with you. And I think that's a piece of the problem of scrapping it and saying that we want to go with this immediately, is that the transition necessary will take time.

Just to speak to some of the other things, United Healthcare -- and the article was November of 2013. I will refer you to that because it's a nice summary of several large groups being dropped from United Healthcare's network for various reasons. And they do quote quality, but they also quote cost. And it was in Ohio in several places: Cincinnati, Dayton, Florida.

My point is that it's not always the doctor's choice to be able to say I want to be that APM in the sky, let me go join it. So that you don't have the liberty to do that all the time. And so that flexibility of being able to kind of easily migrate into a sophisticated APM is not there. So that's the choice that we make an assumption that that's possible.

The other piece of it is many of the patients were considered in one of the groups to be high cost, but it is in that article that they discuss that some of them had a lot more co-morbid conditions, and so then their costs in their resource utilization is going to be much higher. So it speaks to the whole notion of risk adjustment. And even in the OIG's report, it actually speaks to one important piece of it, that the high-performing ACOs, they looked at health status risk adjustments within, but they did not compare the risk adjustment between the high-performing and the low-performing.

So I am one who -- I embrace the change in looking at population measures. I don't think it's something that we can do, I personally feel, right away. Now, I know there are people around the corner that is hurry up, let's go, let's go, let's get it done. But just even in this OIG report are people, physicians, and providers who are really on board and really concentrated on doing a good thing. It took them three years. And it's not 100 percent, even with this report that just came out in August of 2017.

So I think there's a lot more I'd like to talk about, but I won't hold you hostage.

DR. MILLER: Can I get just a yes or no to this? Because we should move on. So you would leave MIPS as it stands in place?

DR. COOMBS: I would like to say that the way that MIPS is working right now with the primary care focus is very different then the specialists. There's not a lot you can do for the specialists to change things right now. I would leave it as it is, and I would consider some kind of tweaking that involves the population measures to do as Jay had said, how can we make this MIPS progress to a collective measure? But I think it takes time for us to figure out what's the magic formula to do so, and that's my conundrum, is that we had a lot of I don't know, we've got to figure this out. Even the whole thing with the workforce.

DR. MILLER: I think I got it.

DR. CROSSON: Paul.

DR. GINSBURG: Yeah, you know, going back to when MACRA was enacted, I think the direction of MACRA as far as alternative payment models was a very good one. But when

they wrestled with, you know, how do you deal with the fact that you can't measure value for individual medical practices, they could have just left it at that and just did APMs, but they decided to try to do the impossible, and they wrote a provision and they created MIPS. And CMS has valiantly done its best to implement this in a way that won't do as much damage as it could have done. But, you know, I think we need to get real about this, that there really isn't much potential and that the long-term direction continues to be provide support and incentives for physicians to get into alternative payment models. And I could go either way as far as just ending MIPS or ending MIPS and putting in the option that David and Kate have described.

I lean toward the latter because my sense is that the politicians don't want to do nothing, they want to do something. And so I think we ought to just come up with a better way.

I'm really concerned about the burden on physicians, and I'm concerned about some of the outlandish potential rewards for groups under MIPS that can really dissuade them from investing and moving into APMs.

DR. CROSSON: Okay. So now we'll --

DR. GINSBURG: One more thing to mention.

DR. CROSSON: I'm sorry. Go ahead, Paul.

DR. GINSBURG: You know, David Grabowski in our clarifying questions brought up this issue of the importance of risk adjustment, and I agree with that. And I would say that, you know, the risk adjustment issues are very similar here to those with alternative payment models. We need those in ACOs and bundled payments. So we might want to make some mention about drawing on all that's being done and learned in these other spheres and applying it to a reformatted MIPS.

DR. CROSSON: Okay. We're going to proceed to the general discussion, and this time we'll start with Jack.

DR. HOADLEY: So, first of all, this was a really good analysis, and I thought you made a very clear presentation of the issues here. I guess I'm swayed more by the view that says what we're doing under MIPS is not working, and like Paul, I mean, whether you sort of get rid of it or get rid of it and replace it, you know, are both options, it does make sense to replace it. And relative to

what Alice was saying, what I'm thinking is with all the issues we're raising with the current MIPS, if we had put in a version of what we are envisioning back when MACRA was passed, we'd be saying, well, there's these things that aren't working about it. But it seems like there's still better qualities to that replacement system than what we have now.

And so if what we have now has a lot of the bad qualities and the bad incentives and the burden that we characterized it, then before we get sort of really locked into the system, it seems to make sense to say let's back off of that and try to see if we can put a better system in place.

You know, I think we've got a lot of issues about how to fine-tune the replacement system, and then maybe the point is that it's not -- if it took a couple more years to phase all that in, that's not the worst thing in the world to work out some of those things. I think what we need to at the very least do when we're laying this out -- and I said this in the clarifying round -- is to sort of make sure that we've, A, built the case for the problems, as thoroughly as we can for the problems with the current

system; and then, B, raise at least enough of the issues of the risk adjustment, the other kinds of things that would be in trying to design this replacement. And if in the end it feels like that takes more working through to get there, then, you know, take the time to do that. But it does feel to me that that's the right direction to go.

DR. CROSSON: Rita.

DR. REDBERG: So, first, I want to compliment Kate and David on this chapter because it was really clearly laid out for a very complex issue, and it was really easy to understand.

I agree with Paul. I think we really have to get rid of MIPS and either replace it with this system, which I think has a lot of merit, or just get rid of it. And because -- I mean, as a clinician, I really worry about the trend of MIPS, because it just -- it puts a lot more measures on physicians, it's a lot of -- you know, the measures that have come in the last 20 years were all well-intentioned but the actual practice is they are a huge pain, and nobody -- you know, none of us went into medicine to fill out, you know, all these boxes. We went into medicine to take care of patients and try to do a good job,

and I think that is the kind of system that we want to try to get back to, and I think MIPS takes us in the exact other direction.

You know, we had SGR and it was well intentioned but it was clearly not working, and we finally replaced it, but I think it would be even worse to go down a path like what MIPS will take us on. I mean, we all know here health care is very complex and we really need to think about it, but I think it is better to take the time and do the right thing than to start building structures for the wrong thing, because it is very hard to undo things once they have started, and it is clear that -- it is clear to me that MIPS is not going to, you know, get us towards high-value care, it is not going to make clinicians' lives better, it is not going to make patients' lives better, and there is a lot of money at stake.

And so I think what you have laid out here, as a possibility, has a lot of potential. I like the population measures and trying to look at high-value care, but the important thing is we need to start thinking about the replacement now and not go further on the MIPS pathway.

DR. CROSSON: Brian.

DR. DeBUSK: Well, first of all I would like to thank you both for a very well-written chapter. I agree with Rita and several of the other comments that are made here. I think we are off to a fantastic start with the voluntary value program. I was expecting something -- this was more than I'd expected, so thank you.

I, too, agree with Paul and some of the other people who have said that MIPS does need to be repealed. My preference would be to repeal it and replace it, again, because I think you are off to a great start.

But what I want to focus on is this concept of value. You know, the concept of value transcends both MIPS and the VBP, and we've got an August 18th comment letter where we talk about needing a -- focused, really, on the episodes of care, where we comment that we need a theoretical framework that forms the basis of all episode measures. I hope -- and I know that time is short here -- but I hope we get a chance to explore that a little bit, because I could see us as developing at least some of that framework, and I like it because I think it is a great opportunity to engage specialists but it is also a great idea for us to demonstrate thought leadership in an area

that is particularly difficult, because I think we have to get those episodes right, we have to get them correctly grouped, and we need to get them correctly risk adjusted.

So, again, thank you.

DR. CROSSON: Dana.

DR. SAFRAN: I will join my colleagues in thanking you and complimenting you on a really well-done chapter.

I guess I would, on the first question of are we better off without MIPS, I believe the answer is yes, that we are better off without MIPS, in large part because of all the reasons that have been said but, in addition, as I think about the amount of money that we will pay to clinicians to reward their participation in MIPS, I don't think we are getting value for that money. I think that the measure set that exists is still, you know, from the fee-for-service era, paying for bits and pieces, and the burden piece has been mentioned and written about a great deal. And the beneficiary, at the end of the day, is not going to be getting better quality care or better outcomes because of MIPS. I just fundamentally believe that's why I think we are better without it.

Then the question is, can we replace it, and I really like the direction that you take in this paper, but I guess I would ask kind of three questions about it for us to think about. The first is, are we creating something that is so similar to the A-APM structure that it is almost not worth it, that actually what is better to do is for those that aren't going to be in A-APMs, that's fine. You're not in an A-APM and we have a payment system for you, and it's not all that appealing, but you can still participate in Medicare and that's that.

The other pieces I'll mention as my question is if we were to say no, this is different enough and maybe you can spell that out in the next version, how is it different enough? Who are the people who are in this and what is it they are producing that is of value, in its own right that is different from the A-APM?

But the other two things that I worry about and would throw out there is, one, are we, in a sense, from a behavioral economics perspective with these virtual groups, are we creating a kind of mini version of the problem we had with SGR, where individuals really aren't accountable to each other, even though they are grouped together, and

so that really undercuts the desire to behave in the way that the incentives should make them behave because somebody else could kill their incentives so why bother.

So that's one concern, and then the final one that I will put out there, as a challenge for us to consider, is in a broad category of, is it worth putting this together? Will those who are not in A-APMs find themselves in these measures? And by that I don't mean, you know, will I see, in these population health measures, something related to the specific processes I do in my practice, because we don't want that. We want to move away from process measures. But I do want to feel that, you know, whatever my specialty, I have some connection to the measures that, where I think, on Slide 11, right, some of them in every category. There should be something in every category. Now patient experience will apply to me, but, you know, as a gastroenterologist, can I find myself in avoidable ED use, and if I can't, can I find myself in some of the quality measures, or can't I? I think that's a really important question to ask ourselves, as we pursue this. Thanks.

DR. CROSSON: David.

DR. GRABOWSKI: Great. Thanks again. I will reiterate everyone's comments about what a great chapter this was, so chalk me up as another person in favor of repealing MIPS, and I am in favor of replacing. I like the approach you have outlined. My biggest concern is around the voluntary nature of the program, and I think voluntary raises two concerns.

One is just the selection we have been talking about into these virtual groups, and, you know, a number of Commissioners have already raised concerns here. But am I aligning myself with other really strong clinicians that, you know, we want to think about how those groups are set up and we also want to think about them based on the mix of specialists. And Alice, your point about the anesthesiologist joining that group -- and I will come back to my earlier comment -- we want to risk adjust, and I think, Dana, you were just pushing at this as well. We want to make certain that as we have these very different mixes of clinicians, and as they fit to these measures, that we are properly accounting for the different risks they face and the types of care they deliver, and how that maps to these different outcomes.

The second issue, and I raised this in the first round but I just want to touch on it quickly again, with voluntary, I am really worried about which clinicians might get left out, and whether that's clinicians treating largely dually eligible patients, whether that's clinicians in rural areas who can't find a group and why. I think we want to be very thought about thinking through potential barriers and trying to build in some incentives to make certain that it's easy for clinicians to find groups and that nobody is sort of left behind here. Thanks.

DR. MILLER: Can I just --

DR. CROSSON: Yeah, go ahead.

DR. MILLER: But you're not saying there is any mandatory feature. It is still voluntary but it's overcome -- right.

DR. GRABOWSKI: Yes.

DR. MILLER: I heard you. Okay. I just wanted to make sure I was following.

DR. CROSSON: Sue.

MS. THOMPSON: Thank you, and I, too, am in support of repealing MIPS. Now on the question of replacing, as long as these indicators are in alignment

with the alternative payment model measures, I think the more they look the same, the better.

But I just want to call out a couple -- I am just overwhelmed by the complexity and the expense associated. You know, $1 billion in reporting burden to physicians? I mean, I just think that that, on its own, stands in, like, whoa. And I contrast that with the same OIG report that Alice referenced, and that is in the first three years of the MSSP program, providers saved over $1 billion to the system, and outperformed the fee-for-service providers on 81 percent of the quality measures.

So as stewards of the Medicare program, and looking out for beneficiaries, I think this -- I think we just stand at such an important point in time here where we actually have any opportunity to make recommendation here that truly makes a big difference in where we take this program and where we take the transformation of health care in this country. I mean, are we going to continue to tinker in this fee-for-service world or are we going to provocatively, if you will, say it's time that we take this up?

DR. CROSSON: Craig.

DR. SAMITT: So thanks, as well, for a great chapter, and I think my thinking is very much in line with Dana's. You know, I am very much in favor of repealing MIPS, but I don't get the sense that we've gotten the replacement model quite right yet. And the reason why I say that is if we harken back to MedPAC's, I would say, contribution to the repeal of SGR, you recall that one of the things that we wanted to encourage, as part of the repeal of SGR, was the pursuit of APMs, and that we had even had the notion that, well, perhaps there could be incremental incentive if you become an APM, and a bit of a penalty if you choose not to and you choose to pursue status quo volume-based care.

So on Slide 12, when we talk about the reasons MIPS is not sustainable, we have to remember there were two other things that we wanted to encourage and that we would worry about beyond significant burden and identification of high-low value. It was, are we driving providers to higher performance, and are we encouraging providers to pursue A-APMs? I think one of the other reasons for MIPS is it could serve as an encouragement to improve performance and pursue A-APMs, and what I worry about is the replacement

model, as derived, allows providers to essentially stay where they are. If my worry is purely a 2 percent penalty, in my experience a 2 percent penalty will not drive behavior change. And so, from my point of view, we need to understand perhaps the number needs to be higher than 2 percent as a withhold, which would further encourage a focus on performance and further encourage a focus on A-APMs. So I question whether that is the case.

I also question, to Dana's point, when we talk about virtual groups and what it will take for virtual groups to actually fare well under this model, how is this different than an A-APM? And so perhaps one alternative is we don't replace MIPS, that there is a penalty for not being an A-APM but that our encouragement is that everyone seek out an opportunity to become an A-APM.

And then, finally, there are some other things, modifications, that we may want to consider if we do want a replacement model that is more effective. One thing we could consider is, well, if the problem we are trying to solve is to find a voluntary solution for specialists, well maybe what we say is that there isn't a replacement for primary care, that if you are in primary care you must be

part of an A-APM, but this voluntary model is available for specialists, so that there is an alternative for specialists that may not exist in the A-APM world.

And then, finally, one of the things -- I don't want to lose momentum by having a voluntary program. So, for example, the meaningful use measures. If I have a 2 percent penalty and then I choose to opt out, and then I am no longer contributing to the advancement of data collection and analytics, because I'm not going to adhere to meaningful use criteria, I think we've gone backwards in a significant way. So one of the other things that we may want to consider is, are there some elements of an expectation that's mandatory, that isn't voluntary? It's not the whole program but we say meaningful use reporting is mandatory, whereas other elements of what we would want in a MIPS program are voluntary as designed. That would be my perspective for how we can potentially strengthen the replacement recommendation.

DR. CROSSON: So, Craig, let me just -- I don't want to pin you down because we are still in the formative stages here, but I did hear support for repealing MIPS, and I think I also heard -- but this is where I'm kind of

questioning -- perhaps qualified support for some replacement, or some set of replacement ideas, or not?

DR. SAMITT: Well, I'm comfortable with a replacement if the replacement actually achieves the expectations or the objectives of why we would have it in place in the first place.

DR. CROSSON: Yeah.

DR. SAMITT: So if a replacement is a voluntary model that would allow us to just keep practicing health care the way we've been practicing, then that replacement is not a good replacement. If the replacement is strong and powerful enough to continue to instigate evolution of the industry, then I would say very much, let's consider a replacement model. I just don't feel that what's been designed today will advance our entire provider sector toward where we want the industry to go.

DR. CROSSON: And I guess that's an important question. Again, we are in the early stages of doing this.

I think, you know, two motivations here that maybe haven't been articulated so far, is, number one, although there has been liberalization, it's been clear in the physician community that the limitation to entry into

A-APMs is still significant. And so if it were, you know, smooth and easy for any physician who wanted to, and was able to join an A-APM, I think we would have a little bit different situation than we do right now.

So I think it's a perfectly valid argument about whether or not, given that, there should be an intermediary kind of thing or not, and you can argue that both ways. I think where we ended up, at least in formulating a proposal so far, is that were we simply to say let's repeal MIPS, we would, in fact, be saying for those physicians who can't make it into A-APMs we are not suggesting any way to assess the quality of care, and that is partly how we ended up where we were.

But, you know, just based on the conversation so far, I think our intermediate model needs to evolve.

DR. SAMITT: This may be a clarifying question and I may have missed it somewhere. Have we done an analysis of the limitations to becoming an A-APM, how that's divided between primary care and specialties, and what the real drivers are of those limitations, because maybe we are trying to solve a problem that is a much narrower problem than we think, if we were to complete that

analysis.

DR. CROSSON: And it's a moving target, but I think that's a good point and it's something easy for me to say, I think we could get to.

DR. COOMBS: Jay?

DR. CROSSON: Yes, Alice.

DR. COOMBS: I just wanted to speak to the notion of a transitional. That, to me, seems like a reasonable piece, given some of the discussion around the table. And the other piece that I wanted to add is that we should consider winners and losers in our next rendition of this, in terms of both sides of the coin, and we can kind of map it out in a chart, in terms of who does better, who does worse, and if there's a way in which we can break that out, even with the workforce data that we come up with.

DR. CROSSON: I'd have to think about that. I mean, I think the intention here is to try to provide, based on the notion of improving value, improving quality and helping to manage the cost of the Medicare program, that there is an opportunity here for everyone to do better. Not everyone will do better, but if we structure this properly, there should be an opportunity for everyone

to do better than they would do if they did nothing, I think.

Okay. Comments? David, yeah.

DR. NERENZ: Yeah, thanks. I've spoken up many times in the past of concerns on some of the core concepts of this new proposal. I won't waste the group's time this morning repeating those. They are in old transcripts anyway.

Just a couple of other things. If we could go to Slide 11, I want to get back to the measures, and I understand absolutely these are just illustrations. They are not meant to be set in stone. But I really think before this goes forward really seriously as a proposal there's got to be some attention paid to the measurement properties of these, in one of two ways, either argue, given the known measurement properties of these, in a context like this, how they would perform -- reliability, stability over time, ability to discriminate groups of the type we are talking about, minimum group size requirement, are these NQF endorsed. When you look at the HRQ prevention measure website, what I see are individual condition-specific admission rate measures, not an overall

one.

So I think a much stronger case has to be built, which would be one approach, to say, you know, these are really good and valid and useful measures in this context. Or, if that information doesn't exist, at least lay out the criteria by which measures would be selected, and say these are illustrations, they might be the right ones and they might not, but these are the criteria that we would request or demand of measures to be used, and, you know, are they informative and all those kinds of things.

So I think that's a gap that has to be filled one way or the other.

DR. CROSSON: Can I just interrupt for a second? Sorry, but I think that's a very good point, David, and I wondered if you have some notions already about what those criteria would be, it would be helpful to communicate those to staff.

DR. NERENZ: Well, that leads me to my next point. Thank you.

DR. CROSSON: Not necessarily now.

[Laughter.]

DR. NERENZ: Well --

DR. CROSSON: No, I was kidding.

DR. NERENZ: Back last January, I waved yellow sheets of paper around. I made a lot of comments about that, include, say, the concept of signal-to-noise ratio. If you look at a number and you look at the variability, how much of that variability expresses true quality of care variation, and how much is something else? And I pointed out that some of the things we have currently in other contexts are 5 percent signal and 95 percent noise, and I said when we propose measures, we should take that opposite criterion. Now, maybe that's an acceptable measure; maybe it's not. But that would be one example.

Now, I actually -- when you sent around the materials, I went looking to see what do we know about these measures, and there's an interesting article in BMJ. I'm sure you looked at it in the run-up to doing this, but since not everybody would have seen this -- in England, this was done 20 years ago to evaluate sort of regional networks in care, the preventable admission rate.

It's a real -- I'll read this. It's interesting. "At the health authority-level socioeconomic characteristics, health status, and secondary care supply

factors explained 45 percent of the variation in admission rates for asthma, 33 percent for diabetes, and 55 percent for epilepsy. When health authorities were ranked, only 4 of the 10 with the highest-age sex standardized admission rates for asthma remained in the top 10 when allowance was made for these characteristics," so David's point about risk adjustment.

There was also substantial year-to-year variation in the rates, okay? So I'm saying either -- let's look carefully at what's known about this and bring it forward and defend that these are truly good and useful measures, or if the body of knowledge doesn't exist, so here's what we demand should exist, before I take them forward.

So I think -- and then last thing -- well, two little things. I do agree with David's point that as -- if this thing rolled out in the way it was designed coupled with positions the Commission has taken in the past on risk adjustment, this will exacerbate socioeconomic disparities. I don't think I need to walk through the mechanism, but it will happen. So I worry about that.

And then last thing, I just fell in this by accident, an interesting Health Affairs study. Larry

Casalino and Steve Shortell were two of the authors. I think 2014 is the date. They looked at preventable admission rates, and the finding -- it was part of the study -- is that really small groups had the best rates, groups of one and two providers, and then slightly bigger groups, a little worse and then bigger.

And I understand now all the arithmetic naturally flows together, but a lot of the design of this is pushing in the direction of larger groups. But if you take at least that one little study, it says that's not a great direction. Maybe it is smaller groups that do better.

I don't know that that is the firm conclusion, but at least we've got to be thinking about the measurements properties of these measures if the thing is going to be built on them.

DR. CROSSON: David, thank you for that, and again, I would emphasize, beyond the one or two you mentioned, since you work in this area, if you do have ideas about those characteristics and you could flesh that out, that would be helpful.

DR. MILLER: And what I would say -- and also, if you have other things, because I was tracking the risk

adjustment, the SES, the stability, minimum group sizes, whether there's endorsements, and so I caught a lot of it, but if there's other things that you want to add to it, let us know.

It is assumed that we would have paid as much attention to risk adjustment and the SES issue, which you've brought up many times, in contemplating these measures, using the tactics that we've talked about in the past. Of course, the criteria that you set up, one wonders how much of that was applied to the current system, which brings me to this question. Is your posture -- and, again, I'm trying to flesh out where people are. That line of questioning should be clearer as people are going around. Is your posture that you hold the MIPS in place as is? If you can't create, like say to Craig's point, the alternative system doesn't rise to the criteria that, say, Craig or you are articulating, do you repeal MIPS, or do you keep MIPS as it stands?

DR. NERENZ: Good question.

No, I agree with something that the chapter said about the problems with MIPS. It's the problems I've found inside ways -- I have no concerns, no disagreement with

that.

I think Dana expressed maybe pretty accurately. Well, I guess I should say as a bridge concept. I'm not convinced this is better. I mean, it's different. It's different in all sorts of ways, but to me, it brings in a whole different set of concerns. And I guess I'd say as an about-to-be beneficiary, I wouldn't be interested in looking at any of these numbers that we're talking about as a measure of clinician quality. I don't think they're informative, but that's again -- so what I might do is say let's just take down MIPS, and let's let other entities, particularly ACOs in MA plans, do the work of quality measurement, quality improvement.

There are also mechanisms like the statewide quality collaboratives we have in Michigan that I think are doing a really superb job of both measuring and improving quality, and so that's where those dynamics play out. I'd probably be happy with that.

So I think I sense some common ground there with Dana on that point.

DR. CROSSON: Okay. Kathy.

MS. BUTO: So I would support, as Dave says,

taking down MIPS, and I think Paul expressed it well. Either repeal it entirely or repeal and replace with something that goes in the direction of population-based measures. But I would say even if you repeat it entirely, I would leave in the withhold or the penalty. So, in other words, I don't think it should be like budget neutral, no penalty at all, but just staying out of APMs.

So if we go in the direction of we're not ready for population-based measures, I would really think we want to look seriously at the penalty part. And then I would put -- invest that in APMs. So take that money and reward good APM performance in some way.

In fact, one of the questions that kept occurring to me is why does this have to be budget neutral. Even if we came up with an alternative approach, we may want to have some of the withhold go to APMs, maybe not all of it, because I think we really are hoping that the rewards for -- on that side would be much more substantial, so just something to think about.

What occurred to me, as I'm listening to the conversation about these measures, is even if CMS thought they had the measures correctly identified, they would

probably want to start with the ones that are least subject to a lot of question as to the validity of the measures.

I notice that a lot of them are data that would be pulled from claims, so --

DR. CROSSON: By design.

MS. BUTO: -- minimizing all of them.

DR. CROSSON: By design, yeah.

MS. BUTO: Minimizing the burden on the physician.

DR. MILLER: Yeah.

MS. BUTO: So if I put myself in their shoes, I'm thinking I might want to identify areas, but I might want to start with ones that I think are the most likely to succeed in being valid measures of performance.

Then the other thought, if you go in the direction of repealing MIPS entirely, say with a withhold, there might also be other things not related to quality measures but requirements that make staying in just pure fee-for-service less attractive. I don't know what those are right now.

I mean, things that occur to me are not very good, like not accelerating payment for fee-for-service

claims. Those measures are already -- or those time limits are in the statute now, maybe things like that.

Back to Craig's point, though, I think there are some things that you lose with respect to collecting data, and I think we need to think more deeply about what is it that we're not getting as a result of just total repeal of MIPS.

So it's a lot of thought, but I guess where I come down is I think there is very little to redeem MIPS. Maybe nothing. And we ought to go in that direction at least and then think about how this would play out.

I would actually increase the penalty and make it less attractive to stay in MIPS, regardless.

DR. MILLER: Kathy, Jim and I will escort you to your car at the end of the meeting.

[Laughter.]

DR. CROSSON: All right.

MS. BUTO: I remember those days well.

DR. CROSSON: Bruce.

Bruce is raising his hand. He's volunteering to escort you.

[Laughter.]

DR. CROSSON: Bruce.

MR. PYENSON: I think we'll both need an escort.

Thank you very much, David and Kate. I really enjoyed the chapter. I really learned a lot.

I support repealing MIPS. I think in replacing it, we have an opportunity to advance a population health agenda, and I'd like to talk a little bit about the slide that's up there now.

In particular, that we can align the measures there with the measures for the Hospital Value Program, so that physicians and hospitals are measured on the same things, which I think overcomes one of the biggest siloes in the health care system.

In fact, if we're going to do that, we could go further and tie the penalties or rewards from the Part B side to payments on Part A, and in doing that, I think we change the local dynamics dramatically. Two percent may or may not be sufficient to change the incentives of physicians, but 2 percent is probably sufficient, more than sufficient to incentivize hospitals to work with the physicians and their communities.

So I think we have an opportunity to think more

broadly on making a shift to population health here, but for sure, just repealing MIPS would be an improvement.

DR. CROSSON: Warner.

MR. THOMAS: So I would agree with much of what Kathy indicated. I would eliminate the MIPS program.

I think that we ought to be incenting folks to go into either MSSP or APMs, and I think that all specialties can be focused on some type of population health measure.

The measures that are better outlined here, I would like to see us just look at measures that are currently in the APMs and the MSSP program versus duplicating or creating an alternative set of measures.

And I agree with Kathy that this to me doesn't need to be budget neutral. There ought to be the penalty, and if people want to opt into MSSP or APMs, then they can earn the dollars back and potentially can do better by having an upside potential or whatnot.

The other comment I would make is that -- I also agree that if there's extra dollars there, those dollars ought to be invested in APMs or in transition or incentive payments to get folks into APMs.

Mark, you had mentioned the additional dollars

that are outlined around the MIPS program. I would really like to see us consider directing those towards primary care physicians who are either in MSSP or in APMs, not just primary care in general but ones that are willing to move forward into these other types of payment mechanisms, because I think we've got to continue to shift the thinking.

I get Alice's point around saying it would be difficult for some physicians, but I think we want physicians incented to try to get into MSSP or APMs and to be engaging those entities to try to join them. And what I see is that most entities are trying to convince physicians to move into those types of models. So I think this gives us another vehicle to try to create a different discussion with folks and get them headed in the right direction.

DR. CROSSON: Pat.

MS. WANG: I just wanted to -- since there is some attention to where the Commission is a group, to be clear, I really think that MIPS should go away.

As for the replacement, I think the comments of the other Commissioners were really, really good and well taken.

The one thing that I would try to avoid is to hold up the force of the consensus of MIPS should go away with trying to find the perfect replacement for it.

I think directionally trying to -- and I appreciate the comments on this. Is the lemon worth the squeeze? Is it really kind of already like an APM? Is it sort of like a mini-me APM that has sort of been described and framed out here?

I would still, I think, at least for a transition period, be inclined to try to make it better, even if it is like a shadow APM, because for reasons that I'm not sure I fully understand, not everybody has joined in APM. So for the folks who are still in fee-for-service trying to push in the direction of value-based population health measures, I think is still worthwhile.

To Brian's point, though, maybe there could be an augmentation of that alternative model that does for certain specialists -- for example, for whom these measures or because of their geography or what have you or just they're not, as Dana says, going to recognize themselves in that. That to the extent that there has been work done on evaluating quality in episodes, which might be more

specialty based, that those be added to the mix, and that CMS be asked to sort of flesh out quality metrics for the MIPS replacement that push in the direction of population health but also push in the direction of value assessment for episodes of care.

So I don't know what the replacement should be. There should be a repeal -- and want to be on the record that. But I think, directionally, that it's okay to figure out if there's something for those docs who are still in fee-for-service that kind of directionally move this in the right direction.

DR. CROSSON: Okay. Thank you, Pat.

And, again, I want to compliment Kate and David. This is very good work. It's the kind of work we do once or twice a year, where we're really thinking of something substantial that needs to be changed, and it's always difficult. At least all the ones I've been through have been difficult, and it's supposed to be. That's why we have a Commission with 17 people here.

So I'm going to try to summarize where I think we are.

Alice.

DR. COOMBS: Yeah. I just wanted to, first of all, echo what David has said in terms of disparities, and I think that there will be a sign group of providers who will be left out because of a number of reasons in infrastructure development.

But, Jay, before you do the last summary, summarizing comments, can you walk through what in your mind -- I know you had a vision -- if you were to repeal MIPS and not replace it, what does that look like?

DR. CROSSON: Well, actually, I mean, I think more than a vision, I think we have what we've been presented, which is a basis for a discussion here. The vision gets crafted by us collectively.

So in saying I want to summarize the discussion, I'm kind of doing that. So let me do that and then see if I've satisfied what you've asked, because I think with almost -- well, maybe very limited exception, we have very close to consensus that MIPS should be repealed. Maybe one Commissioner doesn't agree with that.

I think we also have a consensus, at least among those, that it would be good to advance population health as the basis for accountability. I mean, that's consistent

with where the Commission has gone in other areas of quality measurement.

Where we had a difference is like how to do that -- well, I guess whether, whether we can do that at all with a replacement, which would be the -- well, let's just replace MIPS -- I mean let's just eliminate MIPS and leave nothing with respect to measuring accountability for cost and quality in that practice environment.

I think my notion, Alice, was we could take that direction, but we ought to try, before we do that, to think through whether or not there are some ideas that we could put forward, which would -- and I guess I'm not sure I like the term "replacement for MIPS," but to substitute something or some set of things.

And a lot of this is predicated on the question of whether or not A-APMs, as they're structured, are, in fact, open and available to the majority of physicians, and I'm still -- I know there's been liberalization. I think the comment that we should try to see where exactly that moving target is right now is a good one. Craig is not here, but I agree with that.

I have some concern with the notion that we would

call for the repeal of MIPS and then as a Commission take the position that for those hundreds of thousands of physicians in practice, we have no idea about how quality and cost accountability should be assessed. We might take that position because we can't agree on something else, but I would hope that we can.

And I think my hope is that when we come back in December, we take a look at two possible options for replacement here, and they could be both ideas that we bring forward in the end as options for CMS or the Congress.

One would be based on this voluntary group idea with the adjustments that I've heard or suggestions for improvement that I've heard, everything from risk adjustment, which we did have in mind, and dealing with SES, which we did have in mind but were not explicit about.

But some of the other issues that have been brought forward, you know, David, what would be the criteria for the development of measures? We always have this problem when we're bringing something forward, which is a major change, and that is how specific do we get as a Commission, do we try to -- you know, as they used to say,

make the birthday cake, put the candles on it and light them and turn it over to Congress and the administration, or we do, in fact, point a substantial direction and enough detail to indicate our intent. And we have that issue now. We've had it before on major issues.

I think we need to land where we can with that, and we'll never, I think, satisfy every concern about, well, we didn't really get every detail of this right. We're not writing regulations; we're making policy recommendations.

And then the second idea -- I think, again, these could be either/or, or they could be both as options presented to policymakers -- would be to substantially change the rules and regulations governing A-APMs and broaden them so that, in fact, we could say with a straight face that for the physicians who are willing and capable, that is a path that the vast majority of physicians could pursue. And if that's the case, then I would agree our intermediary position would be less necessary, but that's not, as I understand it, the situation we have now.

So I think our intention would be to come back in December with draft recommendations for the repeal of MIPS

and then work through at least two options for what -- again, I'll use the term "replacement." I don't like it, but what we would suggest be present for physicians who could not access A-APMs. It would either be something, a more fleshed-out presentation about the voluntary grouping as well as addressing the question whether A-APMs could be made more accessible to physicians. And then we could say in formulating our recommendations finally, we could suggest that -- that is, one of those two options I said, let's choose one or the other, or let's suggest both to policymakers as options if we can get to that level of consensus.

Warner.

MR. THOMAS: Just a question, Jay. I mean, what precludes physicians from getting in an MSSP program or an APM?

If you're a rural physicians -- and I know there's rural physicians that are reaching out to systems like Sue's or others. I mean, I guess I would like -- and maybe we can talk about it in December as to why physicians are not in these programs because, frankly, I think they're available to everybody.

DR. CROSSON: Warner, you bring up the substantive question that Craig, who is now here, brought up earlier, and as I suggested a minute or so ago, one of the pieces of information that we would come forward with in our December discussion is what is that reality for A-APMs. And if you want to put in there ACOs that are not A-APM-qualified, we can discuss that as well, okay?

MS. WANG: All right.

DR. CROSSON: All right. So does that satisfy, Alice, your request for a vision?

DR. COOMBS: [Nods head yes.]

DR. CROSSON: And does the rest of the Commissioners think that that's a reasonable summary of our discussion?

Okay. Jack.

DR. HOADLEY: Just to clarify, so what would come in December is either you will draft the Chairman's recommendation among those kinds of options you just laid out or you might actually give us two routes and then have us sort of pick and then come back in January to vote on --

DR. CROSSON: Right. My idea would be pick one or the other or --

DR. HOADLEY: Or both.

DR. CROSSON: -- realizing we're not legislating, suggest potentially both as options to policymakers.

DR. HOADLEY: But the notion is still to package whatever we end up with out of that realm into our January vote --

DR. CROSSON: That's correct.

DR. HOADLEY: -- and for the March report?

DR. CROSSON: That's correct.

Kathy.

MS. BUTO: I'm sorry not to have picked this up, but on the MIPS side, was one of the options just the elimination, a repeal of MIPS with maybe a withhold or something like -- in other words, a more limited option?

I agree with you it would be desirable to have some quality measures, but I guess I'm wondering if we envision that there could be a fall back, if you will.

DR. CROSSON: I'm sorry, Kathy. I can't draft it in my head.

MS. BUTO: Yeah.

DR. CROSSON: But to me, the notion of the second pathway, which would be to smooth the availability of A-

APMs could include your suggestion for the withhold to remain.

MS. BUTO: Yeah. I'm just thinking if we can't come to agreement on the quality measures set for the population-based measures, then we may need to think about, at a bare minimum, we'd like to see MIPS go away, and how would that look? But maybe we don't want to go there yet until we've gotten through that discussion fully.

DR. CROSSON: Yeah. I mean, I guess I'm trying to figure out if in December, if we would say, "Well, we don't think we should either do any kind of voluntary group or smooth the pathway to A-APMs as advice." If we got to that point, which I think would be odd, but could happen, then I think we'd have to have a fallback.

But at the moment, I'm predicating that we won't need it.

MS. BUTO: Yeah. Thanks.

DR. CROSSON: Okay. Good discussion. Thanks again.

Let's move on to the next topic.

[Pause.]

DR. CROSSON: Okay. Next topic, Brian is going

to talk to us a little bit about the entities known as PODs. Brian?

MR. O'DONNELL: Good morning. Today I'll be providing background on physician-owned distributors -- or PODs – and discussing the legal framework under which PODs operate and seeking the Commission's feedback on potential approaches to limit the use of PODs through the Stark law.

This presentation is a continuation of the Commission's work on medical devices. At the Commission's April meeting earlier this year, several Commissioners questioned the utility of PODs and suggested we explore options to limit their use.

Before I discuss PODs in more depth, I'll review a few key background points on medical devices that will help set up today's discussion.

Medicare does not purchase devices directly. Rather, the program reimburses providers when they use devices in the course of delivering care.

The payment for those devices is typically bundled with the payment for other inputs. For example, hospitals purchase implantable devices and get reimbursed through Medicare's inpatient or outpatient prospective

payment systems.

While hospitals spend significant sums on devices, as the slide indicates, they often face challenges when trying to purchase devices efficiently.

One challenge hospitals face are the legal roadblocks preventing them from participating in gainsharing. Gainsharing programs are initiatives that reward physicians for lowering costs below a benchmark while improving or not affecting the quality of care. The Commission has twice recommended allowing broader participation in gainsharing programs.

Another potential challenge hospitals face in trying to lower their device costs is PODs.

PODs allow physicians to profit from sale of devices they use. Specifically, PODs are entities that derive revenue from selling, or arranging for the sale of, devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients.

PODs can be structured in different ways. I've listed three common models on the slide. I'd be happy to take questions on any of the models, but I want to

highlight the manufacturer model, as I'll return to it later in the presentation.

Under the manufacturer model, a POD will typically sell devices that it has arranged for another company to manufacture on its behalf.

Regardless of their structure, PODs create incentives for physician-owners to perform more and potentially inappropriate surgeries and to sell devices to hospitals at the highest possible price because they directly profit from the use of more and higher-priced devices.

OIG has found that growth in spinal surgeries was three times as high at hospitals that used PODs compared to those that didn't and that devices purchased through PODs were either equal to or more expensive than those not purchased through PODs.

Also, Department of Justice lawsuits against a related group of PODs and physician-owners provide examples of patients being referred for surgery unnecessarily in order to increase POD profits.

We know relatively little about the prevalence of PODs, but what we do know largely comes from two industry

reports and an OIG study that examined the prevalence of PODs in the spinal implant market -- the market in which PODs have historically been concentrated.

A Senate Finance Committee report that relied on industry sources found that PODs were operating in 43 states as of November 2015.

In 2013, OIG found that roughly one in five spinal fusion surgeries used devices acquired through PODs and that a third of all hospitals purchased spinal devices through a POD.

So, based on what we know about them, PODs create a conflict of interest for physicians and may encourage financial considerations to influence medical decisions.

Two key laws that apply to PODs and that help regulate such conflicts of interest are the anti-kickback statute and the Stark law. I've included a discussion about the anti-kickback statute in your mailing materials and would be happy to discuss it on question, but the presentation focuses on the Stark law because: the conflicts of interest that PODs create is the type of problem that the Stark law was designed to address; and the Stark law likely represents a more fruitful way to broadly

limit the use of PODs.

While industry stakeholders disagree whether PODs are currently legal under the Stark law and the legality of any given POD depends on its specific characteristics, the next few slides walk through some basic Stark law concepts and how PODs might currently be structured to operate legally under the Stark law.

The Stark law prohibits a physician from referring designated health services, or DHS, payable by Medicare to an entity with which he or she has a financial relationship unless an exception applies; and, second, prohibits that entity from filing claims with Medicare for those referred DHS -- again, unless an exception applies.

So before I talk about how the Stark law applies to PODs, I want to unpack some key concepts from that last sentence.

First, the Stark law only applies to specific services. These are called designated health services or DHS.

A DHS entity is an entity that performs or bills DHS. Generally, the Stark law defines a financial relationship as an ownership or investment interest in an

entity or a compensation agreement with an entity. Either of these types of financial relationships can be direct, meaning the relationship is between the referring physician and the DHS entity; or indirect, meaning that there is some intervening entity between the DHS entity and the physician.

Once a financial relationship exists between a physician and a DHS entity, the physician is prohibited from referring DHS to the entity -- again, unless an exception applies.

Exceptions are basically carve-outs that allow for otherwise prohibited referrals to occur if certain criteria are met. A number Stark law exceptions exist. The next slide applies some of these concepts to an illustrative example involving a POD.

In this example, a physician owns a POD. As depicted by the line at the bottom of the diagram, he or she refers a patient for surgery at a hospital. As shown by the two dotted lines, the hospital purchases the devices needed for the surgery from the physician's POD, and the POD then transfers the profits from that sale to the referring physician.

In this case, the hospital service is the DHS, and the hospital is the DHS entity, as it performs and bills Medicare for the DHS. This is shown in the upper left-hand portion of the figure.

Given the flow of money, we believe that PODs often create an indirect compensation relationship between physicians and hospitals because: the hospital does not directly pay the referring physician, but there in an unbroken chain of financial arrangements between the referring physician and the hospital -- that is, the hospital pays the POD, and then the POD pays the physician.

Additional technical details regarding indirect compensation arrangements are included in your mailing materials.

Also, before I leave this slide, I'd like to note that the payments physicians receive from PODs is in addition to their normal fees they get from Medicare, which is depicted in the upper right-hand corner of the figure.

If an indirect financial relationship exists between a physician and a hospital, then DHS referrals are prohibited, unless an exception applies. We believe the key exception for PODs is the indirect compensation

exception.

This exception contains several criteria. One key criterion is that the compensation received by the physician from the POD does not take into account the volume or value of referrals from the referring physician to the hospital.

Because a physician-owner's compensation does vary by the volume or value of referrals, the relationship would appear to not qualify for the indirect compensation exception.

However, the "per unit of service" rule deems the compensation not to take into account the volume or value of referrals so long as the per unit compensation is fair market value and the per unit compensation does not vary over the course of the agreement in any manner that takes into account referrals of DHS.

For example, if a hospital agrees to pay a POD $1,000 per surgical screw over the course of a year, such an arrangement should meet the "per unit of service" rule so long as $1,000 is a fair market price for such screws and the $1,000 price does not increase or decrease based on referral patterns. This is true even though the physician-

owners' aggregate compensation from their POD will naturally increase as the number of referrals increases.

Therefore, the "per unit of service" rule appears key to allowing such relationships to qualify for the indirect compensation exception.

Now that I've discussed how the Stark law applies to PODs, the next several slides discuss two potential policy approaches to limit the use of PODs through the Stark law.

The first approach is removing the application of the "per unit of service" rule to PODs. As I mentioned, without this provision, many PODs would likely not qualify for the indirect compensation exception and, therefore, physicians would be prohibited from making referrals to hospitals for services in which their PODs supplied devices.

There is precedent for making such a change. In 2008, CMS removed the application of the "per unit of service" rule to space and equipment leases because of reported abuses. So this approach could be seen as a logical extension of CMS' regulatory history and likely does not require new legislative authority to implement.

The second approach entails classifying PODs as DHS entities. Under such a change, physicians who have an ownership stake in PODs would have an ownership stake in a DHS entity and would, therefore, be prohibited from referring their patients for services that use devices supplied by their PODs, unless another exception applied.

Many believe that regulating ownership relationships through the Stark law, as this approach would, has been effective at reducing self-referral, as the prohibition is clear and there are relatively few ownership exceptions.

However, this approach could require new legislative authority for CMS and brings with it some ambiguity. For example, the primary penalty for violating the Stark law is non-payment of Medicare claims, but PODs don't submit claims. So additional provisions would likely need to be added to reflect this situation.

Regardless of the approach, policymakers will face several challenges in adapting the Stark law to limit the use of PODs. The next three slides discuss some of those challenges.

First, the Stark law currently does not define

PODs, so a definition would need to be added. The core definition that is included in italics on this slide is similar to how we defined PODs earlier in the presentation.

In response to prior legislative changes, PODs have reportedly changed their structure while maintaining the fundamental incentives embodied in PODs.

Recognizing this, the Commission could consider adding language to the definition of a POD that would prevent superficial organizational changes from allowing PODs to avoid being recognized and regulated as such. I've included suggested language in your mailing materials.

One of the difficulties in defining PODs for the purposes of the Stark law is that some entities might unintentionally be included in any definition of a POD.

Physician ownership of device manufacturers is not uncommon, especially among startups.

Under the proposed Stark law changes, a physician who has an ownership stake in a device manufacturer could be prohibited from referring their patients to a hospital for surgery in which that manufacturer supplies the devices, even though such companies are not traditionally thought of as PODs.

Such a prohibition could be considered appropriate based on the premise that physician-owned companies should be able to convince non-owners to use their devices if the devices represent an improvement compared to existing technologies.

However, some may argue that such a prohibition could provide a disincentive for physicians to innovate because their ability to profit from their invention could be reduced.

To address that concern, self-referral could be allowed in certain circumstances. For example, self-referral could be allowed if the physician: invented the device in question; or the physician ownership is in a large, publicly traded company such that their self-referrals are unlikely to substantially affect their compensation; or a POD generates 40 percent or less of its business from self-referrals.

From the perspective of the government, any Stark law changes would largely be self-implementing because hospitals would have a strong incentive to restrict their dealings with PODs, as their claims could be denied and they could face additional False Claims Act liability.

In the past, some hospitals have unknowingly purchased from PODs, and some PODs are likely to exist even after Stark law changes are made. Given that, transparency of POD-physician relationships could be beneficial.

However, under the Open Payments program, which is designed to shed light on industry ties to physicians, only a small number of POD have reported because: not all PODs are currently required to report under the program; and some PODs that are required to report appear to have failed to do so.

This last slide summarizes some potential options that improve the incentives in the device market, both by limiting potentially abusive relationships and encouraging the development of other relationships with more appropriate incentives.

The first option on the slide is reiterating the Commission's support for allowing gainsharing in Medicare. The next option is limiting the use of PODs through the Stark law.

As I mentioned earlier, there are concerns that more strictly regulating PODs could hurt innovation, so some options are listed to prospectively address those

concerns.

Finally, as I mentioned today and was discussed in the Commission's June 2017 report, very few PODs have reported under the Open Payments program. Even without efforts to revise the Stark law, universal POD reporting under the Open Payments program could be beneficial. And if Stark law changes were made, enhanced reporting could help hospitals monitor their supply chain, as some PODs would likely continue to exist.

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

DR. CROSSON: Okay, Brian. Thanks very much.

We'll do clarifying questions. Can I see hands for clarifying questions? Let's start here with Rita.

DR. REDBERG: Thanks very much, Brian. I just have a question on that last slide, and it was in the mailing materials, too, Slide 13, because not all PODs report to Open Payments. What is the penalty for not reporting?

MR. O'DONNELL: So I'm turning to my Open Payments colleague. Do you know, Amy, off the top of your head?

MS. PHILLIPS: It's a fine. It's not [off microphone].

DR. REDBERG: Do you know if that has occurred in those cases?

MS. PHILLIPS: If they haven't reported and if [off microphone].

DR. CROSSON: Jack.

DR. HOADLEY: Thank you. A really helpful chapter. I'm still trying to sort out the definition of "manufacturer POD," and you used the term later "a manufacturer with some physician ownership," so maybe that's a way to help me distinguish between those two concepts.

MR. O'DONNELL: Yeah, so I'll take you through like conceptually what I'm talking about, and then the implementation is really the issue.

Most PODs, as we think of them, don't actually manufacture devices themselves. They'll contract it out with another actual manufacturer.

But then when we say, okay, how do we define a POD in statutes, you don't want to lose those kind of POD manufacturers, so then you define -- in the definition you

say, okay, a POD is -- it could be a manufacturer with physician ownership, right? And that catches some other things like startups or large device companies that have a small chunk of their ownership owned by physicians. So it's really a definitional problem of how we take this thing that we know are PODs and then we can define it in law. And when you actually do that it kind of catches some things that we're not exactly trying to catch.

DR. HOADLEY: You get into that gray area.

MR. O'DONNELL: Yeah.

DR. HOADLEY: The manufacturer POD has some kind of a partnership relationship with the manufacturer?

MR. O'DONNELL: Typically, yeah.

DR. HOADLEY: Okay. The other question, you know, you were talking about the Stark law and what could be done with regulatory. I guess I'm wondering what history there is of CMS looking at this specific area of PODs. Have they ever surfaced the idea of making a change of the sort you're talking about here?

MR. O'DONNELL: Right, so, yes, they have. In, I think, 2009, IPPS final rule, they solicited some comments on saying should we -- should we go look at these and

should we regulate them? They didn't finalize those rules, so they didn't -- they just solicited comments. But also keep in mind -- and we know this from the OIG -- that, you know, the growth of PODs really started in the mid-2000s and grew all the way through 2012. So at the time they were making the rule, you know, PODs existed, but they weren't as prevalent as they kind of became, you know, three, four, five years after that.

DR. HOADLEY: And then that 2009 regulatory phase, was there a lot of pushback? Did they give any particular reasons for not going forward, or was it just one of those things they just chose not to act on?

MR. O'DONNELL: I think it's the latter.

DR. HOADLEY: Okay. Thank you.

DR. CROSSON: Questions over here? Bruce.

MR. PYENSON: Thank you very much, Brian. I've got three questions.

On page 11, you offer a definition of a POD, and then note the potential problems with the POD definition. Would this definition, do you think, affect entities such as dispensing pharmacies, dispensaries or pharmacies that are sometimes associated with oncology practices or others?

MR. O'DONNELL: So I'll need to think about that, but I don't think so because it's particular to medical devices. So in the definition there is medical devices. So long as they are not dispensing devices I would say no.

MR. PYENSON: Okay. Thank you. Another question is, Medicare Advantage organizations have the ability to contract with suppliers, device management companies, and I'm wondering if that has been successful and how these discussions would affect Medicare Advantage plans.

MR. O'DONNELL: Right. So I'll need to look into the device management companies, but there is an exception for -- to the Stark Law, kind of in general, for Medicare Advantage plans. So I didn't include that in the mailing materials but I can add more detail about what exactly that exception is and how it applies, in the future.

MR. O'DONNELL: Okay. Thank you. And last question is related to that, is perhaps the application in non-Medicare patients. So would the issue with innovation and manufacturing, does that -- would that be considered differently if the patients were not Medicare patients?

MR. O'DONNELL: So the Stark Law really only applies to Medicare, and there's been a few cases recently

that have tried to apply it to Medicaid but it doesn't apply to, for instance, private-pay patients unless the state has a state-based law or something of that nature. So the Stark Law is really kind of particular to Medicare.

DR. CROSSON: Kathy.

MS. BUTO: Thanks, Brian, for a really helpful chapter, and I think it sheds some really important light. Do you have any data on the sort of percentage of PODs that are manufacturer-based versus distributors versus GPO types? Do we know what the distribution is, and is one of them growing faster, like the manufacturer, versus the other two?

MR. O'DONNELL: Right. So I'll give you some anecdotes and then I'll give the one piece of data I have.

MS. BUTO: Okay.

MR. O'DONNELL: I tend to hear more about the distributor and the manufacturer models when I kind of talk to industry, and I think -- so that's the anecdotes. And in the OIG report, they mentioned that, I think it was three-fourths of the PODs that they identified through their surveys purported to manufacturer their own devices. So the manufacturer model, in their survey, stood out.

MS. BUTO: And was the fastest-growing?

MR. O'DONNELL: I didn't see that but --

MS. BUTO: Did you get that sense?

MR. O'DONNELL: I didn't see a gross statistic there --

MS. BUTO: Yeah.

MR. O'DONNELL: -- but --

MS. BUTO: Yeah. Yeah. I guess the other related issue would be whether we'd have the same concerns about self-dealing or self-referral in a way with the GPO model, or just the sort of business model around GPOs, and the distribution model, which are probably much more transactional, but I don't know if you looked at that.

MR. O'DONNELL: So, to me, the concerns are very similar between all three models. They just -- they kind of package it different. And so why I broke out the three models is really just to focus on the kind of manufacturer, because of the definitional problem we were talking about.

MS. BUTO: Right.

MR. O'DONNELL: So that's really why I broke that out for you.

MS. BUTO: Okay. Second question is, you know,

we've obviously focused on spinal surgery devices, but do you know what, or do we have data on the volume of other devices that are provided through PODs? Do we have any sense of that or is that the one that comes to the surface whenever you have these conversations?

MR. O'DONNELL: Right. So it's typically the spine that comes to the surface and they offered a few kind of reasons why that happens. One is that the spinal market is a little bit more diffuse than, let's say, knees and hips, and so they will say things like, well, the POD can convince, you know, a spine screw manufacturer to sell to them, as to where in the knees and hip market there is really maybe three or four large manufacturers that kind of screen who they sell their devices to. So that's the reason I've been, kind of -- I've heard that -- why this potentially hasn't spread as much in the knees and hips and other markets.

And then the last thing I will say is that, you know, we have heard concerns that it would spread to other markets, including, you know, things like prosthetics and orthotics and things like that, but we don't have any good data outside of the -- out of the spine world.

MS. BUTO: Okay. And the last question I have is about, there used to be, and I don't know if there still is, an in-office ancillary exception in the Stark Law, and that exception, as I recall -- and this is reaching back -- really went to exempting solo physicians and group practices from self-referral restrictions or prohibition. So, in other words, if you are a solo physician and you're ordering clinical lab tests in which you have an ownership, you are under an exception. Same thing for a group practice -- which is a pretty big exception, if you will. The devices, particularly orthotics and prosthetics you're talking about, are something that would be an in-office kind of service -- could be. And I'm wondering whether you've looked at that, because although I think the issue there is more about the volume of ordering versus the cost to the system per se or the price, it might be both, but I think volume was a greater concern with in-office, and I don't know if you looked at that at all, in considering this.

MR. O'DONNELL: Right. So the -- you know, so obviously I'm aware of the in-office ancillary services exception, and for the IMDs, right, it doesn't really apply

because these surgeries are happening ASCs or hospitals. So we didn't really explore, you know, how this would apply, you know, the concept of prosthetics and orthotics, you know, whether basically they could get around the exceptions that we are talking about today, because what we really focused on was what we know exists, and that's the spine implants.

DR. CHRISTIANSON: [Presiding.] So, Brian, I know you want to get in on this. I have David and Craig over here. Is this on this particular topic? Okay.

DR. DeBUSK: Kathy, to your comment about the in-office ancillary exception, typically, like embracing in orthotics, that would be an L code. So, you know, in the L code, the physicians has the incentive to already bill to purchase that item as cost-effectively as possible, so you really don't have the rub there.

The ASCs are an interesting exception because when you look at the device itself, because they are paid under an APC, and presumably the physicians have at least a significant, if not majority or whole ownership stake, they would have the same incentive. And if they bought from their own POD, in theory, they're just moving money from

one pocket to the other. Where it gets interesting is when you have a bona fide third party, like an HOPD department or an in-patient. But there's at least a little bit of self-correction, I think, even if the ancillary in-office exception remains intact.

MS. BUTO: Right. I was just thinking volume, though, Brian.

DR. DeBUSK: Yes.

MS. BUTO: Even though cost-effectively there's still an incentive to, if you will, pump up volume where you have the ability to do that.

DR. DeBUSK: Yes. Totally agree.

MS. BUTO: So that issue --

DR. DeBUSK: Well, that's where they would have to rely on the "per unit of service" exception.

MS. BUTO: Right now it's exempt, though.

DR. CHRISTIANSON: Is that it, Kathy? Okay.

DR. NERENZ: Yeah, thanks. Slide 5, please. Just on the first sub-bullet point, we've got the 16 and the 5 percent. I'm wondering, does the information allow to distinguish between two different scenarios? The one scenario is that you've got a hospital with a group of

surgeons attached. You've got another hospital with a group of surgeons attached. One has POD, one doesn't have POD, and the numbers say if you track growth over time the POD one grows faster. That's one scenario.

The second scenario is you've just got one group of surgeons but they split their procedures across two hospitals. They form a POD and then they go to the two hospitals and they say, "We want you to buy through our POD." Hospital A says yes, Hospital B says no. The one group says, "Okay, we're going to do our procedures at A," but now what's going on is a shift. They do fewer at B, more at A.

The difference between the two is the first one would probably involve a net increase. The second one would not necessarily. It's more of a shift. Is there any way to tell, is it one or the other or just a blend of both?

MR. O'DONNELL: Yes. I'm not sure the data is that granular, but what I will say is that they did two things. One is they just did a cross-section, right, and they looked at, you know, of hospitals that purchased from PODs what's their utilization of rates, right? And so in

that case, the hospitals that bought from PODs had much higher utilization.

They then did kind of a pre/post, or almost kind of a difference in difference type of approach, where they said, okay, this hospital began buying from PODs in, you know, 2009, and they did this six months before and then six months after utilization, and the utilization bumped more at hospitals that started to buy from PODs.

Now, to your question, can we tell whether a surgeon said, "Okay, I'm going to switch and throw all my volume over here"? No, I don't think we can tell that.

DR. NERENZ: Okay, and that was my implication. I was just trying to sort out, you know, if these numbers could either reflect then or be a basis for a net rise in surgeries, or could be a not net rise in total but just a shift across hospitals. I was just trying to see, is it one or the other.

MR. O'DONNELL: Right. On the last point, I don't think they present a kind of a pooled number. Right, yeah.

DR. CHRISTIANSON: We'll go down the aisle here and go to Pat, and then you, Craig.

MS. WANG: Just a quick question. You had mentioned concerns about possible inhibition of innovation by physicians if PODs were somehow restricted. Can you say more about the extent to which, you know, the devices that are going through PODs do represent, you know, a physician-invented device, it really is -- is it 1 percent, 20 percent, 50 percent?

MR. O'DONNELL: Right, and this, again, gets back to the definitional question. From what I've heard from industry is that, you know, the purest POD, in the sense that we think about them, really aren't kind of designing and making their own devices in large. They are just contracting out for -- maybe they get a 510(k), which is kind of a copy, a generic copy of a device, and then contracting out the manufacturing.

I think, really -- there might be, you know, an odd physician here or there that designs it for their POD, but I think what we are really concerned about are those companies that we catch, just based on definition, of defining a POD, that are legitimate start-ups, that are trying to kind of invent new devices, that it's a device manufacturer and it has some physician ownership, therefore

it falls under how we define a POD, but it isn't really a POD in how we kind of generally think about them.

DR. SAMITT: Can we go back to Slide -- oh, do you want to --

DR. REDBERG: Just on that point, I still am not clear how a POD would stifle innovation, because if you're the only one who is using your device, it's probably not innovative. You really have to depend on other people using it. And, in fact, you know, it's kind of -- well, like every kid's mother thinks their art is as good as what you sell.

MR. O'DONNELL: Right. So what I was trying to do -- and that's kind of the bullet point that I kind of said, was that, you know, if you can't convince other folks to use your device, is it really innovative? That's the question for the Commission, right? When I talk to people -- yeah, so --

DR. REDBERG: As a journal editor, I think it should be a peer-reviewed publication and other people should get it.

DR. MILLER: But this was also -- he touched on some of these rules. You know, you could ask questions

like, what percentage of your -- does some percentage of this actually occur in a different hospital, across different physicians, or how much ownership do you have? You could set some rules that you were trying to say, if somebody really did invent something in their garage and it was really for everyone, not just for me to run through my own patients, in my own hospitals, there might be some rules. Obviously, you know, subject to gaming, but rules that you could put in place that try to contemplate that, because this is the first over-the-transom criticism. It will wipe out people inventing things in their garage.

DR. REDBERG: I mean, I'll leave it at this comment, but I think that's a big problem, is inherent conflicts of interest in somebody who's making and, you know, and they're the one, then, recommending and implanting their own device. I think that's got a lot of problems.

DR. CROSSON: [Presiding.] Craig.

DR. SAMITT: So can we go back to Slide 5 again, and I'll use this as the branch point.

My question actually stems from the "per unit of service" rule, because you described that the rule deems

the compensation not to take into account the volume value referrals if the compensation per unit is fair market value. So it struck me that if, on average, we are paying $845 more when supplied by a POD, that isn't fair market value. And so how would the "per unit of service" rule exemption apply if the experience that we've seen is the per unit cost is far higher than the market?

MR. O'DONNELL: So I think I would say two things. One is that, you know, five out of the six devices that the OIG looked at were not statistically different, in terms of the prices for POD versus not. So in this one case, maybe you are right. Maybe there's a good lawsuit hanging out there. But I haven't seen any cases prosecuted kind of based on Stark Law violations. So --

DR. SAMITT: So is it an enforcement issue that -- I mean, is there a process whereby we look for whether the "per unit of service" rule truly does apply, POD by POD, or device by device?

MR. O'DONNELL: So I -- I'm not sure, but I would say one thing, is that the variability you see in device prices is pretty substantial. And so I made this point in the mailing materials, perhaps unartfully, that when we

look at device prices we see these huge variations in prices. So in terms of defining, for legal purposes, in terms of defining a fair market price, I would suspect there is a lot of variation there, a lot of kind of wiggle room.

DR. MILLER: So I -- and follow me on the second point. I would have said that, like, first of all, there's so much variation you tell us what fair market value is. And then to his second point, he sort of was saying -- he's sitting right here so let's talk like he's not here.

[Laughter.]

DR. MILLER: It sort of felt like he was saying is somebody watching this, and I think the point is, no, it's really kind of by exception that people say, "I think something is wrong here," a whistleblower or somebody says, "I'm getting jacked here. I'm going to bring a lawsuit."

DR. CROSSON: Okay. Questions? Coming this way. Amy.

MS. BRICKER: Brian, I had two questions. So focus on the cost, realizing that the hospitals are the ones that are bearing this discrepancy that is noted here in 5. But in the mailing materials you cite that, on page

7, higher device prices put pressure on hospital margins -- got it -- and can contribute to calls for higher reimbursement from Medicare. Have we seen the latter? Has that actually occurred?

MR. O'DONNELL: That hospitals are calling for higher reimbursement?

MS. BRICKER: Yeah, or that the reimbursement has changed?

MR. O'DONNELL: I haven't tracked kind of like DRGs over time for spinal surgeries. No, I haven't.

MS. BRICKER: Okay.

DR. MILLER: But, you know, what do you mean, exactly? Can you just say it again? What have we seen?

MS. BRICKER: So it's not that Medicare is paying more, right? It's just that hospital is paying more, and because they're paying more they could then put pressure on the program to reimburse them more. Isn't that what we're saying -- what the point is here?

DR. MILLER: Yes.

MS. BRICKER: And so has that actually happened? Have we seen that pressure actually translate into higher reimbursement?

DR. MILLER: Well, I mean, that -- it's just the very last clause. We've seen the pressure, for sure, and then, you know, the very last clause, you know, have we seen it translate into higher reimbursement. And there's big arguments about -- I mean, hospital reimbursement gets swept up into larger issues, you know, like in 2010, making productivity reductions. The pressure is certainly there. And there was also pressure to do things, although I don't know how much of this gets captured in it, to pull certain -- when new technologies show up, pull out and pay them separately for a while until they are built back into the DRG. You've seen that result from people saying, "This technology is expensive." Although I'm not 100 percent sure how much --

MS. BUTO: That rarely happens.

DR. MILLER: Yeah, and it doesn't happen a lot, and I'm not sure how much of this. But you see that in response to these kinds of pressure. There's a technology here, it's expensive. Pull it out of the payment system. Pay an additional amount and then put it back into the payment system once --

MS. BUTO: But Amy's right. I mean, if all

hospitals end up paying more, because there are PODs everywhere, for these final devices, then eventually, after a year and a half or two years, the DRG payment may go up relative to the other costs in the system. It may not. It depends on what happens with all the other DRGs. But it could happen.

DR. MILLER: And that's why I was trying to pin her down, because, in theory -- and you stay with me because I know you know this too -- that's shuffling dollars around among DRGs, and I wasn't sure whether you meant that, because that could mean, well, I'm paying these prices. In any given year somebody steps in and goes, "I'm recalibrating it," and moves dollars away from -- I'm going to make this up -- you know, a diabetes admission and moves dollars to an implantable device admission. That definitely goes on. But the total dollar is what I thought she was asking --

MS. BRICKER: It's total, the latter.

DR. MILLER: -- across all hospital payment. That has a whole bunch of other pressures and is often fought out in a different arena, but there will be pressure because as their input costs go up, that will start to be

reflected in, you know --

MS. BRICKER: That makes sense.

DR. MILLER: -- right.

DR. SAMITT: But correct me if I'm wrong, but the bigger current concern is not even just unit cost increase. It's an increase in utilization.

MS. BRICKER: Yes.

DR. SAMITT: So if I benefit from an implantable device --

MS. BRICKER: Certainly.

DR. SAMITT: -- if there is a question as to whether I should surgically implant the device, I may be more likely to do so.

DR. MILLER: No question about that --

MS. BRICKER: Certainly.

DR. MILLER: -- and I thought she was asking a price.

MS. BRICKER: Yeah, I was just isolating the cost piece of this. I agree, though, with you, Craig.

DR. MILLER: But you're right, Craig.

MS. BRICKER: The second question, I imagine what POD owners would feel about this. In your conversations

with stakeholders, what have hospitals -- are they in favor of reform? Are they sort of silent? Are they behind the scenes saying, "Please help me"? Like what -- where are they in the conversation?

MR. O'DONNELL: So the sense I get is that, you know, that some large hospitals have already put out policies that say, you know, we're not going to deal with these entities. They put out policies, and I think HCA has a policy, Intermountain has a policy. So they've kind of -- they are able to kind of say no, we're not going to deal with you.

I think what we've heard is that, you know, some of the midsized and smaller hospitals, they kind of feel like they have to do business with some of these physician-owners, and even if they don't really want to take on the legal risk, they kind of feel forced to. So I think those are the types of hospitals where, you know, if we kind of leveled the playing field and say, "Look, you're going to have your kind of claims disallowed," that would kind of put them on a stronger footing to say, you know, "Listen, I'd love to buy from you but I can't."

MS. BRICKER: So you haven't heard from a

hospital system per se that's against some sort of reform? Is that fair?

MR. O'DONNELL: So the only thing that I have heard, and actually just read from congressional testimony, is that some hospitals, when they have implemented these policies, it's not a flick of a switch. It takes time to go through their vendors, because they have a lot of vendors and there are kind of unique circumstances. So I think that's the thing that I've heard, that, you know, it's tough to get into your supply chain and manage all of these folks.

MS. BRICKER: Thank you.

DR. CROSSON: Questions? Alice.

DR. COOMBS: So I had a question because -- and I'm in the OR daily, so one of the questions is, to what extent do you know about the relationship that the physicians have with either being hospital hired, which is very different than a private practice guy on the side, because that physician has access to information regarding volumes of surgery, the number of cases that are done in each of the categories, especially on the ortho side. Ortho drives the margins within a hospital.

So my question is the relationship, not just with the -- specifically the physicians that are part of the POD being hired by the hospital, or some kind of financial relationship, and not just being hired as an orthopedic surgeon but they may be working as a chief of service, or they may be doing a non-clinical job and having some kind of financial compensation.

MR. O'DONNELL: So the short answer is I don't know, and I don't think there's data on it. When I think of this, I think of, you know, docs who are not employed by the hospital. But that's just a notion that I have because I would think hospitals would have more control if they were employed by them. But that's based on nothing.

DR. COOMBS: And I can only say that because there's a number of hospitals, small hospitals, where orthopedic surgeons are employees of the hospital.

DR. CROSSON: Okay. We're going to proceed to the general discussion. We've got the summary slide up, so we have got kind of four questions there. We've also used up a fair amount of our time this morning, so Brian is going to start off. But I would ask you, those of you who want to comment, to kind of run through those quickly, "I

support this, I support that," so we can get a sense of where we want to go next. Brian?

DR. DeBUSK: Well, first of all, thank you for your very well written report. I really like the tone of the entire chapter, which worked with the underlying premise that PODs need to be at least minimized, if not eliminated. I think you put it best in the presentation when you referred to them as a "challenge in purchasing effectively" to hospitals. I think between the unit price issues and the inductive effects of these arrangements, I think even a well-intentioned POD is going to eventually take a turn. I mean, I think this model is just too susceptible to contamination and ultimately to a fix that we don't want to see in the program.

I think you have a very novel definition of a POD, by the way. I hope we can stick with that definition throughout this process. I like the broad approach as opposed to trying to narrowly define them.

And I also think that your approach on using Stark is an excellent, excellent approach. I don't know that you could go wrong with either one of those options. I am inclined to go the DHS option. I am sort of mulling

through why we couldn't do both just in case, because these PODs do tend to morph. And it may not hurt to have a belt-and-suspenders approach here because whatever they're doing today, they're going to be doing differently six months from now, especially if we start making changes in the rules.

I also really applaud the fact that you incorporated gainsharing into the chapter. I think we need to reiterate previous Commission positions for sure there, because I think being silent on what we could positively would not be as effective in trying to combine those two.

The other thing, I do like the fact that you set aside some thought on how to deal with innovators and the innovator physicians. I think that we could develop that out a little bit more, for example, maybe looking at the age of the 510(k)s on the devices that are involved. You know, if you're distributing a device that's 510(k) that's ten years old, you're probably not innovating anything. So I think we could probably develop some inclusive and some exclusive criteria for what would put you back into the POD category and not necessarily as an innovator physician company.

The other issue that was sort of in and out of our discussion was this idea that ultimately if we're going to use Stark, it's the hospital that's on the hook. I mean, it's sort of the fruit of the poison tree, that it would ultimately deny their claim. When I first read through that, I was thinking, you know, that could be potentially problematic, but I'm also encouraged by that because -- and, Warner and Sue, feel welcome to throw something at me if I say this, but if we give them the right tools, what they might have is an excellent excuse to be able to go back to that spine surgeon who's bringing 300 fusions a year to your hospital and say we just can't do that anymore because the rules told me so. So I'm hoping what we're giving you is a convenient tool to combat PODs through better regulation and not being too disruptive to day-to-day hospital operation. But please disagree with me if you want to.

The other issue or the final issue for me is when we talk about this, I noticed several questions here in the Q&A about, well, are we shifting procedures, or are we adding procedures? How do we measure inductive effects? This underscores the need to do UDI information on claims

forms because if we had UDI in claims, we could look for material shifts or displacement, because we would have the provider's number, we'd have the UDI, so we could watch these devices move and look for migration and trends. So that's my standard plug for UDI in claims. I hope we do it.

Thank you.

DR. CROSSON: Okay. We're going to have a discussion now, again, referencing what's on the table. Amy.

MS. BRICKER: You know, I think based on what's been presented, the whole concept just smells bad, you know? So I am absolutely in favor of reform. I agree with Brian, I would like to understand coupling the two, what downside there would be to that. So if you could educate me at some point on thoughts around coupling the two, I would be in favor of that.

I agree with the point Rita made around I'm not worried about innovation. If you've created the next best thing, everyone's going to use it. So, you know, I don't know that that's -- it should stand on its merits versus, you know, the structure that's -- or loophole that's been

created.

I'm certainly in support of reporting Open Payments, if, in fact, you have invented the next best thing, disclosing that to your patient population, and being quite transparent about that, in support of that.

DR. CROSSON: Rita.

DR. REDBERG: I also want to compliment you. It was an excellent chapter, and I agree with the statements of Brian and Amy. I mean, there's clearly a problem here. I honestly am not seeing any advantages to physician-owned distributorships. I'll read AdvaMed's letter that was in the references there. It states that the PODs are created primarily to allow physicians to enter the supply chain in order for them to profit from selling profits to hospitals at which they treat their own patients. And I can that -- I mean, but introducing PODs seems to result in higher prices, increased volume of surgeries, and these are -- let's get to the basic point. These aren't surgeries that are necessarily ones that our beneficiaries are benefitting from. I mean, the use of -- and the examples in spinal surgery and the increased volumes that we saw in spinal surgery for PODs, and, you know, spinal surgery is one of

those surgical techniques that has never been shown to be better than conservative treatment. So, you know, there's no randomized trial showing better outcomes. There's data showing clearly worse outcomes, and the more you do, the harder the outcomes are, and I see that every week in my practice.

So we have, you know, something that's encouraging hospitals and doctors and physician owners to do more expensive, unnecessary surgeries that cost a lot and are not good for patients. So it seems to me there's very little in favor of PODs, nothing in favor of PODs.

Just to the point about Open Payments, I wonder if there's any directory of PODs, because it seems if they're not reporting, it's probably -- you know, maybe we don't know because nobody knows about them. So it would seem like some more light should be shed in listings unless we were going to actually be eliminating PODs.

And the last thing I'll say about innovation, besides what I've already said, because the examples you gave, Brian, were for 510(k)s. But to me, if you're a 510(k), you've already said you're not innovative because to get on the market as a 510(k) you have to say you're

substantially equivalent to something already on the market, so then it's hard to argue you're also innovative.

DR. CROSSON: Alice.

DR. COOMBS: This one's like apple pie. I support all of them.

DR. CROSSON: Wait a minute. Do you like apple pie or you don't like apple pie?

[Laughter.]

DR. HOADLEY: I could say it's like chocolate.

No, I think really just echoing the comments I've been hearing. These are not arrangements that seem to serve a whole lot of positive purpose. I mean, I think the Open Payments proposal in the last one is kind of like the lowest-hanging fruit of that. We ought to at the very least do that. But we should really go beyond it. And I don't see a lot of need to do very much on this exceptions area. It seems like, you know, maybe you don't need exceptions at all, or maybe it should be a pretty high bar.

DR. CROSSON: Okay. Warner.

MR. THOMAS: I just think that we should eliminate PODs. I don't think that they add value. I think hospitals that use them are somewhat forced to. I

think systems of any materiality in size don't use them, such as ourselves and many others our size. I think your comment that it's usually smaller or mid-sized organizations that somewhat get forced to use them. I think if there's someone that creates a new device or what-not, they should go the route that every other organization goes to sell the device, whether it goes through a GPO or some other model. But I just don't think PODs add value to our system.

DR. CROSSON: Clearly, four-letter acronyms ending in "S" are at great risk today.

[Laughter.]

DR. CROSSON: Bruce.

MR. PYENSON: Yeah, a couple of things. I'd like to echo Brian's support for UDI, and if there's a way to introduce that into this discussion, I would support that.

Given the shift to hospital outpatient services and ambulatory surgery, although am surg centers may be owned by physicians so there's a shift from one -- the incentive would be to buy cost effectively, that may not be the case with hospital-owned outpatient surgery. So I think an important concept would be to extend this beyond

the hospital inpatient setting.

And, likewise, extending the concepts we're talking about to Medicare Advantage might be important because in some communities, of course, Medicare Advantage dominates, and it could be the case that PODs could survive in that environment, and that's an issue for Medicare perhaps. So perhaps we could get clarification on that.

Finally, I'd like to disagree with Rita a little bit about 510(k). In this context, I agree it's probably not associated with innovation, but we've actually seen in the device side much more willingness for things that are the device equivalent to biosimilars under 510(k) than we've had to biosimilars through a much more rigorous process. So I think the advantages of 510(k) could include innovation, could include lower price on a substantially similar basis. So I think 510(k) is a good thing for innovation, probably not in this context.

DR. REDBERG: Do you disagree that the criteria for 510(k) is substantially equivalent to something already on the market?

MR. PYENSON: Yeah, and that's a good thing.

DR. REDBERG: You agree with that or you disagree

that that's the criteria?

MR. PYENSON: Yes, that's the criteria.

DR. CROSSON: Kathy.

MS. BUTO: But I think he was -- I think you were then making the leap to sort of generic drugs and the fact that 510(k)s could exert some competitive pressure against whatever other devices are out there of the same type?

MR. PYENSON: Yes.

MS. BUTO: And I'm not sure that's -- I'd have to see the data on that. I don't know that that's the case.

I just wanted to support the recommendations, Brian, or the direction you're going in. I think the Stark changes are easier to pull off than a legislative change just because it's very hard to get legislative change in this area.

The thing I think would be important for us to look at is whether, since what we're talking about with the "per unit of service" rule and taking away that exemption, is then these arrangements would fall under compensation arrangements and, therefore, be largely prohibited. Do we feel confident that compensation arrangements are really policed or enforced? And if we don't, we might want to

look at making recommendations in that area. I just don't know. These Stark rules have been very difficult from the beginning to actually enforce, detect, you know, et cetera. And maybe they're just a deterrent factor.

But I agree with everyone else who has spoken. I don't think there's any value, savings to the Medicare program, to beneficiaries, or hospitals from the role that PODs are playing right now in Medicare.

DR. CROSSON: David.

DR. NERENZ: I'd just say I support the general direction here. Not much new to add. I just would echo the point others made. I'm not worried about the possible dampening effects on innovation. There are plenty of other non-financial rewards for innovation. The history of medicine is loaded with wonderful things that have come out by people who then didn't form PODs to sell them. Pick any example. There are hundreds of them. And there are financial pathways that don't involve PODs. So I don't worry about the innovation problem here at all.

DR. CROSSON: Pat.

MS. WANG: So I agree with the general consensus here. The only thing that I would add is not only don't I

see these as having redeeming value; I see them as actually being harmful to the extent that they result in unnecessary procedures and provide insidious incentives to move in that direction.

So I think that it's a more urgent issue for Medicare to take a strong stand because the incentives are just wrong, and at best, it adds no value. But at worst, it sounds like it might be resulting in unnecessary care, which is a really bad thing. So Medicare should make it a priority to do something.

DR. CROSSON: Craig.

DR. SAMITT: I'm in agreement with everyone else, but I wanted to be explicit because we talked about these four things. I would very much be in favor of the first two, but I'm against the second two. So the granting of exceptions for the benefit of -- or encouraging device innovation, I would not agree with. I think we need to understand the publicly traded company element here. But if the principle here is that physician decisions should be based on clinical considerations not financial ones, then I think we violate that if we grant the exceptions as noted in the second two.

DR. CROSSON: And you're also opposed to the reporting under the Open Payments --

DR. SAMITT: No.

DR. CROSSON: Just the second two -- the two bullets and the third --

DR. SAMITT: I meant --

DR. MILLER: The next to the last block.

DR. SAMITT: Yeah, the next to the last block.

DR. CROSSON: Got it.

DR. SAMITT: Sorry about that.

DR. MILLER: No problem.

DR. CROSSON: Okay. Anybody else?

[No response.]

DR. CROSSON: So thank you very much. It was a great presentation, a great discussion. I'm trying to sort out where we go here, and I want to -- there's two ways we could do this. We could kind of conclude that there's general agreement here. Now, we have a couple of exceptions to that. Bruce, you had some information you wanted to see, and, Craig, you disagree with one of the four bullet points.

MR. PYENSON: I'm not sure mine was information.

It was more expansion.

DR. CROSSON: Well, okay. But that expansion is information. So --

DR. SAMITT: I think, Jay, the only other thing that I would say is I don't know if others also disagree with the third major bullet, but I got the sense that most people did not agree with that as well.

DR. MILLER: Yeah, that --

DR. CROSSON: Okay. All right. So maybe I didn't hear all the conversation. So I'm kind of thinking like we're almost like 98 percent here, and to come back again, you know, with formal recommendations, go through this all over again, given the priorities that we have, is probably not the best use of time. So what I'm going to suggest is that, with the exception of the third bullet point -- and I'm sorry I missed more than a few comments on that -- one comment -- that we go ahead and propose that we construct a chapter with the exception of that third bullet point, and then that goes forward without a further meeting, without formal recommendations, that we vote on at two meetings. That chapter, as all other chapters, will then be available for everybody to review. So if we've

missed something or, you know, you feel something should be stated differently, we'll have that opportunity. And I'm seeing kind of a bobblehead of consensus on that. Bruce, we can probably take your information offline and provide that information for you.

Is that generally acceptable?

COMMISSIONERS: Yes.

[Nodding of heads in the affirmative.]

DR. MILLER: And I'm good with all that. I just want to restate the Craig bullet point. What I heard through all of this -- and we put this in because this is, when we've discussed this outside, you know, these are the things that people said: "Oh, but wait a minute, what about the innovator?" There was a very strong consensus that people did not feel that that was a huge factor, and so those things created to potentially accommodate it would fall away, and you'd end up with the gainsharing, the two possible Stark rule approaches, legislative and regulatory, and the Open Payments reporting. That's where we'd be.

DR. GINSBURG: Yeah, and, also, we would want to make sure to add why we don't consider innovation an issue that has to be addressed.

DR. MILLER: We will summarize your comments, which were quite clear.

[Laughter.]

DR. MILLER: Yes, you're right --

MS. BUTO: Mark, can you clarify, though, the exception for large publicly traded companies? I took that to mean that if a physician owned stock, that's not what we're talking about. Is that not what that means? Brian, maybe you could clarify.

MR. O'DONNELL: Yeah, I can flesh that out when I write it up.

DR. CROSSON: Are we good?

DR. MILLER: Everybody good?

DR. CROSSON: Okay. Thanks very much.

We now have time for a public comment session. If there are any members of the audience who wish to make a comment, please come forward to the microphone.

[Pause.]

DR. CROSSON: I see one. I am going to ask you to state your name and any organizational affiliation, and you will have two minutes to make your comment. When this light comes back on, the two minutes has expired. Thanks

very much.

MS. GAINER: Thank you. I'm Kara Gainer, and I'm here on behalf of the American Physical Therapy Association. Our association represents more than 100,000 member physical therapists, physical therapist assistants, and students of physical therapy.

We thank the Commission for evaluating the topic of physician-owned distributorships and potential policies to address the inherent conflict of interest presented by physician-owned distributorships. However, we would recommend that MedPAC also examine the physician-owned physical therapy services and the in-office ancillary service exception to the physician self-referral law.

The in-office ancillary services exception is intended to improve coordination of care and promote patient convenience by allowing physicians to self-refer for designated health services integral to their care furnished in their group practices. The fact is the use of this exception goes well beyond its original intent specifically in regards to physical therapy.

While including physical therapy in the exception list was intended to offer convenience to patients, it's

actually incredibly rare for a patient to receive physical therapy services during a regularly scheduled physician visit.

Both the Commission and CMS have previously found that the in-office ancillary services exception has substantially diluted the self-referral law and its policy objectives, allowing Medicare providers to avoid the law's prohibitions by structuring arrangements meeting the technical requirements for physical therapy services while violating the true intent of this exception.

We believe the promulgation of laws and that the unintended abuses under the in-office ancillary services exception are essential to the success of future payment models. As such, we strongly recommend that MedPAC develop and offer policies to Congress that limit the scope of the in-office ancillary services exception and remove physical therapy from the list of exceptions.

Thank you.

DR. CROSSON: Seeing no one else at the microphone, we are adjourned until 1:15.

[Whereupon, at 12:22 p.m., the meeting was recessed, to reconvene at 1:15 p.m., this same day.]

AFTERNOON SESSION

[1:20 p.m.]

DR. CROSSON: Okay. Maybe we can get started.

We have Carol back with Dana, and we're going to continue our ongoing on post-acute care. And who is going to start? Carol, you have the floor.

DR. CARTER: Okay. Good afternoon, everybody.

This afternoon, we're going to talk about the next block of our work on the unified payment system for post-acute care. As a reminder and for those of you who are new to the topic, Medicare spending on post-acute care totaled $60 billion in 2015. The IMPACT Act of 2014 addressed some of the longstanding concerns with the services and payments in these settings and required studies of a unified payment system to span the four PAC settings.

In the Commission's mandated report in 2016 and its follow-on chapter this past June, we analyzed various design features and estimated the impacts of a unified payment system using 8.9 million PAC stays from 2013 and looked carefully at how 40 different patient groups would fare under a unified payment system.

Based on its analysis, the Commission recommended to the Congress that the PAC PPS be implemented beginning in 2021 with a three-year transition. This timetable reflects the Commission's belief that it is important to begin the redistribution of payments that would result from such a payment system so that providers would have less incentive to prefer to treat certain conditions over others, yet give providers some time to adjust their costs and practices to the new payment system.

Given the high level of payments relative to the cost of stays, the recommendation includes lowering the aggregate level of payments by 5 percent, absent any prior reductions. And, concurrently, the Secretary should begin to align regulatory requirements across the PAC settings. In addition, the Secretary should have the authority to periodically revise and rebase payments to keep payments aligned with the cost of care.

You may wonder why we're continuing to work on the PAC PPS, and there are a couple of reasons to do so.

[Laughter.]

DR. CARTER: Right? You were all thinking it. I thought we were done with her.

[Laughter.]

DR. CARTER: First, we want to keep this issue front and center on the minds of the Congress, and you'll recall that the IMPACT Act requires studies but actually doesn't require that a system be implemented. Second, because a unified system is a complex undertaking, there are many issues to work through. And, finally, we expect industry opposition to the changes, so it will fall to the Commission to nudge this along.

Over the summer we began work on two more implementation issues. First, we'll consider the issue of sequential stays in post-acute care -- that is, when beneficiaries transition from one PAC setting to another or when they are treated in place by one provider. These sequential stays may present challenges to accurate payment.

Second, we'll consider aligning regulatory requirements when a PAC PPS is implemented. Under a unified payment system, payments will be based on the characteristics of the patient, not the setting, so aligning regulatory requirements makes sense.

We raised both of these issues in the 2016

report, and I'll start with sequential stays, and then Dana will talk about regulatory requirements. We plan on including this information in a chapter in the June '18 report.

The Commission's initial work on a PAC PPS considered each stay separately, yet many stays are linked, with patients transitioning from one setting or provider to another during their course of post-acute care. Currently, patients most often transition from higher-cost settings to lower-cost settings, as their care needs shift from requiring more intensive services to needing less intensive strengthening and managing of chronic conditions. Infrequently, beneficiaries transfer from less to more intensive settings.

We've focused on sequential PAC stays because we want to make sure that the new payment system doesn't inadvertently shortchange or influence the care that beneficiaries receive due to the sequence of their post-acute care. Over the course of sequential PAC stays, the average cost of stays is likely to decline as patient care needs change. While the average cost of stays also reflects the mix of settings, a PAC PPS would not consider

this in establishing payments. Rather, payments will be based on patient and stay characteristics.

This chart illustrates the issue of establishing accurate payments for sequential PAC stays. Here we compare two identical beneficiaries, but one has sequential PAC stays -- that's in the first row -- and one has a single PAC stay -- and that's the second row.

In the PAC PPS work we've done to date, we based payments on the average cost of the three stays and predicted costs based on patient and stay characteristics. But it's likely that the costs of these stays are different. In a sequence of multiple stays, Stay B may have lower costs than Stay A because the beneficiary was already treated during Stay A, and the patient probably improved or stabilized. With payments based on patient and stay characteristics, the predictors may not adequately pick up changes in the patient between the earlier and later stay.

Now let's compare Stays A and C. Both are first PAC stays, but Stay A is the first of multiple stays while Stay C is a first and only. The first and only stay may have higher costs because the provider cannot shift some of

the costs of care onto a second provider. And, again, we may not have -- with the patient having identical stay and patient characteristics, without an indicator of the sequence of stays, we may establish inaccurate payments for these scenarios.

We want payments to neither encourage nor discourage second PAC use. In this work, we'll be exploring the systematic differences in costs depending on the sequence of stays. It's possible, for example, that an adjustment that lowers payments for later stays would improve the accuracy of payments, similar to the adjuster in the home health PPS for later episodes of care.

There are a few reasons why we care about the costs of sequential PAC stays. First, if payments are not accurate, providers may base their care on financial reasons rather than focus on what is best for the beneficiary, which we know goes on in the current settings. For example, if payments for the first stay are low relative to their costs, providers would have an incentive to refer beneficiaries to subsequent care even though they had the capacity to treat the patient and avoid the transfer. Not only would unnecessary referrals expose

beneficiaries to the risks associated with care transitions, but they would raise program spending.

Now let's turn our attention to providers that opt to treat in place. Under a PAC PPS, distinctions between settings will blur and a provider may opt to "treat in place" beneficiaries with evolving care needs.

Currently, when a beneficiary transitions between providers, there are two stays, each with its own admission and discharge, and Medicare makes two payments. I have identified those in orange. When a provider opts to treat in place, there would be one admission, one discharge, one stay, and one payment. That's outlined in white. For providers that treat in place, we'll look at ways to help ensure that payments are accurate. For example, we could consider ways to create two stays so these providers are not disadvantaged compared to those that refer beneficiaries to another provider. If we think there is a benefit to treating in place, we need to make sure that the design does not discourage it. At the same time, we want to make sure that treating is place doesn't result in unnecessary volume of second PAC stays.

Over the coming year, we plan to examine the cost

of stays based on their timing. We'll look at the costs of initial stays versus later stays, and among initial stays, those with and without a subsequent PAC stay. Depending on our findings, we will consider policies to adjust payments so that they more accurately reflect the cost of care.

We will also evaluate alternative ways to delineate stays when a beneficiary is treated in place and consider how to discourage unnecessary second PAC use.

Now Dana will talk about regulatory requirements.

MS. KELLEY: The Commission has previously discussed the need for regulatory reform under a unified PAC PPS. In recent reports to Congress, MedPAC outlined the broad strokes of a two-part strategy that would align regulatory requirements across PAC settings. In the near term, policymakers could waive or modify certain setting-specific requirements. Over the longer term, the Secretary could develop a common core set of requirements for all PAC providers. Additional requirements could be developed for providers that treat patients requiring specialized resources.

Commissioners may want to provide more detailed guidance to Congress and the Secretary on regulatory reform

under a PAC PPS. To aid your discussions, staff have worked with an outside contractor to compile and review conditions and requirements of participation and payment for PAC providers. In your mailing material, we've provided some detailed information about the differences in regulatory requirements across settings. For today, we've attempted to categorize the requirements to help you consider their intent and effect, and the potential consequences of changing or removing those requirements.

First, let me review why regulatory reform is so important. Currently, Medicare has different regulatory requirements for the four different PAC settings, which both reflect and influence the intensity of care provided. This is important under the current payment systems, where different payments are made to different PAC settings. The Medicare program has a fiduciary responsibility to ensure that higher payments in some PPSs are made only to providers that furnish higher-intensity services to more complex patients.

Under a unified PAC PPS, payments will be based on the characteristics and clinical needs of the patient rather than on the setting in which care is provided. In

this scenario, it would be unreasonable for Medicare to maintain very different regulatory requirements, with different associated costs, since providers caring for similar patients will receive the same level of payments.

Changing regulatory requirements will give high-cost PAC settings the flexibility to lower their costs in line with those of other providers and settings that treat similar mixes of patients. And a more flexible structure could give providers the option to consolidate separate PAC operations into a single, larger institutional PAC unit to achieve greater economies of scale.

So let's consider the types of regulations PAC providers currently face. We've identified important regulations that differ across the PAC settings and organized them into the framework you see here, though there is some overlap in the categories. As you can see in the left-hand column, some requirements are intended to distinguish levels of care. These include the 25-day average length of stay requirement for LTCHs and the 60 percent rule for IRFs. These regulations discourage the admission of patients with relatively low-intensity needs to these higher-payment settings.

Other regulations limit coverage of services, which acts as a check on volume. We've listed some of these in the middle column. Note that some of these coverage rules also help distinguish levels of post-acute care. For example, Medicare's coverage criteria require that beneficiaries admitted to IRFs must require therapy in at least two modalities, and they must require and be expected to participate in and benefit from roughly three hours of therapy a day at least five days a week. Medicare has determined that beneficiaries who need less therapy, or who cannot tolerate that much therapy, are not appropriate for admission to IRFs.

Other coverage rules limit volume by attempting to distinguish between PAC and long-term care. For example, Medicare covers SNF care only after a medically necessary inpatient hospital stay of at least three days. This requirement acts as a barrier to prevent nursing homes from recertifying long-stay residents as Part A-covered SNF stays to receive higher Medicare SNF payments.

Most regulations are designed to ensure adequate and appropriate of care. These regulations generally cover the five domains listed in the right-hand column, including

services and staffing, quality and safety, and patients' rights.

Regulations that are aimed at ensuring appropriate care differ widely across the PAC settings. For example, the service and staffing requirements for LTCHs and IRFs generally are more stringent and costly to meet than those for SNFs and home health agencies. LTCHs and IRFs must meet all Medicare conditions of participation for acute-care hospitals. The regulations require that physicians be more integral to the provision of services in these facilities compared with SNFs and home health agencies. Requirements for nursing staff in LTCHs and IRFs are also more stringent than those in the other two settings.

Some of the differences in the regulatory requirements that ensure appropriate care can be attributed to the fact that LTCHs, IRFs, and SNFs are facilities in which admitted beneficiaries receive care and services around the clock, while home health agencies provide discrete services to patients in their homes on a part-time and intermittent basis. For example, while all four PAC settings are required to have an emergency preparedness

plan, only the facility-based settings are required to have provisions for subsistence needs for staff and patients, such as food, water, power, and waste disposal. Additional differences exist among the facility-based PAC providers, in large part because many SNFs are also long-term-care facilities where residents live.

There are also significant differences in Medicare's required assessment activities -- and the staff time needed to complete them. Patient assessment in SNFs and home health agencies generally requires more time than it does in IRFs, and especially in LTCHs, which have very minimal requirements.

When considering how to align regulations under a PAC PPS in the near term, the Commission might want to consider eliminating the 25-day average length of stay requirement for LTCHs and the IRF 60 percent rule, since we may no longer need to distinguish PAC providers by setting. The Commission might also consider whether and how to align the different coverage requirements. Here is where we note that not all requirements lend themselves to alignment. Presumably a homebound requirement, if maintained, would continue to apply only to beneficiaries receiving PAC at

home.

In the longer term, regulations designed to ensure appropriate care -- including staffing and services requirements -- will need to be better aligned across the PAC settings. This doesn't necessarily mean applying the least stringent requirements to all providers. It could mean, in some instances, more stringent requirements than is currently the case for some settings. And the Commission might want to consider whether special requirements for certain conditions are necessary. These might include prolonged ventilator dependence, intensive therapy, severe wounds, brain and spinal cord injury, or other conditions that require specialized care.

As we review current federal regulations, we will want to be cognizant of state requirements. As you know, in addition to federal regulatory requirements, PAC providers must meet licensure, certificate of need, or other regulations imposed by the states in which they are located. This will continue to be the case under a unified PAC PPS.

Some states have codified their own setting definitions, including distinctions between facilities that

provide primarily intensive rehabilitation services to patients with physical disabilities and those that provide skilled nursing and supportive care, with specific staffing requirements for each. Some states have mandated minimum staffing ratios, especially for nursing facilities.

Some states also have specific requirements for facilities that treat certain conditions. For example, New York has detailed requirements for facilities that offer comprehensive spinal cord injury programs and traumatic brain injury programs.

And, of course, many states have certificate of need laws that could affect the ease with which some providers can adapt to a unified PAC PPS.

So, in summary, we plan to continue to work on the PAC PPS, with attention to two important implementation issues: how to pay for sequential stays and how to align regulatory requirements. We plan to conduct this work over the coming months for inclusion in the June 2018 report. We welcome your comments on the planned analyses and any guidance on regulatory reform.

Now we'll turn the discussion over to you.

DR. CROSSON: Thank you, Carol, Dana.

We'll start with clarifying questions. David.

DR. GRABOWSKI: Thanks, Carol and Dana. That was a great presentation. When we've looked at sort of the sequencing of PAC events in our data and claims, we tend to see varying gaps, and so how do you define -- and this may sound like I'm being persnickety here, but how do you define "sequential" and whether it's direct in a day or is it five days, and kind of what are those windows? And I think that it's really going to matter here when we start to think about planned analyses and also ultimately payment policy, because, you know, how stringent or loose you make that rule is really important. Thanks.

DR. CARTER: Yes, so we are just starting to look at the data, and we have noticed the same thing. And so we are in the process of developing rules. Some of our rules are going to follow billing rules, so when LTCHs have an intervening hospital stay, and it depends on the length of it, there's one claim. So we will adopt that same rule. Where there are payment policies kind of in place about how to define when a new stay starts, we'll be using those.

For SNF, you know, because they bill by the day, you don't have that same -- there's nothing in payment

policy that would -- or billing requirements that would address that. So we are looking at sort of a minimum gap that we think is okay, like seven days or something like that. But we definitely have noticed the same thing.

We're also thinking that when there are intervening events, like going to the hospital, when does that trigger a second stay and when doesn't it? And if somebody goes home and then comes back, how do you think about that? Because that's an intervening event, and we're thinking about, well, if the person comes back to the same provider, is that different than when they go to a different provider? And the same with did they go to a different setting? So, absolutely, and we're sort of thinking about all of those things. In fact, I was just reviewing data yesterday on -- and then, of course, there are the things where you can't make heads or tails of the dates.

[Laughter.]

DR. CARTER: What to do with those. So, yes, exactly, we need to -- when we finalize those decision rules, we'll share them with you.

DR. CROSSON: Sue.

MS. THOMPSON: Yes, Dana and Carol, thank you so much, and it's great to have you back.

As you looked at the differences between IRFs and LTCHs and SNFs and home care, did you look at the existing assessment tools that are used, because they are different. I mean, in the hospital we do one kind of an assessment, and SNF – and you've obviously thought about this -- the Oasis and the MDSs, and they're not the same. Is there anything to learn from all of that or have you begun to think about how the assessment piece would fit in here?

MS. KELLEY: Well, CMS is required to begin standardizing some of the assessment instrument questions across the four settings, and that is happening. I think, in the short term, we will probably continue to have different assessment tools, with, you know, increasing numbers of cross-setting measures. But it is an issue.

Providers seem very attached to their own particular assessment tools, you know, so I think there's some tension there, a little bit, whereas it might seem reasonable to go one standard instrument. You know, that's not always, I think, universal.

MS. THOMPSON: Well, and a subset question around

assessment that's a little bit more in the weeds is the whole assessment of homebound status and the variation on the same day that two different organizations might assess the same patient, coming up with a different answers. There's just a lot there.

DR. CARTER: Well, the only thing I would add is certainly, as least through transition, you're going to need the current assessments because that's what drives payments. I mean, that's how payments are determined. And so you are going to need to keep all of the payment fields that are used off of the assessments during the transition.

DR. CROSSON: David.

DR. NERENZ: Thanks. Slide 5, please. Just a concept question. Is this meant to illustrate, like, if each one of these rows in the diagram is a patient, is the basic assumption that the patient who gets two stays is fundamentally different at the beginning, from the patient who needs just one stay, and if so, then the overall payment could just be big enough to cover both segments. Or is this meant to illustrate two people who are essentially the same at the beginning but one improves and one doesn't, so one needs a second stay, and then you maybe

do an independent assessment? What's -- how should we be thinking about this, in terms of patients and their up-front characteristics?

DR. CARTER: So these are meant to represent, at least now, how stays occur. And so these would be patients who look the same, in terms of the characteristics we are gathering.

DR. NERENZ: The second of my two then.

DR. CARTER: Right. But that's what we are concerned about, is whether the items that one might use to create a risk adjustment are sufficient to detect that there are actually differences. And so that's why we are thinking maybe we actually want a risk adjustment that considers whether you're first in line, second in line, whether somebody is before you or after you, in term of providing care, because we were suspecting that the cost of these stays are different, even though when we looked at the characteristics of the stays, they might look the same.

DR. CROSSON: Warner.

MR. THOMAS: Did you think about just looking at one stay, aggregating these to just one stay, and just looking at a -- instead of trying to think about cutting it

between different stays just having a global fee and that sort of thing? How would you think about that?

DR. CARTER: You mean are we thinking about episodes? That's sort of a joke.

[Laughter.]

DR. CARTER: We know that even with a bundled payment, you would need -- since at least, currently, those are driving off a fee-for-service chassis. And so the idea of getting the payments accurately reflecting the cost is important. This could be a stepping stone to that, and one might think about putting these together, but only thinking about post-acute care. I mean, we have heard over and over again how complicated bundles are to administer, and particularly the more services you include and the more providers, the more complicated they become.

So something like this, where you're just putting together post-acute care might be the baby step.

MR. THOMAS: And I was thinking about it more just in post-acute care versus a bundle across the acute care and, you know, the pro-fee side as well. I was thinking about just, you know, post-acutes, because it seems like it's going to be hard to, you know, bifurcate

these and to really look at what's the condition of the patient, you know, based on where they ought to be, versus letting the clinical situation drive that, and essentially having a global payment around certain diagnosis. Because, I mean, right now, as you've done previously, you know, different patients, or patients with a similar diagnosis end up different types of post-acute, versus just having a post-acute payment that's an aggregate. And if you're worried about, you know, people or providers, you know, trying to shorten length of stay or whatnot, you could have readmission penalties and things like that, which I think would maybe mitigate some of those challenges.

But I think the idea of having a global payment in post-acute, regardless of the type of entity that they're in, that a beneficiary is in, you know, to me just has more creativity. So I just wasn't sure how you were thinking about that.

DR. CARTER: Well, at least for now we are just thinking about, you know, the PAC PPS was supposed to be a fee-for-service construct, but the obvious next question is, is this -- why once you think about a bundled payment. And it's possible that certain types of conditions are much

more likely to have second or multiple PAC stays, in which case that might simplify, at least. You know, the Commission has gone on record before saying maybe not everything is appropriate for bundled, and so maybe looking at where multiple stays tend to concentrate, in terms of types of conditions, might be one way of saying, well, for these things maybe they make more sense. So we are just at the beginning of all of that.

MR. THOMAS: And I was thinking about fee for service as well. I was just thinking about, I mean, your sequential stay. It sounds like you're thinking about as those being two stays, and I guess what I'm thinking about is them being potentially one. I mean, so, I'm not necessarily talking about a bundle where you would either bundle it with the acute or bundle all post-acute together, because obviously there could be -- you know, you might have different stays versus them being sequential, like you have in --

DR. CARTER: And so, that's more like in place, where we are thinking about if somebody is treated in place but they seem to be transitioning from one phase to another, then we're thinking about, hmm, okay, so how do

you mimic sort of two stays.

DR. MILLER: I also just wanted to -- because I think we have had this conversation internally. So the first thing I want you to understand is we are aware of your thinking here, and remember, at the end of our report, we said, "You know, this is a stay-based system but we need to start thinking about episodes." So don't think that your comments are -- you know, like we're not -- we don't get it. We definitely get it.

The way I think about it is if the Congress or CMS or whoever the right actor is ultimately chooses to keep a stay-based one, these rules and understanding have to be ticked through and understood and rules have to be made. And if you want to move to an episode system, you probably need to tick through this anyway and sort of figure out what you're looking at and then say, "Oh, I think I can start drawing circles here and making episodes there." That's the way I think about it.

So it is not off the table. It is, I see, at the end of this conversation, us potentially talking about both strategies, if we get that far down the road and all the data behaves and all the rest of it.

DR. CROSSON: Kathy.

MS. BUTO: I wondered how big a deal you think it is that different states have different requirements for these different providers. What I guess I'm thinking is, what is the experience of states eventually coming around to modifying their own standards to conform to Medicare standards? I think it's pretty good but I just wondered if you had looked at that, because I know that at least for things like nurse practitioner, physician assistant, and CRNA licensing requirements, which are, of course, at the person level, not at the institutional provider level, that eventually states seem to accommodate Medicare's changes in that area. So I don't know if you looked into that at all.

MS. KELLEY: So I think you're right that, in large part, states do tend to sort of go towards what Medicare has regulated. There are some that stand apart in having more stringent regulation.

I think our thinking is that the situation ultimately wouldn't be much different than it is today. The regulations might be different and there would be some states that perhaps would have some more stringent requirements, as they do today, but that sort of -- it

would -- the states would tend to evolve towards what Medicare has done.

DR. CROSSON: Jack.

DR. HOADLEY: So I had essentially the same question Warner did, but I had one thought in trying to think of it that may relate to it, which is, in looking at the data I wonder if there is value in separating out situations where the sequential stays were within the same health system or the same ownership in some way versus ones where that differed. You know, you could think about that may or may not matter. There may or may not be much there. But it seemed like maybe that would offer some ability to think about that.

The other thought, which picks off of what David was asking, and Davis second scenario, which you said was what you had in mind here, which is these patients start out the same and then their care evolves in different ways. And David used the sort of scenario that, you know, one responds and one doesn't. But there might also be scenarios here where they start out the same, they actually respond kind of the same, but because of other reasons -- patient choice, gaming the system, you know, who knows, or

just a realization along the way that maybe the care is needed -- that there was not really a change in their physical status but just a choice to go to a second.

And I don't know whether, again, that's something you could play out of the data, given the limitations of what you've got. But it might be something, at least a scenario to think about those two different situations and whether that's possible to distinguish those. And then, of course, if you can distinguish them, see how it plays out differently.

DR. CROSSON: Questions? Paul.

DR. GINSBURG: Yeah. On Slide 11, the regulations that distinguish levels of care, you pointed to one for, you know, LTCH and one for IRF. And these regulations were to separate them from acute hospitals. Won't that issue still exist, even if you merge all the post-acute facilities into one?

MS. KELLEY: That will depend. If we are going to continue to require IRFs and LTCHs to meet the standards for acute care hospitals, then, yes, you would think there would still need to be that differentiation. If we are not going to do that, then presumably that would relieve that

problem.

DR. MILLER: And there again, don't think that that conversation hasn't been internal back and forth. And so far I'm bingo. I think I'm doing pretty well. But that question has been implicated internally and we are going around on that.

DR. CROSSON: But help me understand because I thought the direction we were going was that the regulations, particularly this type of regulation, in terms of what capabilities an entity had, would be related to the patient, as opposed to the nature of the entity, right? So if we didn't do that, then what we would now call an LTCH, if they did not meet the standards for an acute care hospital, they wouldn’t be able to take care of long-term therapy patients, right? What am I missing here?

MS. KELLEY: So currently a long-term care hospital is simply a hospital that meets the regulations of an acute care hospital and has an average length of stay of greater than 25 days for its Medicare patients. Now we have, for select Medicare patients, because we have the whole site-neutral thing, but just to keep it simple.

The services that they provide are sometimes

provided by acute care hospitals but they are also sometimes provided by SNFs. So the question of whether or not the services that they furnish require a hospital level of care I think is a question to be discussed, and if the services that they provide do require that, then perhaps that's about the services and not about the facility in which they are taking place.

But I really think this is a fundamental question about how you perceive LTCHs and IRFs, but probably especially LTCHs. Do you think of them as PAC providers or not?

DR. MILLER: And then, just to complicate things further, you also have this thought drifting around that in legislation the Congress started to talk about how to pay for, you know, critical care.

MS. KELLEY: That was the part I didn't want to complicate it with.

DR. MILLER: Okay.

MS. KELLEY: But, yes, that's right. So Congress has -- based on, to be fair, work that we did, Congress has started to define -- has defined sort of a CCI patient, a chronically critically ill patient. We recommended that

that patient be defined as one who has had a previous hospital stay with an ICU stay of eight or more days. Congress implemented a law that has the number of ICU days at three.

But those now currently are the patients that are eligible for higher LTCH payments and other patients -- and also patients who have received prolonged ventilator services in the LTCH. Other patients admitted to the LTCH are paid on a rate that is similar to the IPPS rate for a similar patient.

So, you know, there's --

DR. MILLER: Yeah, I'm sorry, and I didn't meant to take us quite down that deep, but that is the backdrop. More of the philosophical question is that you could make a decision and say, actually, you know, the PAC is not going to -- the PAC -- the unified PAC is not going to encompass LTCH. LTCH is going to be thought more of as long as the person meets a CCI type of definition as something that's more like a hospital. And you can almost philosophically say, should PAC be in this unified PPS or should this small sliver of things --

DR. CROSSON: LTCHs.

DR. MILLER: -- sorry, I'm sorry -- LTCH be part of this unified PAC or should it be sliced off and thought of as more of this CCI hospital type of thing. And both of those thoughts are floating around in legislation, which is why this is a bit complex. That was the thinking process.

DR. CROSSON: Yeah. Okay. I think I see Alice.

DR. COOMBS: Yeah, so one of the things -- thank you very much. I'm always excited about this chapter. One of the things I was thinking about, as we talk about the regulatory changes that are necessary, it's possible that as we have this transition to a uniform PAC that some LTCHs, the volume of their CCI might go down to such a critical level that they may not have the infrastructure to continue to support what they had traditionally been -- or say, for instance, you do get regulatory relief in terms of some of the overhead, and some of the inputs that they have to have goes down considerably. They may think it is more profitable to go another route. So it's possible that, say, for instance, you have an LTCH that normally takes care of, you know, wound vent and ESRD, and they were formerly like an 18 percent kind of range with those kind of complex patients, and they go down to 2 to 3 percent.

They may want to reconsider.

And you mentioned something in the paper about transitioning from one type of entity to another type of entity. Have you heard much about that from the industry, I mean, in terms of reaching that critical level where you don't -- and there's two things at work here. One is the probability and the other is the skill sets that are necessary has a lot to do with the volume of how many of those type of patients that come through your institution, because the nursing actually doesn't get that kind of exposure.

MS. KELLEY: So I think that's a very good point and I think also relevant to this point is the fact that beginning in fiscal year 2020, LTCHs are required to have -- in order to continue to be an LTCH they will need to have 50 percent of their patients be CCI patients, as currently defined. So that may also be sort of a tipping point for some providers in determining, you know, what kind of care they are going to be providing.

DR. COOMBS: That being said, what about the 25 percent rule, in terms of just thinking about some of the geographic concerns, where an LTCH cannot receive more than

25 percent of their patients from one single institution?

MS. KELLEY: So I'm going to ask Stephanie to talk about this. The 25 percent rule is now her area of expertise.

MS. CAMERON: So currently the 25 percent rule is on hold in terms of its implementation for at least another year. In CMS' last rule that they put out for fiscal year 2018, they will not be implementing this policy. And it's not clear what they're going to do in the future.

The 25 percent rule is something that CMS does have discretion over, so if they decide to not implement it indefinitely, that is a possibility.

DR. COOMBS: Thank you very much [off microphone].

MS. CAMERON: You're welcome.

DR. CROSSON: Questions coming up this way? Brian.

DR. DeBUSK: I had two questions, both related to sequential stays. If you look at the $60 billion spend, do we have a rough estimate of how much of that goes toward stays that have two or more stages? I mean, sequential stays, is it $5 billion of the $60 billion, or is it $25

billion of the $60 billion?

DR. CARTER: I think it's about half.

DR. DeBUSK: Oh, wow.

DR. CARTER: But we actually haven't looked -- that's just our estimates from other analysis, not with this data set with this exact question in mind.

DR. DeBUSK: Okay.

DR. CARTER: But looking at discharge destination from IRFs or from SNFs or home -- how many -- you know, almost half of home health stays, and that's a bulk of this business, are multiple home health episodes. So, yeah.

DR. DeBUSK: So that gives up my hope that there's some way to -- that it wasn't material.

[Laughter.]

DR. DeBUSK: Then you have that 50's probably material.

So if you look at that, say, almost half, would you at least see certain patterns where maybe we could -- and this builds on Warner's comment earlier. Is there the potential there to at least carve out, say, 25 different patterns as almost like super PPS bundles and almost treat them to try to get them back into the model in their

entirety? This sequential stay thing worries me a little bit, and that's why I was wondering, if there are some -- do you have a feel for how many correlations there are or like patterns in sequential stays?

DR. CARTER: I don't. We honestly just aren't quite that far. But it's the first thing we'll be looking at, is how frequent are they and do they tend to be for certain conditions. I mean, we know most, almost all of them -- maybe, I would guess, less than 1 percent -- are from less intensive to more intensive. So they're all going towards lower intensity. But we haven't looked at the pattern, so I can't --

DR. DeBUSK: So there is hope that if we see a patient that has a certain, say, SNF profile, we know they're going to get home health. Or if they have a certain IRF profile, we know they're going to get home health, which at least keeps the door open for a super bundle. Okay. Thank you.

DR. CROSSON: Okay. Seeing no more questions, let's put up the last slide, number 17. So, again, we're looking for comments on the analysis as well as more discussion, if you have it, on pros and cons of changing

the regulatory environment. And, David, you're going to start out.

DR. GRABOWSKI: Great, thanks. Once again you made a very complicated topic very clear, so thanks again for your presentation and chapter.

The unified PAC payment system predates my time on the Commission, but I'll start by saying I'm very supportive of it. The current system with four very different PAC payment models creates incredible distortions and incredible inefficiencies. So this is a real step in the right direction.

Of course, it comes with great complexity, and two of the real complex parts of this are: One, how do we deal sequential stays? And, two, how do we deal with all these regulations?

As Jay just said, you want some guidance on the planned analyses. I was wondering if you could just go to Slide 8 here where you have your plan analyses.

I think this is a great start, and I think what you propose is very reasonable. I would encourage you not just as a first comment to look at cost but also to look at outcomes. I think you heard that in a lot of the questions

here, the tone. Are these sequential stays good? Are they bad? We don't know. And I think in order to begin to understand that, we don't just want to know the timing of cost; we also want to know outcomes; and not just outcomes in that post-acute care setting, but also outcomes, readmissions out over time.

I'd also want to know the conditions. What are the hospital discharge -- are they strokes? Are they hip fractures? What's leading to these kind of sequential stays? Who are these individuals? Are they duals? Are these concentrated in particular markets or states? Urban-rural, for example? And who are the providers that are involved? Are they for-profit? Are they nonprofit? And one issue that I've touched on, I believe, with my research are joint ownership issues, and I'd want to know if there's any kind of referrals across entities with a common ownership stake. So those are some areas where I think the analyses could be expanded.

On Slide 5, you really raise what I think is the most challenging issue in your question there on the bottom. How do we set up a system here where we won't encourage these sequential stays? I thought, Brian, you

were very much pushing in the right direction. How prevalent are these? And they are very prevalent. And, you know, I think Warner came up with a great solution to bundle this. If that's not an option, can we keep this in a fee-for-service model? If we do, then I think putting up some guardrails is really important. And I don't know if those are demand side guardrails like cost sharing for sequential stays or if they're supply side, paying differently for conditions, only allowing sequential stays -- or if they're quite valuable, if that's what the data shows, then we should encourage, you know, this kind of model.

I would most encourage a bundled type model, but if we're going to go to a fee-for-service type approach, then thinking about the demand and supply side models to potentially hold this in check is really important.

Shifting gears then to some comments on the regulations, if you'd put up Slide 11, please. I think the regulations there to distinguish levels of care on the left, I would be very much in favor, as you suggest, of eliminating them. We've talked about the complexities with the LTCHs, but I think with inpatient rehab, the 60 percent

rule could very much fall away.

I think to go to the far right column, hopefully over time we could see some real consistency and alignment across the different current PAC settings. So I'd very much be supportive of aligning the regulations to ensure appropriate care.

The one that really concerns me the most is that middle column, and I'll use one example. We've studied the three-day rule. I think that's a really important check. You have nursing homes -- and, Dana, you mentioned this during your presentation, but caring for long-stay patients who go to the hospital and come back on the SNF benefit. And I think we want to be really careful there if we remove that three-day rule about, you know, nursing homes sending individuals down the street for a short inpatient stay and coming back at a higher payment rate. I just really think that's important, whether it's -- there's nothing magical about three days, but some sort of check there, whether it's a rule like that, to help keep that in check. I think if you eliminate that three-day rule, you're really looking at opening the flood gates.

So I think I'll wrap up on that point, but

hopefully I touched on some of the data and analyses and regulatory issues. Thanks.

DR. CROSSON: Okay. Thank you, David.

So let's have a general discussion. I see Jack, Warner, so we'll go this way.

DR. HOADLEY: So I really like David's comments, and, you know, some of the things that we asked in the first round really kind of got over into some analytic ideas, I think. And I do like this notion of trying to think about whether the data will give us some evidence on whether some kind of super bundles or whatever, without -- you know, just staying within this sort of fee-for-service side of the thing, whether there are these common patterns like a SNF followed by a home health or an IRF followed by a home health, that, you know, is common, has sort of a logical flow to it, and could there be a single payment? Obviously, if we do that, we have got to think about how do you divide it up and who's in charge of dividing it up and all those other kinds of things. So not that it's going to be simple, but at least whether the data lend themselves to supporting that kind of notion. And I think I had brought up the same idea about, you know, whether there's ownership

in common and, you know, does that lead to gaming, sort of inappropriate stuff? Or does it mean that they're actually able to look and do this in a logical way? There at least you would have fewer issues about dividing up payment. You just give it to the system, and they figure out the division of the payment. So it does seem like there's some good stuff to support, and we'll obviously see what the data allow you to do.

I don't think I have much to add on the regulatory side, but I think David, you know, kind of identified the right questions, and you identified them in setting this up. They're the right questions to look at, and we'll just see where the information leads itself to.

DR. CROSSON: Warner.

MR. THOMAS: Yeah, I think this directionally is great. I just would really encourage us to -- and hopefully I was clear before in bundling the -- or connecting the post-acute payment together to create -- my guess is there's a lot of efficiency opportunity between LTCH, rehab, SNF, et cetera. And, frankly, SNF doesn't get used as much because it's not reimbursed well, and there are patients that could go to skilled nursing that I don't

think do because of the economic situations, why many SNFs have been closed, you know, across the country, especially more urban environments.

So I would just encourage us to continue the direction and think about how you group those payments together and think about some sort of readmission penalty, incentive, or what-not, to avoid someone trying to limit the length of stay, but also really trying to challenge the providers to think about efficiencies between those different components of post-acute areas.

DR. CROSSON: Kathy -- Bruce, did you have your hand up?

MR. PYENSON: Thank you very much. I like the direction this is going in. I have a comment on page 11, which is up there, in particular the regulations that limit coverage, that to the extent possible we suggest that advanced APMs are exempt from those regulations, because I think the coverage limitations become obstacles when organizations are taking prospective risk.

DR. CROSSON: Kathy.

MS. BUTO: Yeah. Also on that call, on regulations that limit coverage, I struggle to think about

how we balance developing a post-acute care system across providers yet keep provider-specific coverage limitations. So I think that's a struggle. I'm wondering whether underneath our concern -- and David probably has a sense of this -- is that there are certain conditions for which we're worried that there might be abuse or greater use of post-acute care where it's not appropriate, where we might consider thinking about applying some of these coverage restrictions. In other words, try to keep it consistent with the condition focus rather than a provider focus, because at least in my mind, I was imagining, you know, the evolution of a core provider, post-acute care provider, and that provider might actually offer more intensive services for ventilator-dependent or certain stroke patients, certain kinds of patients, and may get enhanced payment or different payment for those, but that there be a core that would be somewhat interchangeable among post-acute care providers, with the exception, of course, of home health providers. So trying to figure out how to get away from the provider-specific requirements and more to the approach we're trying to take of the patient condition focus.

DR. CROSSON: David.

DR. NERENZ: Thanks. Great work, as always. Like Warner, I'm attracted to this idea of a bundled approach that would try as far as possible to link the beneficiary characteristics at the start of a whole PAC episode to a payment that may or may not include multiple segments.

I fully appreciate the difficulty. For example, if there's going to be one payment, you know, who gets it? Is it Provider A? Provider B? You know, those are hard questions.

Is there anything coming out of the BPCI demo model 3 that in any way is informative about this? I realize it's not structured exactly that way. But it does at least, you know, have the semantics, the terminology of a bundled payment for all PAC. Is that shedding any light on this option or opportunity?

DR. CARTER: We can look into the next year. The first-year evaluation was very preliminary, and so I'm not -- even the authors thought we needed to see more before we could really draw any conclusions. But I think that that's close to being -- the second-year evaluation I think is close to being done, so we can look into that.

DR. NERENZ: It would just be on points, for example, is there, you know, some way to tell? And this touches on Jack's comment to my comment. You know, just given the assessment, if you do the assessment up front, can you actually identify those people who will need two segments? And then can you generate a payment sufficient to cover those two segments and then worry about how to distribute it?

Now, if you can't do that, if the two-segment is essentially unpredictable at the front end, then you've got to approach it differently. So I'm just wondering if in that demo, is anybody helping us understand that?

DR. CROSSON: Pat.

MS. WANG: I may be really wrong about this, but I am a little bit worried about kind of sort of assuming that state regulatory apparatus will just kind of go with Medicare simply because in post-acute care there's so many different types of providers around the country that seem to -- I mean, LTCHs exist in certain parts of the country but not in others, IRFs, a lot of SNFs only do custodial. I was just a little bit careful on that front and maybe it's -- I don't know what to do about it, but just maybe at

some point in the research talking to some of those states with particular types of regulatory, CON requirements, things like that, to make sure that whatever is recommended for Medicare is not going to run into some really obvious barriers on the state side, because you'd like to think that states are just going to, you know, understand, well, Medicare is doing it this way, so we just have to get with the picture. But I'm not so sure on the post-acute care side because Medicaid is involved in that side, too, and they tend to have layers and layers of layers of regulation over the years that result in the system looking a certain way. So it's just a cautionary note.

DR. SAMITT: So great chapter. Thank you. Just a couple additional comments.

I do wonder whether there are any benchmarks that we can use as we think about aligning payment for the sequential visits and whether we look at things like maternity care or post-op care that we've tackled this to some degree, where the first visit has the obligation for everything that follows and such. So I wonder whether there's an opportunity to think about alike treatment here.

The other thing, though, that is a bit more

concerning to me is this whole notion of what is the driver of the sequential visits. Is it that there is something that's different about the patients that treat in place versus sequential? Or is there a gaming phenomenon going on? And to some degree, it feels like there are two issues we have to solve. What is the equitable payment when a sequential visit must happen? And then what do we do about the potential gaming behavior, regardless of the payment methodology, and what do we do about that?

And one of the things that we did not touch on and Bruce may have alluded to is what's the responsibility upstream from the PAC, so the referring provider, to really look at the frequency of sequential visits to diminish unnecessary sequential visits? And is there some kind of incentive or accountability vehicle for the PCP in this process so that we minimize any of the gaming that could come from this, assuming that we get the comparative reimbursements right?

MS. THOMPSON: Just to restate a couple of things to just express my support for the direction we're going here. David's comments I think were very, very good and opening up our thinking about whether or not sequential

stays are good or bad. And not to put a value on it, but I think it costs us to go in to a different conversation of thinking, which probably led us to this thinking more around a bundled payment.

But in our experience, in value-based and in ACO, the skilled partners that are in our network, I mean, the minimum criteria is, you know, to be a three-star provider. So there's something inherent in some of the already existing quality performance metrics that I think at the risk of stating the obvious, but keeping it as simple as we can in all this complexity, there's a lot of existing structure around the regulations that ensure appropriate care that I think we can build on.

I would just call out, you know, the ambulatory sensitive conditions that exist, the quality metrics that exist within the bundled payment. I just think we don't have to reinvent the wheel here.

So those would be my comments.

DR. CROSSON: Actually -- I'm sorry -- Brian had his hand up first.

DR. DeBUSK: Well, first of all, great chapter. I think you really identified where the problems are -- or

the challenges are.

I have one comment on the planned analysis. It looks like so much of this is going to come down to episodes and what do we consider an episode, what's your underlying philosophy, and it's really interesting because it reminds me of the session we had earlier when we were talking about the voluntary value program. I think episodes are going to be a big part of that too.

So I know this sounds a lot like more work, because it is, but we may want to go back and develop some principles that maybe could even transcend both post-acute care and the physician payments.

What is an episode? I think the comment letter from August really hit some great questions in it. So it's clear that we understand that there's an issue there.

But the final thing that I wanted to throw out there, as we develop a philosophy around episodes, I hope we don't limit ourselves just to trying to build prospective episodes. What would be really interesting is to just look at the data in place and try to identify correlations and patterns and let the data define the episodes for us, and I think that would be sort of an

interesting take because then we don't go in with any assumptions that, well, an episode of SNF care has these following characteristics.

If we can find it in the data, we may be able to just passively define these episodes. I am botching this just a little bit, but I'll get a chance to explain later. But I would be really interested because one of my concerns is, as soon as we build these episodes that are based on these really sound principles, now the question is who is going to maintain it.

I mean, it's almost like the RUC all over again. How do you keep these bundles up? And that's why I really hope that we can develop something that's passive that does more of an in-place calculation of what these bundles look like.

DR. CROSSON: Dana, I'm sorry. I broke my pattern without any notice. Go ahead.

[Laughter.]

DR. SAFRAN: No problem.

So thanks for this great work.

I am very much in agreement with the idea about trying to think about a bundled concept for all of this and

just had two ideas to add into the others that have been on the table about that.

One is -- and this may be an out-there, sort of nonstarter idea, but I'll just throw it out there, anyway. If the owner of the bundle -- I wonder if the owner of the bundle could be the hospital because -- the reason I say that is that what I think those of us who have sort of been working in the ACO space have been seeing is that ACOs have really become kind of smart purchasers -- or the good ones, anyway -- smart purchasers of post-acute care, and post-acute care facilities are almost like marketing themselves in a very new way to ACOs like, "I will be a good partner for you. You will not get readmissions if you work with me," et cetera.

And so I just wonder as we play with this bundled concept if there's a way to make the hospital the owner of the bundle so that they're making smart decisions about the post-acute care.

And then the other thing I wanted to add into the mix that I haven't heard mentioned is with any bundled concept, we would want good quality measures surrounding it, and even though we haven't, I would say, had great

quality measurement in the post-acute care space, I do think it really lends itself to some of the low-hanging fruit for good outcome measurement because it's almost all about functional status and what you're doing to improve that or maintain that, and gosh, we sure know how to measure that.

So I think that having a bundled concept with good quality measurement that's outcomes-based accountability for the post-acute care facilities is a direction I'd love to see us consider.

DR. CROSSON: Dana, just to be clear, you're talking about the hospital owning a purely post-acute care bundle, not a hospital acute care, post-acute care bundle.

DR. SAFRAN: Correct. Yes.

DR. CROSSON: Thanks.

Amy.

DR. CARTER: Can I just say one thing about that? One hiccup that we will face is about half of the home health episodes don't have a prior hospital stay, and about 15 percent of IRF and LTCH admissions are from the community as well.

We do have work under way to have common PAC

measures of quality and resource use under way, so we're to address some of those concerns. And I think a resource use measure actually might get at unnecessary PAC use if we put in place a value-based purchasing program with enough money at risk that people pay attention to it and have a resource use measure that would at least be one speed bump.

DR. CROSSON: Amy.

MS. BRICKER: I'm a bit still worried about the practical matter of the state issues that you raised, and maybe this was a Round 1, but were the only issues just in those six states, or you just looked at those six states and those were the kind of notable exceptions?

MS. KELLEY: We chose six states to look at --

MS. BRICKER: Okay.

MS. KELLEY: -- sort of to get a sense of the range of requirements that are out there.

MS. BRICKER: So there could be issues in many?

MS. KELLEY: For sure, there are issues in some states. It wasn't meant to be an exhaustive look. It was meant to sort of get an idea about how states regulate their post-acute care providers and how aligned or not they were with Medicare regulations, and we tried to choose

states that we knew were sort of -- had more stringent regulations and other states that did not. I think our exercise sort of did give us a sense for what is out there.

I don't believe we had planned an exhaustive look at all the states.

MS. BRICKER: Yeah.

MS. KELLEY: I think the state regulatory issue is certainly an issue, but it is right now as well. So I'm not sure that we're pushing something that is different from the situation that providers deal with right now.

Yes, there would be changes, but I don't see this as necessarily a different situation from what they currently deal with.

MS. BRICKER: That's helpful.

Maybe, as Pat recommended, a few conversations around the recommendation and how they would -- what's the time to implement or what would be the barriers from their perspective, that would essentially translate into success or not of adoption.

Thanks.

DR. CROSSON: Other comments?

Paul.

DR. GINSBURG: The materials in the presentation were really good. It's a very complex issue, and I thought that you really handled the complexities very well.

I have been thinking as the people talk about this bundling issue and we keep coming up with better and better ideas that my suggestion now is the first provider that the beneficiary hits, whether it's the acute hospital or the home health or the IRF -- would all in the bundle, and we might get some useful things.

I think the state perspectives, state regulations, very good to know about them. To the degree that they really interfere with a post-acute provider in the state, there may be some motivation to change them. I don't think we should withdraw because some states have regulations.

I think CLN is probably particularly challenging because states use that for long-term care to keep their budgets down, and they're not going to give that up. So I guess it just reduces the flexibility to substitute.

DR. CROSSON: Alice.

DR. COOMBS: I won't repeat what everyone else has said, but the one area that I think -- I would like to

make a re-recommendation still for the eight days under the LTCH. Can we go back to that as well? Because I think we said eight days. I think we can put that forth again and maybe get some gravity with everything else that we're doing with the PAC, just kind of slide it right on in there.

[Laughter.]

DR. MILLER: Did you want to say something, Stephanie?

MS. CAMERON: I was going to say there is a mandated report for LTCHs, so I think we will be taking a deep dive, if not this year, the next year.

DR. CROSSON: And so we'll slide it right on the agenda. Thank you.

[Laughter.]

DR. COOMBS: And then the other thing is that we're talking bundles, but, Carol, you guys have pointed out so clearly that you can't have the acute care hospitals be the head of something that originates within the PAC system. And the whole question is who is the head of the -- who is going to be the head of the bundle? I think that's an important piece of this in order to get the

outcomes that you desire.

And I agree with having some evidence of ADL measurement and looking at some functional status going forward because I think that's really important.

I agree with David on the three-day because there's opportunity. I know there's opportunity for a different decision-making based on that three-day. I admit a patient the critical care area, and I have to check off a box about my projection of how long the patient is going to be there. So I think that three-day is really important, and I just wanted to reiterate that again.

DR. CROSSON: Pat.

MS. WANG: I wanted to comment on the bundles that people are talking about. I think it's conceptually a really, really good idea. I'd just be careful.

Like, Paul, your suggestion is really creative. To the extent that you're paying the bundle to like the first contact post-acute care provider who is then unaffiliated with subsequent post-acute care providers, there's like no -- there's no scheme around there for beneficiary protection. I would be just really careful about -- I mean, if you're paying the bundle to an ACO, for

example, that has structure and eyes on beneficiary protection and appropriate levels of care and all of that, that's one thing, but for traditionally fee-for-service providers to be responsible for paying and having financial incentives for where they send patients, when they discharge patients from their own service, I'd just be careful about that. I'm not sure it's such a great idea to rush into giving somebody a bundle for services that are situated elsewhere without an understanding of how the beneficiary is protected in that, in that travel.

DR. MILLER: Yeah. Actually, I was going to say some things along those lines because, on the one hand, Warner and maybe somebody else came right out of the blocks and said -- and David, I think as well -- you know, why aren't we thinking about episodes, and I was saying we are. We understand logically that this lends itself to bundles or episodes.

But there's also some things to step back and think about as you do that. One thing that's gone on in the Commission is there's been this discussion of, well, maybe we think ACOs and the notion of taking risk more broadly is a better mechanism, where the person takes

responsibility for the entire experience of the patient instead of going in and starting to carve out underneath. So there's that tension and the tension that if the ACO has a set of incentives, do you want the incentives drained off by bundles underneath them and people, say, capturing the savings before they move up to the ACO level. So you have to think about that tension, and I'm going to help you think about it in just a second.

The other thing that Carol hit pretty well is some things may lend themselves to being in a bundle and others maybe not so much, and so you'll want -- in other words, it might not be the panacea to everything.

To Brian's point, I think it would be natural for us to construct some bundles that can be passively maintained as opposed to defined once and having to have a RUC or anything like that redefine them. We would decidedly stay away from them. We should stay away from that.

And so then to this last point of who's responsible, who owns it, and what about if it's the first person who touches it -- and thinking of the ACO concept -- maybe a way to think about this is you don't have any

owners of the bundle. You pay fee-for-service in a bundled way, but you're consciously paying providers. But everybody gets their fee-for-service payment, and that what you're really thinking of is this is a unit of payment. And that helps you both with your ACO incentive structure, and it helps you with things like this.

Well, I reacted to Paul's thing too. Somebody says, "Oh, you picked up that patient first. You just got the bundle," and I'm like not in a position to pay someone, have a contract with someone, that type of thing.

The hospital, decidedly, to Dana's point, probably could be in that point of view -- be in that position, but keep in mind that the real firestorm that starts whenever you start talking about bundle is who owns it, and that often brings you to the end of the conversation very quickly. And one way to sidestep that issue is to say nobody does. Everybody gets fee-for-service inside that bundle, but you'll be held to your fee-for-service payment based on this unit.

You can keep the incentives for the ACO present, and you don't have to worry about who pays how underneath. Now, I don't want to be really dismissive of the ownership

concept because there are arguments for it, but politically, sometimes that's where the wheels come off the train in conversations.

And so I'm just trying to say there may be another way that gets around two or three of these problems, not that it doesn't have its own problems, as always.

DR. COOMBS: So I want to address that because we have talked about this. It's kind of like an almost bundle, but you don't have the agency of the person at the head of the helm who makes the clinical decisions -- when to get a consult, when not to get a consult -- these other things that go on with a bundle that I think are positive things that result in either cost extension or unnecessary testing, those kind of things.

DR. MILLER: Unless you say this is occurring in the context of an ACO.

DR. SAMITT: Mark, I would very much support that notion, and it's what I was alluding to when I said how are we focusing on sort of the upstream refer to the post-acute care services.

You could argue that ACOs ultimately own the

bundle, given that their focus is on total cost of care.

And to Sue's point, I think what high-performing ACOs do is they'll say, "Well, if we see a post-acute care facility that immediately then generates a subsequent visit, that we may want to use that post-acute care facility less" --

DR. MILLER: Right.

DR. SAMITT: -- "than the ones that have a higher level of accountability and avoid repeat use or readmissions." And that's essentially how ACOs are thinking about it today.

It then goes back to the discussion we had, I think, at the last meeting about directing and referring to certain post-acute care facilities because that's exactly what ACOs would want to do to concentrate on the highest-quality organizations.

DR. MILLER: And in a sense -- and I know -- I'm sorry -- I'm talking too much about this, but in a sense, it's like you're almost saying if I create this passive bundle and use it as a unit of payment, fee-for-service reaps the benefit of having sort of a set price for a unit of payment. And the ACO still has the opportunity to go

after the volume issues. That's the thinking.

DR. CROSSON: Okay. Kathy, last comment.

MS. BUTO: Just I get nervous talking about bundles before we've built the new system --

DR. MILLER: Yeah. Well, there is that.

[Laughter.]

MS. BUTO: -- because the new system with all the regulatory changes that might go with it are going to change the nature of the way care is delivered, and it just seems to me before we jump into the bundling concept and how it would be executed and blah-blah-blah that we talk about it as something that could be staged in at stage two rather than right off the bat. Too many moving parts.

DR. MILLER: And I think analytically, the way these guys -- and I'm looking at them -- you know, the way they're approaching it is really thinking of it first as stays and how the stays line up with each other, and then that would kind of lead to, all right, now let's talk. I think that is the natural sequence -- notice I'm using the title there -- to talk about these issues, and I think it's the way you guys are thinking about it.

DR. CROSSON: Jack, last comment.

DR. HOADLEY: Yeah. I mean, I think what Mark is talking about is consistent with some of what I was saying, with the notion that if we are seeing certain patterns that sort of reoccur -- the one slide that said the challenge is trying to make sure we're not giving incentive one way or the other way, so it's sort of that notion of finding an amount that covers the sort of back-to-back episode, and then I think the way Mark defined it may get us around some of these broader issues that complicate bundling, but just as a starting point, think about are there dollar amounts, are there dollar amounts that overlay the way we've defined this new PAC payment that sort of is taking these into account and then try to figure out exactly where to put it in the broader system.

DR. CROSSON: Well, good discussion.

Dana, Carol, thank you for your usual good work.

I do have a concern about an induced demand here. I think you probably now have earned chairs with your names on the back --

[Laughter.]

DR. CROSSON: -- because my guess is that we're going to be seeing a lot of you for many, many years as

your work goes through, but thanks again. Appreciate it.

Okay. Let's move on.

[Pause.]

DR. CROSSON: Okay. For the benefit of our guests we have a set of presentations to come here. This work is the second phase for MedPAC in preparing its report, mandated by Congress, on the subject of telehealth. At the last meeting we talked about the current state of Medicare coverage of telehealth, under Medicare fee for service. Today we are going to talk about telehealth as it exists in the commercial, non-Medicare world, and then at the November meeting we will entertain proposed changes for how Medicare goes about covering telehealth.

We are going to have two presentations. We will have a brief discussion after the first presentation, asking for clarifying questions from the Commission. Then we will have the second presentation, and then we are going to have a combined discussion. So the more substantive discussion will follow the second presentation.

The first presentation is observations from site visits and focus groups. We have Evan, Andrew, and Amy, and it looks like Amy, you are starting. Thank you.

MS. PHILLIPS: Good afternoon. During this first of two sessions on telehealth we are going to talk to you about telehealth results of our annual summer site visits and focus groups as well as the results of a project we conducted on Medicare home health agencies and their use of telehealth.

We will start our presentation by reviewing the mandate to contextualize the information we are about to present. We will briefly review our methodology and fill you in on who we interviewed, and then dive into the results of our analysis of the use of telehealth among health systems, beneficiaries, primary care physicians, and Medicare home health agencies.

As a reminder, the above slide outlines the mandate given to MedPAC in the 21st Century Cures Act. While not addressing a specific answer to the three parts of the mandate, the information in this presentation will contribute to your understanding of what is happening on the ground level with telehealth in health systems and home health agencies, as well as provider and beneficiary attitudes about telehealth.

DR. JOHNSON: This past summer we interviewed a

variety of stakeholders about key issues in telehealth, including the types of programs being developed, the motivation for using telehealth, program financing and coverage, information about utilization trends or outcomes, and perceptions of the different modes of telehealth.

For our telehealth site visits, we identified stakeholders to interview based on their size or their existing telehealth programs. Across Indiana, Virginia, and Washington state, we interviewed 16 organizations, including 9 health systems, and we conducted 12 focus groups with 29 primary care physicians, and 81 Medicare beneficiaries. We would like to thank Laura Summer, Elizabeth Hargrave, and a team at NORC, including Mollie Hertel, Lauren Isaacs, and Lindsay Shapiro for their work on this project.

For home health, we interviewed 11 home health agencies about their use of telehealth. Some of these interviews were conducted during site visits to Maine, New Jersey, and Pennsylvania, and the remainder were conducted by phone to other home health agencies across the country. We would like to thank Alana Knudson for their work on this project.

Before we begin, I would like to make clear that the statements in this presentation are presented as they were reported by interview respondents and we did not identify or verify their accuracy. Any opinions expressed are those held by those of the interviewees and not the Commission, and the examples we provide are meant to add context, but may not be generalizable.

We are going to start by discussing the telehealth programs being used in large health systems for patients of all types of coverage. Of all the programs we heard about, Telestroke had the most reports of success. Telestroke uses two-way video to connect an on-call neurologist with paramedics responding to an emergency call for a possible stroke. By video, patient registration can be initiated, and neurologists can assess the likelihood of a stroke and determine whether the patient should go to the local hospital for confirmation or be diverted to a major medical center.

Telestroke programs reported shorter times before administering a clot-busting IV, which is associated with improved patient outcomes, when that treatment is appropriate. Stakeholders reported that emergency doctors

became more comfortable administering the clot-busting IV, which allowed smaller, more rural hospitals to retain more patients. We did not hear that any insurer provided separate reimbursement for equipment or cellular data costs. However, more than one system suggested that their Telestroke program was financially viable under current reimbursement policies.

Given the success of Telestroke programs, some stakeholders planned to expand emergency telehealth to other programs focused on possible heart attack patients or trauma victims. In addition, several health systems reported using inpatient telehealth to connect to specialists, particularly those in shortage. Psychiatry services were cited most often as a focus for these telehealth connections, both in the emergency room and for inpatient stays during nights and weekends. Some health systems noted plans to expand to other specialties as well.

Next, several health systems we spoke with were using telehealth services for pre-operation and follow-up visits, allowing some patients to avoid some travel to the hospital and to improve their compliance with instructions. Stakeholders were motivated to avoid Medicare’s inpatient

readmission penalty, and a few health systems had conducted evaluations and found a reduction in readmissions. However, stakeholders believed that the program was only financially justified for conditions associated with a penalty and most did not include any other conditions in their program.

Moving beyond inpatient stays, most of the health systems we spoke with also offered direct-to-consumer virtual visits, or had plans to do so soon. These programs allow patients to initiate a virtual visit with a provider anytime and from any place. Most programs used a vendor or separate clinical staff within the health system, so patients are generally not accessing their regular doctor.

Stakeholders told us they were motivated by competition with other health systems in their region. Some health systems received reimbursement for virtual visits from insurers or employers, but others passed along a portion or the full cost of the visit to the patient, which we heard ranged from $10 to $50. All stakeholders reported the use of these programs was very low, and most users were relatively healthy, and younger than Medicare age.

A few health systems offered virtual visits for behavioral health as a way to more efficiently spread access to these services across their health system. Behavioral health was viewed as a good candidate for telehealth as it generally did not require hands-on interaction, and telehealth could reduce the perceived stigma associated with seeking in-person services, potentially reducing the number of missed behavioral health appointments.

Finally, we heard a few concerns that affect all use of telehealth, some focused on the Medicare program, specifically. The most common concerns were with Medicare's requirement for a rural initiating site. Stakeholders noted that areas on the edges of some MSAs have a need for telehealth that is more similar to rural communities than urban communities, and even in urban settings, Medicare beneficiaries who are more frail could benefit from avoiding travel, including the use of transportation services, which are sometimes undependable.

Stakeholders also noted that some rural areas lack broadband access and certain programs that subsidize the cost of broadband were being cut back. Next, state

laws that mandate payment parity between in-person and telehealth services were perceived to support the expansion of telehealth, but laws that mandated only coverage parity were perceived to have little effect. And finally, telehealth program developers reported facing new forms of administrative burden, such as completing more detailed billing practices for Medicare, licensing telehealth clinicians in each state, and credentialing telehealth providers for each facility, and sometimes for individual health plans.

And now, I'll turn it back to Amy.

MS. PHILLIPS: During our focus groups with beneficiaries we found that the majority were not familiar with the use of telehealth, but were open to the concept under certain circumstances with mixed opinions on cost-sharing. A few beneficiaries admitted to being overwhelmed by technology, but the majority were familiar with smart phones and webcams that could be used to do a virtual visit. Opinions on cost-sharing were mixed with some beneficiaries who thought they should not be charged for telehealth visits because it is more convenient for the doctor and saves the practice time and money, while most

thought a copay would be appropriate if it was less than what they pay for an in-person visit.

Most understood the potential benefits associated with home monitoring, but also had reservations due to the perceived invasiveness of the technologies. Those who had CPAP machines unanimously disliked the way in which the machine would "snitch" on their use, or lack of it. One beneficiary talked about a heart monitoring device she was given to help prevent heart attacks, but said she hadn't used it because no one had provided instructions and she was overwhelmed with the technology. Conversely, another person talked about monitoring equipment her wheelchair-bound husband received from the VA and appreciated how it had been useful to her in taking care of him, especially when she could avoid transporting him on days with bad weather.

Many insisted however that even if telehealth visits were an option, they "liked the hands-on approach better" as the enjoyed seeing their doctor in person, and feared that a virtual visit would miss important information. Most pointed out that they already have access to their regular providers via e-mail or telephone

when they needed them, and the majority believed telehealth would be more appropriate when they could interact with one of their regular physicians as opposed to a random physician who may not be familiar with their entire medical history.

Across the nine focus groups, beneficiaries identified many situations where telehealth would be useful to them. Most of these suggestions revolved around increasing access when they felt going to the doctor was inconvenient, such as transportation and parking issues or discussion of lab results and minor problems, or when they felt they had an urgent, but minor acuity problem, such a cold or needed a prescription refill. Beneficiaries did not suggest telehealth for remote patient monitoring of chronic conditions and noted that many of the uses they listed for telehealth they already have access to via e-mail and phone calls. Overall, beneficiaries thought telehealth was interesting and a good idea, but were not expressing that they would actively seek it out.

During our three focus groups with primary care physicians, we found that physician attitudes about telehealth were generally positive with overall attitudes

hinged on the operational details of the programs, and we found that physicians were more likely to have familiarity with telehealth if they practiced for a health system, and only one of the physicians of the 29 in our focus group was currently using it.

When thinking about the concerns expressed by physicians, the first and most important to them was impact on their schedules. They already felt overwhelmed and worried that virtual visits would be an addition to their day. This sentiment was a carry-over for many of them from the way in which electronic medical record systems added time and technical complications to their days instead of simplifying or making care more effective or efficient for them.

Remote patient monitoring and the idea of more electronic outputs that would require interpretation had the primary care physicians wondering if remote patient monitoring is merely an unnecessary "extra layer of care" with little clinical benefit that takes a lot of time, and that left them wondering how this additional work would factor into compensation. Their concerns also extended to worries about their patient population mix. They feared

"easy cases" would be diverted to virtual care and, in turn, their daily caseloads becoming burdened with consistently more difficult patients.

Most thought that compensation for virtual visits should be based on time and pointed out that virtual visits have lower overhead costs since they could deliver care via technology they already owned, in almost any location. And some physicians even pointed out that some telehealth compensation would be getting paid for something they already do, in the case of patient phone calls and e-mails.

The opportunity for telehealth most frequently suggested was schedule flexibility with options to work from home or take less traditional breaks in their days to accommodate personal lives. However, as their current practices are structured, they did not express seeking telehealth out and even suggested that telehealth would be a better fit for younger physicians just starting out. Physicians also thought implementing telehealth would have the primary effect of impacting access to care, and there was discussion that Medicare's annual wellness visit could be done via telehealth.

Evan will now talk to you about telehealth use

among home health agencies.

MR. CHRISTMAN: All right. In this last section we will look at telehealth as it is delivered in the home health setting, and as a reminder, Medicare statute permits home health agencies to offer telehealth to beneficiaries while they receive home health services, but it is not a covered service or reimbursable by Medicare. A survey by industry consultants found that the use of telehealth has increased among HHAs, and it was reported that about 20 percent of agencies were using some form of it in 2016, with remote patient monitoring the most common service.

We interviewed and visited several home health agencies to better understand how they used telehealth in practice, and similar to the national survey results, all of the agencies we contacted operated remote patient monitoring programs. In these programs, HHAs would screen patients for remote patient monitoring at admission, and agencies reported that between 10 to 20 percent of patients received the service. The criteria used to select patients varied among providers. Usually the programs targeted a select condition such as patients with congestive heart failure with other complications.

Some adapted protocols from third parties and others developed in-house criteria. In general, the criteria were intended to identify patients with higher than average risk of re-hospitalization. If a patient met the criteria, the home health agency would usually drop-ship a tablet and peripherals to the beneficiary to begin the service. The service is optional, but agencies reported that it was rare for a beneficiary to decline remote patient monitoring when it was offered.

Monitoring would consist of the beneficiary reporting vital signs and health status electronically at least 5 days a week for about 90 days. Vital signs that were outside acceptable limits would generate an alert at the agency's call center, and trigger a follow-up call by an HHA nurse.

The agencies believed that the process of beneficiaries reporting their vitals and receiving follow-up calls improved beneficiary self-care, and that this resulted in fewer re-hospitalizations and lower emergency department use. Though many agencies reported that this was their experience, none of the agencies we spoke to had completed case-mix adjusted studies to assess the impact.

Agencies provided mixed responses on the impact of remote patient monitoring on home health service use, the number and mix of in-person visits. Many were not sure whether it decreased or increased the frequency of face-to-face visits under the traditional home health benefit. One agency said it was careful not to change the number of visits, and some agencies said it made it easier to serve beneficiaries in rural areas that were more difficult for staff to reach.

In general, agencies believed remote patient monitoring improved their ability to care for community-dwelling, frail, elderly patients.

Taking a step back, in this presentation we described a wide range of programs and perspectives on telehealth, so we would like to summarize a few key themes before we finish. Health systems have developed a few telehealth programs that reportedly operate successfully under current reimbursement policies. These include programs for Telestroke, to avoid readmissions penalties, and to connect patients to specialists, particularly those that may be in short supply. Many of the programs we heard about benefitted from grant money, suggesting that some

assistance may be necessary for these programs to gain greater use.

Programs offering direct-to-consumer virtual visits appear to be proliferating as a way for health systems to compete with one another. However, utilization of virtual visits is low, particularly among Medicare beneficiaries, and primary care physicians appear cautious about expanding their practice to provide virtual visits, and also somewhat concerned about fragmented care if use continues to grow through third-party telehealth vendors.

Views on remote patient monitoring varied, and may have reflected that some providers and beneficiaries have little experience with the service, while others have used it extensively. Overall, the beneficiaries and physicians we talked to in our focus groups had limited experience with telehealth but they thought it was interesting and a good idea. They were not expressing that they would actively seek it out or attempt to implement it, and the doctors did not indicate that they would attempt to implement it into their practices.

Now, in contrast in the home health section, we found that agencies believed that remote patient monitoring

lowers readmissions and also found that most beneficiaries accepted the service when it was offered.

This concludes our presentation. Please let me know if you have any questions.

DR. MILLER: If I could just make one quick clarification. Evan, when you were setting up the home health section you said they are free to offer the service, and then you had some language, but it is not --

MR. CHRISTMAN: So the -- what the law says is that they may offer the service if the wish. It's kind of an optional service that agencies may offer. But it's not a -- technically speaking, it's not defined as being covered under the home health.

DR. MILLER: And then you said something about the payment.

MR. CHRISTMAN: Right. Their home health --

DR. MILLER: And the point I wanted to clarify is that, you know, they get paid a 60-day episode --

MR. CHRISTMAN: Right.

DR. MILLER: -- it's relatively well paid, with a 14 percent margin. They can use that money to provide remote monitoring --

MR. CHRISTMAN: Right.

DR. MILLER: -- or whatever the case may be. They just aren't directly reimbursed for whatever action they take.

MR. CHRISTMAN: That's correct.

DR. MILLER: That's what I wanted to get clear.

DR. CROSSON: Good.

DR. MILLER: Sorry.

DR. CROSSON: No. Clarifying questions? I see Alice and Jack.

DR. COOMBS: I thought we were going to ask questions at the end of the second presentation?

DR. CROSSON: No, no. I'm sorry if I wasn't clear. We're going to do clarifying questions, but no Round 2.

DR. COOMBS: Okay.

DR. CROSSON: Then we'll do Round 2 for everything.

DR. COOMBS: Okay. I read the interviews. One of the questions I had with the queries for the providers as well as the patients, was there any issues regarding HIPAA or on the patient side, confidentiality, feeling like

their information might be divulged?

MS. PHILLIPS: As far as discussion with the physicians, I don't think that really came up so much as they understood if they were going to engage in telehealth, they had to have the proper software that was approved. And then as far as patients went, they did feel -- with remote patient monitoring, some of them mentioned a Big Brother and do they need all that information approach, but that was only with like the in-home device monitoring. And that was from a few patients.

DR. COOMBS: Okay. So they weren't doing like Face Time with their patients?

MS. PHILLIPS: No, we didn't hear any of that.

DR. CROSSON: Jack.

DR. HOADLEY: So one of the examples you used on Slide 6 was the pre- and post-inpatient use and where that's sort of a pre-op or a post-op kind of thing. Is that covered under the bundled PPS payment or the surgical bundle for the provider?

DR. JOHNSON: Essentially, yeah. There was no additional payment for the service, so I think whether or not the hospital viewed it as covered under the bundle or

some other source of funds that would benefit them by avoiding the penalty, however they justified it may have been different.

DR. HOADLEY: Yeah. Thank you.

DR. CROSSON: Okay. I'm sorry. I lost track for a second. All right. We'll go this way. Rita then Dana.

DR. REDBERG: Thanks for another interesting presentation. I just had a question on the Project ECHO in the mailing materials. Who funds that project? Because I worry about conflict of interest.

DR. JOHNSON: The programs that we heard about were mostly funded through grants or external providers. This was not a Medicare-funded service. We didn't get into too much about --

DR. REDBERG: You don't know if they were a for-profit or not-for-profit?

DR. JOHNSON: I got the sense they were not-for-profit, but I don't know for sure.

DR. REDBERG: Okay. Then the other question, you had something about state licensure. I just want to be clear. Is that an issue with those remote -- like if the doctor you're talking to isn't licensed in the state the

patient is in?

MS. PHILLIPS: Yeah, that would be a problem. So the physician has to be licensed for the state where the patient resides. So if you're operating near a state border, that could be an issue. Or if you're calling in for a specialist that's out of state, they'd have to be licensed where the patient is.

DR. REDBERG: Thank you.

DR. JOHNSON: To add a little more context, we heard about some national vendors who seem to have solved that problem by having enough staff and enough physicians to cover each state. We also heard about it in the context of some regional health systems that had more difficulty and that it was an extra layer for them to coordinate.

DR. REDBERG: I'll just say I think state licensure is a little funny because we practice medicine the same in all 50 states. But that's a Round 2.

[Laughter.]

DR. CROSSON: There is no Round 2.

[Laughter.]

DR. CROSSON: Very sneaky. Dana?

DR. SAFRAN: I wonder if you could say a little

bit more about the behavioral health care uses, both what you learned about the types of behavioral health care being provided by telehealth and reactions from patients or beneficiaries from providers.

DR. JOHNSON: We heard just a little bit about programs that were currently in place, so there was not a lot of experience. But it was recognized several times by many different stakeholders as a good next use or something that was sort of in the pipeline for a good use of telehealth. So we didn't hear a lot of experience, but many had plans to do so.

MS. PHILLIPS: And one anecdote of when we were talking to patients about that as a possibility, the ones who were in a small town said, "Oh, I don't want to go to the mental health facility because everyone knows my car. If I park it there, then all the town is going to be gossiping." And they liked that they could either access it from home or from their primary care.

DR. CROSSON: I actually have one question with respect to the relatively lukewarm reception from the primary care physicians that you interviewed. Did you get a sense -- or did you actually ask those physicians how

they were being paid, either as a consequence of being part of an entity or individually? And if so, was there a difference between physicians who were being paid fee-for-service and those who were part of some sort of capitated or salary-based relationship?

DR. JOHNSON: For starters, the physicians we spoke to were recruited for a focus group generally without any specifics to whether or not they had telehealth experience. We did hear a little bit about their payment experience. Most I think were fee-for-service; a few were associated with a health system where they were salaried. But --

DR. CROSSON: But you're not aware there as any difference in attitudes between those two cohorts?

MS. PHILLIPS: The only physician who had experience with telehealth was within a health system, so that's the only extent that we have for that.

DR. JOHNSON: I would say we had too small numbers too really draw a conclusion, just that we tended to hear more of the fee-for-service type physician and less of people who were associated with a health system.

DR. CROSSON: Got it. Thank you. Okay, David.

DR. GRABOWSKI: Thanks. There was a section in the report that you distributed titled "Telehealth Coverage in Medicare Advantage," but you didn't talk about that during your remarks today. But I just wanted to ask a quick question. You stated in that section that use of telehealth services in Medicare Advantage was -- that you heard about during your interviews with the plans was quite low. And that surprised me to some degree, that we might expect, you know, here's an opportunity to really leverage telehealth in a kind of at-risk environment, and yet they don't. And I wondered if you would comment on that.

DR. JOHNSON: To be clear, I think that the use was low on the beneficiary side, so several plans seemed to be offering some sort of telehealth benefit, but consistent with what we heard from the beneficiaries, they tended to prefer to see their doctor. And there seemed to be some idea that they had a routine with how they sought out health care, and telehealth was not yet part of that for this population. So it was consistent with those remarks, but we didn't hear any more specifics about why or whether there were other barriers to use.

DR. MILLER: Just a little bit of a commercial

for you and for you. The next session on telehealth is going to be interviewing commercial plans and managed care plans in particular, and I'm not going to give anything away.

[Laughter.]

DR. MILLER: Because Zach would be all over me. But there's a little more -- there's some subtlety there that I think we'll get at some of the things you're asking.

DR. CROSSON: Sue.

MS. THOMPSON: In your visits with pre- and post-inpatient, you saw -- I want you to talk a little bit more about what you saw, that there was more interest when there was a penalty involved or there was some interest in using it in conditions where there was a readmission penalty. I'm just interested in what was your impression, how much of that did you hear, and did you have any conclusions in the car as you drove home about --

[Laughter.]

DR. JOHNSON: We asked each system whether or not they had -- if they had a program, whether or not they focused on just the conditions that were associated with the penalty or all conditions. I think only one said that

they provided it for all conditions, but noted that the penalty tweaked the financial justification enough to make sense for those conditions, and that the one system that provided it for all conditions did so, they thought, at a loss but they did so because they thought it was the right thing to do and not because it made financial sense. So all systems that we spoke to seemed to make a clear distinction between penalty and no penalty for how they viewed at least the finances of their system.

DR. CROSSON: David.

DR. NERENZ: Thanks. A couple questions about Telestroke, if we can go to Slide 5. It's nice to see this featured. The point in the middle about no separate reimbursement, I wonder if you can just elaborate on that a little bit in this scenario. I can understand how the ambulance is being paid and the work they're doing is not fundamentally different. How is the neurologist being paid? If it's not separate, what is it?

DR. JOHNSON: I think the point here was to say that there was not a separate reimbursement to cover the telehealth portion, meaning that it did not cover the equipment or any cellular data services. But as stroke

patient coming in with an ambulance straight to the hospital without any telehealth association had a payment both to the neurologist and to the hospital. And then in the telehealth stroke program, the payment was the same, and that there was no difference in payment for those two types of situations.

DR. NERENZ: I'm not sure I still understand. If a patient goes by an ambulance, ends up in the ED, and then eventually at some point is seen by a neurologist, eventually the neurologist gets paid under, what, an inpatient consult or an outpatient something.

DR. JOHNSON: Right.

DR. NERENZ: But in this case, we're talking about a neurologist who's spending time on some device about the patient who's in the ambulance. I'm just curious. How is that neurologist's time paid or billed?

DR. JOHNSON: You know, we didn't ask specifically about that, whether or not that would be a consulting service that's outside of an emergency visit. That's something we'll have to follow up on more, I think.

DR. NERENZ: Okay. I mean, it's not a major point. I'm just curious when you say there's no separate

reimbursement, because it sounds like the work is separate.

DR. JOHNSON: Right. And I understand the distinction. Again, what we were going for there was that there are certain costs that we focused on associated with the telehealth technology and the service itself, and that should include the neurologist. We'll have to follow up on that.

DR. NERENZ: Okay. Fine. Thanks. Then the other question is: You've highlighted ambulance here, but I've heard anecdotally about Telestroke programs that are structured at two different points, subsequent points, that the patient is now in the ED, and then at that point there's an electronic reach-out to the neurologist; or the patient's in the ICU, and there's the same thing. So you're highlighting of ambulance here, does that mean that this is like far and away what people talked about? Does it mean the others are not important? How do we read that?

DR. JOHNSON: Do you mean highlighting this program as having particular success compared to other --

DR. NERENZ: Well, I mean, you're just saying this is the patient in the ambulance, but there are other Telestroke examples where the patient is somewhere else.

But you've chosen to feature this one. I'm just curious. Should we read something into that?

DR. JOHNSON: I would not. I think that we heard about programs where they focused on their patients who were in areas that had significant travel times, and so that was the mechanism -- and the patient group that they focused on for Telestroke. And not to say that they didn't have other uses for Telestroke where patients are in other locations, but that's just what we heard about.

DR. CROSSON: Other clarifying questions? Paul.

DR. GINSBURG: Yeah, I've been reflecting about the information you got. It was very useful to do these site visits. And it seems to me that you have this very wide range of possible uses of telehealth. A few of them, like Telestroke and, say, patient remote monitoring for congestive heart failure seem to have very high value and the people are going to that. But you have this, you know, potential -- but a lot of it, most of it is pretty marginal. You know, the patient, you know, "I'd really like to see my physician in person." So in a sense -- and maybe someone who really had difficulty traveling would benefit from that. But, you know, you have a big range

where it's very elective, and I think that's just something to keep in mind as we think through about policymaking in this area, how to accommodate this mixture of some very specific, very compelling uses, and a wide range of marginal uses.

DR. CROSSON: And the other thing I think I would add to that, Paul -- thank you -- is something we don't often have to think about, and that is in the provision of telehealth services -- and I've experienced this in my own care -- there's a significant benefit here that accrues to the beneficiary in terms of time saved, but also for beneficiaries who are employed, value that accrues to the employer and potentially to the society. And I don't know that that's going to drive our policy in one direction or the other, but in terms of the overall thought about the value of this, I think it's a consideration.

Okay. So thanks very much. It looks like, Amy, you're going to stay, and thank you to Andrew and Evan. And we've got Zach coming over, and we'll proceed now with the second presentation, and the second presentation will be followed by the more traditional Round 1 as well as Round 2, and Round 2 will incorporate the entire body of

work.

It looks like, Amy, you've got the -- no, Zach. Sorry.

MR. GAUMER: Well, good afternoon.

We're now going to turn to the analysis that we've done on telehealth services covered by commercial insurance plans.

In the larger context of our mandated report, this presentation specifically addresses the second question of the mandate. So commercial plans will be our aim today and the subject of the discussion at the end of the presentation.

I will touch on several topics along the way here. I will describe the research methods we've used. Then I'll cover the various components of telehealth coverage under commercial plans, such as service type and cost sharing.

Next, I'll describe the rationale insurers used to explain their decision to cover telehealth services. I will also describe patterns of utilization and outcomes observed by insurers.

Then we will turn to our discussion.

Okay. To conduct this analysis, we worked with L&M Policy Research, whom I'd like to thank at this time, to produce the work, and our analysis occurred in two phases.

First, we gathered and reviewed plan coverage documentation from a convenient sample of commercial insurance plans to identify telehealth coverage trends in 2017. We gathered three different types of documents from this sample of plans: evidence of coverage documents, statement of benefits documents, and also coverage policy memoranda that we were able to access.

Our sample consisted of 48 individual plans. They were, as a group, available across all 50 states. The plans represented a range of managed care products and various types of commercial markets, such as employer, individual, small and large group, and exchange plans.

No plans in our sample were commercial fee-for-service plans.

As a result, throughout our presentation, we describe the companies operating these plans as managed care organizations, or MCOs.

In addition, plans in our sample included both

FEHBP and non-FEHBP plans. We made significant efforts to ensure our sample was diverse geographically, by profit status and by size, and we made sure to include a few insurers that were part of integrated delivery systems.

In the second phase, we conducted semi-structured interviews with representatives of 12 MCOs from our original sample which covered telehealth. We did this to identify their rationale for covering telehealth, their utilization and their outcomes, and we made significant efforts to ensure that these 12 MCOs reflected the same diversity of the original sample.

This group of 12 MCOs had roughly 28 million enrollees in their plans overall.

We also interviewed two MCOs that did not cover telehealth services in 2017.

The plans in our sample that covered telehealth did so through one of four different delivery pathways. Many of the insurers we studied covered telehealth by outsourcing these services to a telehealth vendor. In these cases, the vendor supplies clinicians to care for patients through two-way video or telephone as well as the technology needed to facilitate communication.

This is the gray box on the left.

A second group of insurers outsourced just the technological component to the vendor. A third group employed their own clinicians to provide telehealth services and created their own technology, and a fourth group covered gentleman services but did not provide them to patients directly.

Our review of the plan documentation found that 94 percent of plans in our sample covered some form of telehealth service in 2017. Synchronous telehealth, such as two-way video and telephone, was far more common than asynchronous telehealth, such as emails and texts.

The most commonly covered services were basic E&M physician visits, mental health visits, and pharmacy management visits. For example, 26 plans noted in their coverage documentation that they covered telehealth physician visits for basic services. The least commonly covered services included provider-initiated emails, such as when the provider sends patients educational materials or reaches out after hospital discharge. And we believe plans are hesitant about primary care physicians reaching out to their entire patient base periodically and having to

pay for that contact.

Remote patient monitoring was also not commonly covered.

The other key finding here is that only a few plans covered several telehealth services, and most plans covered just one or two of these services.

In our interviews, representatives of managed care organizations specified that the coverage of basic E&M physician visits was often conducted using telehealth services referred to as "direct to consumer," DTC. This is something that you discussed in the last presentation. As a part of DTC, patients can initiate contact with a clinician using two-way video and telephone at any time and from anywhere, and they're typically used to treat acute routine illnesses.

All 12 of the MCOs that we interviewed covered DTC services. Seven of these did so through a vendor, and five of them did so with their own employed clinicians.

Insurers also discussed their use of provider-to-provider, or PTP services, where a patient and their clinician connect to a distant specialty clinician. Several insurers covered some form of PTP, most commonly

mental health services. These services are typically not outsourced to a vendor. They are not available around the clock, and several insurers covering PTP happen to be in states with telehealth parity laws in place.

Our interviews and our documentation review revealed that most insurers covered urban-originating sites as a part of their telehealth coverage. In only a few cases did we see plans limiting specialty services to rural-originating sites.

By contrast, fewer insurers covered the patient's residence as an originating site.

Half of the 45 plans covering telehealth in our sample noted in their documentation that they covered the patient's residence as an originating site.

Vendor-based services tend to allow both urban and home use because their goal is anytime/anywhere access. In addition, some plans limit their specialty services to originating sites that are rural facilities as opposed to the home or urban.

Most insurers allow any clinician to bill for telehealth. However, some insurers pay for vendor-employed clinicians to conduct the DTC telehealth visits but do not

pay in-network primary care clinicians in the community to conduct telehealth visits.

Insurers typically make telehealth available to all their plan enrollees, unless coverage is part of a pilot program, and only a couple of cases did we see plans excluding young children from telehealth or hospice patients from telehealth coverage.

Patient cost-sharing levels for telehealth services varied across commercial plans and by type of service. Within the plan documentation, we found that roughly half of the 45 plans indicated that they set cost-sharing levels equal to in-person services.

However, our interviews with MCOs, it was revealed that cost sharing is more variable by service. For DTC services, most MCOs set cost sharing at or above in-person cost-sharing levels. For PTP specialty services, nearly all MCOs set cost sharing equal to in-person cost-sharing levels.

Insurers reported it was uncommon for them to use utilization control policies in telehealth coverage. For the most part, insurers used the same utilization policies for telehealth service that applied to in-person services.

For example, it's common to limit both in-person and telehealth visits to no more than one visit per day for the same physician. However, a few insurers do have utilization control policies that are unique to their telehealth services.

For example, one insurer requires patients to obtain prior authorization. Another insurer requires clinicians to register as telehealth-specific provider, and a couple of insurers conduct pre-payment claims audits on telehealth claims periodically.

Several MCOs used pilot programs to test their telehealth services. These were the services which they appeared more cautious about implementing broadly. Some have more than one pilot ongoing, and among those we heard of from our interviewees were remote patient monitoring for patients with chronic conditions, specialty physician visits, such as mental health services, the use of vendor-based DTC and PTP specialty services, and Web-based live chat technology. These pilot programs tested subsets of the plan enrollment by geographic area or for certain chronic conditions.

The two most common rationales provided by

insurers as the motivation for implementing telehealth were employers demanding these services for their employees' convenience and competing with other insurers.

Insurers provided several other contributing rationales, such as access and convenience for patients and the fact that they were mandated to provide the service by state telehealth parity laws, but we think it is noteworthy that none of the insurers we spoke with reported cost reduction as their primary rationale for covering telehealth services.

Insurers consistently reported lower-than-expected use of telehealth services, with the majority reporting that less than 1 percent of their plan enrollees used some form of telehealth service at some point during their year. In fact, the highest reported use was less than 5 percent of enrollees for one plan.

Insurers reported that the most commonly used telehealth services were basic E&M physician visits supplied by DTC, with mental health services a close second. Women were more frequent users, as well enrollees under age 40. Enrollees generally used telehealth at all times of day, not just after hours or on the weekends, as

some assumed they would.

None of the 12 MCOs we interviewed that offered telehealth coverage stated that they had seen clear cost reductions as the result of offering the service. However, they believe that they have improved convenience and access, and that greater use will translate into cost reductions in their future.

Okay. To summarize, our analysis of commercial plan coverage of telehealth services suggests that coverage is variable. Our findings do raise questions about the extent to which commercial telehealth coverage actually differs from Medicare.

The majority of plans we assessed cover some telehealth services, but few cover a broad array of these services.

Many cover basic E&M physician visits, using direct-to-consumer systems. Some of these outsource to a vendor, while others do it themselves with their own clinicians.

Insurers largely cover urban-originating sites, but only half permit patients to use telehealth from their residences.

Cost-sharing for telehealth services varies by plan and service, but overall cost sharing appears to be equal to or above levels of in-person cost sharing.

Insurers also commonly use pilot programs to test telehealth on subsets of patients. Their rationale for covering telehealth was largely to respond to employers' demands for convenience and to keep up with other insurers, and again, none of them told us that they did so to reduce expenditures.

The use of telehealth service has consistently been low among commercial insurers, and they report the strongest positive outcomes being the expansion of convenience and access rather than cost reduction.

Okay. We would like to focus today's discussion on commercial plan coverage and its utilization. Just as a forecast, in November we are going to discuss a little bit more broadly, Medicare's coverage and how it relates to what we've seen today. In January, we will discuss the full report.

And thank you very much for your time, and we're happy to take your questions.

DR. CROSSON: Thank you, Zach and Army.

So let's proceed to have now clarifying questions on this portion of the presentation. I see Alice, and then we'll come up this way.

DR. COOMBS: I just want to ask you specifically the chronic conditions that are listed as -- do we know a distribution of like was it most congestive heart failure?

MR. GAUMER: So we did a little bit of this in September, and we're kind of updating our analysis.

DR. COOMBS: Okay.

MR. GAUMER: And you'll see that when you get the January mailing materials.

DR. COOMBS: January, okay.

MR. GAUMER: But I can kind of give you a general gist of it.

What we see is that the mental health conditions -- depression, schizophrenia -- those are very common.

DR. COOMBS: So if we subtract those out -- so I'm trying to get to the medical, not the psychiatric.

MR. GAUMER: Sure.

DR. COOMBS: So what comes to the top when you just talk about the medical conditions?

MR. GAUMER: There was CHF in there.

DR. COOMBS: Okay.

MR. GAUMER: COPD.

DR. COOMBS: Okay.

MR. GAUMER: Some of the ones that you would probably suspect.

DR. COOMBS: And so most of them were E&M, but it's interesting from the last discussion -- were any of them because of instrumentation like mass CPAP or BiPAP?

MR. GAUMER: I don't think so.

DR. COOMBS: Okay, okay.

MR. GAUMER: Yeah.

DR. COOMBS: Thanks.

DR. CHRISTIANSON: Amy?

MS. BRICKER: I might have missed it, but we mentioned in the previous discussion the big brother on the CPAP machine and all that. So do you see that in the commercial plans that they cover remote monitoring, but is that prevalent?

MR. GAUMER: Well, we do see some remote patient monitoring in commercial plans, or at least we heard about that, and they have it in their documentation. But my take on this is that what we're seeing reflected are pilot

programs largely in commercial plans, and if they do cover remote patient monitoring, it is targeted to specific populations.

Would you agree with that?

MS. PHILLIPS: Mm-hmm.

MR. GAUMER: Okay.

MS. BRICKER: But most did or not --

MR. GAUMER: No, most did. So I think we only had 8 plans out of the 48 plans that we looked at that covered remote patient monitoring, so it was quite low.

And I think the vibe generally when we talked to these folks in interviews was remote patient monitoring is something that most are still considering -- or those eight are still considering what to do with remote patient monitoring. They're testing it. They're using pilots and demos to figure out what exactly it is and how to use it.

MS. BRICKER: Thank you.

DR. CHRISTIANSON: Anybody else on this side with a clarifying -- I'm sorry. Dana?

DR. SAFRAN: So I was curious about the definition that you used of telehealth because it's very broad, and I wonder if you were asking the plans that you

were interviewing if that was consistent with how they define it or if you just said, "Here's how we're defining it. Do you do these things?"

And I'll say a little more about what's behind my question, but go ahead.

MR. GAUMER: So what we did when we conducted the interviews -- actually, I'll cover both phases. In the documentation review, what we did was in reviewing all the documentation we could get our hands on for plans, we looked for any mention of telehealth whatsoever in a very broad sense, and then we looked for specific types of telehealth that we are aware of. And we were even careful to look for things like telephone contact, call-in lines and that kind of a thing.

When we got to the interviews, what L&M, or contractor, did was they would give a brief description of what telehealth is and say, "We define this quite broadly, and it could include a lot of different things." And so I think there was an effort there to try to develop an understanding that we're talking about a lot of things here. It's not just DTC or remote patient monitoring.

So this was a problem we were really worried

about, so we went broad and tried to capture everything.

DR. SAFRAN: Yeah. If you could put that up -- oh, sorry -- the typology, I think it's Slide 5. Yeah. So the reason I feel a little bit concerned about the breadth of the definition, because I think there probably isn't a plan in the country that doesn't have a call center with nurses, where they're making calls. So if phone contact and care delivered over the phone by the plan itself is considered telehealth, then everybody would say, "Yes, we're doing that." So I wonder if we say, "Scrub that. Let's talk about the other things. Who is paying providers to conduct phone calls? Who's paying providers to have e-mail?

I can say in our case, we don't consider it's telehealth unless it's real-time and there's a visual component to it. So I don't know if we're an outlier on that. I have no idea, but I'm just curious if other plans are actually defining phone calls to a provider as telehealth.

MR. GAUMER: Yeah. I think that some do define them that way, and I think there are several reasons for that, but I think we could go back and take a look and do

what you say and scrub out some of the phone call-in lines and see what we've got --

DR. SAFRAN: Yeah, that would be interesting.

MR. GAUMER: -- and give two versions of numbers.

DR. SAFRAN: Yeah. Great.

DR. REDBERG: Just to add on -- and Dana alluded to this, but almost all of us now have My Chart kind of messaging. It's basically emailing, but it's not real-time or face. But I was thinking, would you consider that telehealth? It fills some need.

DR. CHRISTIANSON: Anybody on this side with clarification questions for Zach and Amy? Why don't we just go down and start with you, Sue.

MS. THOMPSON: Thank you, Zach and Amy. On page 11, where you comment, the primary rationale that these MCOs are covering telehealth has to do with employers wanting convenience for employees and also competition with other carriers. And I'm also thinking about the age group in that cohort, perhaps, but then also reflecting back to the interviews that were done and the comment that was made that those interviewed, those beneficiaries -- Medicare beneficiaries interviewed were overwhelmed by technology.

So in your thinking, as we look out into the future, baby boomers are aging into Medicare, baby boomers being more comfortable with technology, will there be any -- I mean, do you have a thought about how this beneficiary population will be changing from a consumerism standpoint, expectations and demanded and just -- aside from the application of tele-anything, just your thinking about that.

MR. GAUMER: Well, the one thing here, you know, I think a quick reaction would be to say that, you know, the 40-and-unders are using it more than anybody else, and so we are about to see this big wave. But I'm a little cautious to say something like that because use really hasn't been that high, and it's not as though everybody who's under age 40 is dying to do this. Obviously, that's what we're seeing in the use here in the commercial side. So I would say it's unclear.

MS. THOMPSON: Okay.

DR. CROSSON: Craig.

DR. SAMITT: So, Zach, on Slide 12 you talk about none of the plans reporting evidence of cost reduction, and I'd love to come back to that. I guess I'd ask the

reverse. Did any plans report that telehealth drove up the costs of services?

MR. GAUMER: No, we did not hear that.

DR. SAMITT: Thanks.

DR. REDBERG: Were they tracking that, Zach?

MR. GAUMER: I'm sorry. Can you repeat that?

DR. REDBERG: Do you know if they were specifically tracking that?

MR. GAUMER: Yeah, it seemed to me that plans were, you know, on top of what was happening with their claims that they were looking at. And, actually --

MS. PHILLIPS: In terms of increased costs, we did hear about some plans that had contracted with vendors, and in those contracts the utilization was far lower than they were expecting, so they were losing money by paying the vendors for services that weren't being used. So that was one case where we did hear some plans saying, "We need to restructure our contracts with our vendors because we're spending way too much and the utilization is too low."

And, in turn, a lot of them said, "Well, I guess we'll plan to do more marketing," so there could be more increased costs there in trying to make the services to the

patients.

DR. MILLER: And to her question, you know, I wasn't involved in all of this, but in the conversations with you and with others, my sense is that they were tracking how much utilization was going on, but nobody had sort of systematically studied, oh, do I see upstream, downstream, you know, did I avoid a hospitalization, did I do this? I didn't get a sense that anybody was systematically following that, or at least to the extent that they were, we weren't getting that out of this process.

MR. GAUMER: Yeah, so there were a couple of plans that seemed to have a number of variables that they were tracking, and they were not ready yet to provide information. So they are just at the upswing of this and don't feel like they have enough data to do it. But there were some plans that gave us, you know, the list of variables they track and readmissions was on there, as you can imagine, yeah.

DR. SAMITT: Well, and I would weigh in that actually our research division did study the cost implications of telehealth, and I don't know if they had

shared that with you when we connected. Anthem did see a cost savings that actually came from telehealth, and I don't know if that's in the appendix. I didn't see it. We may want to share that study with the group.

And one of the things that is of question is whether those savings from a commercial sector translate in the Medicare world given that reimbursement levels for emergency room visits, urgent care, primary care may be different. And so it also is we may have seen savings in the commercial reimbursement world. The question is: Do those savings translate equally in the Medicare world? But I think there is some tangible evidence that that is emerging now, that shows the value of telehealth.

DR. CROSSON: Craig.

MR. GAUMER: Can I actually just respond to that real quick?

DR. CROSSON: Yeah.

MR. GAUMER: We certainly have the study, and it was included within -- not the whole study, but mentioned and a summary of it was included in the September materials. So that would mean it's going to be in the report. So we haven't lost track of that, and it's

something we're considering very much

DR. CROSSON: My question was just going to be, you know, we have this problem with the term "telehealth," so what area of telehealth are you talking about? Are you talking about all these three areas we've talked about or what?

DR. SAMITT: Most of the telehealth that we currently support at this point is urgent care-related telehealth. So telehealth visits versus urgent care visits or versus emergency room visits is the primary area.

DR. CROSSON: Physician or provider to consumer or consumer to provider, that portion.

DR. SAMITT: Provider to consumer, using a third-party vendor. But I think the paper or the presentation also talks about the optimism that expanding the use of telehealth to other areas could very well reap additional savings even beyond what has been experienced to date. But I think our experience -- and I don't know whether we were one of the 12, but our experience actually has found that it isn't just a luxury, it isn't just for convenience, that there is substitution going on that's resulting in cost savings.

DR. CROSSON: Terrific. All right.

Okay, Paul, on that topic?

DR. GINSBURG: Craig, I was wondering when you rolled out the telehealth service, was it restricted to these areas that you thought it might really add value? Or was it much more general and these were the areas that it's being used the most?

DR. SAMITT: We are one of those organizations that is piloting alternative uses of telehealth as opposed to broad accessibility. So it's very selective in the areas where we think that telehealth can serve as both a convenience and a favorable substitution to alternative care modalities.

DR. CROSSON: Okay. On this also?

DR. REDBERG: And we can talk more about it I think in Round 2, but it depends, I think, Craig, as you alluded to, whether it's a substitution for or not, because I could also see a scenario where especially when you're talking to people that don't know you -- I mean, certainly in my field any kind of chest pain, you know, it's like, "Go to the ER," where someone who knew you wouldn't say that. So it really -- and which would result in increased

service use, you know, for that kind of thing. So it really depends on what was the alternative, what were they using before. Is it additive or substitution? And is it a doctor that knows you?

[Audience interruption.]

DR. CROSSON: Clarifying questions. Kathy, are you --

MS. BUTO: I think somebody else was talking, but I do have a couple of questions for Evan and Amy. One of them was Slide 4 says managed care plans, not fee-for-service. So I guess my question was: How are these plans paid? Are they per member per month? Or when you say not

fee-for-service --

MR. GAUMER: So what I'm trying to say there is that generally these are all defined as managed care plans. None of them were purely a fee-for-service plan. We didn't get any deeper than that.

MS. BUTO: Yeah, so that does strike me as potential not too comparable to the situation we're looking at. Just a comment.

But then the other question was, again -- and I wondered whether you thought this had anything to do with low utilization -- I think I recall from the paper that very few of the plans covered patient-initiated telehealth. Is that correct? And if so, did you think that had anything to do with the low use of --

MR. GAUMER: One thing we note there is that it didn't allow physician-initiated telehealth. Is that what you mean?

MS. BUTO: Well, I thought in the paper there was something about patient-initiated, that, in fact, basically, based on what Craig was saying, the plan might have a very defined area where telehealth is used, but allowing patients to just decide on their own to initiate a

telehealth encounter sounded like it was not that common.

MS. PHILLIPS: Yeah, so when the patient-initiated encounter occurred within usually a vendor system, in that case it was usually allowed because it's their vendor system where it's always going to be patient-initiated. But if you have a patient who wants to contact the regular primary care provider who may be offers their own telehealth service, it wasn't always built into the plan coverage, that that would be a covered service, even if they're contacting that primary care physician for the same reason they would have been contacting a direct-to-consumer vendor physician. It just wasn't built into the plan to be covered.

MS. BUTO: Okay. And so even within the vendor model where the patient was expected to initiate contact, we were seeing very low utilization.

MS. PHILLIPS: Mm-hmm.

DR. CROSSON: Bruce.

MR. PYENSON: I've got a question about methodology. If we go to Slide 4 -- well, it's up there. I understand the documents were probably found on the websites of the MCOs themselves.

MR. GAUMER: I would say most were, but we also obtained several documents using assistance from associations or from other contacts that we had.

MR. PYENSON: Okay. So is there a concern that most of the plan documents were for fully insured business, meaning small group, individual marketplace kind of plans, or fully insured large group where you have a policy form that's typically on the website and may not have the representation from the self-insured employers who might -- their documents, if posted, might be on the employer website?

MR. GAUMER: So we tried to get a range of different models, I guess I should say. So we have small market plans; we have plans that are offered, you know, through an insurer for an employer. We had a fairly wide range of plan or market types in there.

MR. PYENSON: But how would you know about the self-insured if it was mostly on the plan sites?

MR. GAUMER: Yeah, I guess we would not. We would not know specifically. We can go back and check and see what we've got there.

MR. PYENSON: Yeah, if you could, because as you

know, the vast majority of commercial coverage is through self-insured programs, and there could well be benefits that are perhaps not even in a consolidated summary plan description, sort of wellness kinds of programs or EAP types of programs.

MR. GAUMER: Mm-hmm.

MR. PYENSON: Okay. Thanks.

DR. CROSSON: Dana, on that point?

DR. SAFRAN: Yeah, just a comment on that, which is a hypothesis based on my own experience. It's absolutely true that sometimes self-insured accounts have benefits that fully insured don't. But it seems hard -- knowing what we, for example, had to do put in place telehealth benefits and relationships, I think if a payer was doing that for self-insured, they would at least have it as an offering for fully insured. So I think that it would be hard to imagine a plan that had it for self-insured and not listing it in their materials, if that's what you're trying to get at.

MR. PYENSON: I was thinking of the opposite where an employer might decide to go to an outside vendor on its own as opposed to through the carrier for the

benefit.

DR. SAFRAN: Got you.

DR. CROSSON: Okay. So I think we are finished with the questions, so we'll come to the discussion period. I just want to point out, although it includes myself, there's a temptation here to start problem solving. We actually have a set-up, as you heard, in November where we're actually going to say, okay, based on what we've learned, what do we think perhaps some new policy approaches for Medicare should be. So try to avoid the temptation because we'll get an opportunity to do that in November.

Having said that, Alice.

DR. COOMBS: Thank you so much.

First of all, I like telehealth a lot, but this whole notion of what is telehealth is really important I health care. And I think Dana alluded to something earlier. Is it a phone call? Is it a follow-up? I think we can be more prescriptive as what we think telehealth is in the context of what we're willing to say is a supplement or a substitution. And so three areas that we've talked about: one, time-sensitive interventions, Telestroke, you

know, there's several others that are just as important. We know that giving tPA within X number of minutes is going to make a difference in terms of long-term morbidity, people having devastating debilitation and actually needing SNF. I've seen patients who come in with cadaveric extremities who get tPA, and all of a sudden they're actually moving in the ICU. And guess what? They're going to go home in 48 hours. They're out of the hospital. Very different picture from what we used to see before the advent of the research and the literature which suggests that this makes a difference. But I think there are other time-sensitive therapies as well that we need to consider.

Now, the next question is: Urban versus rural, should we say that for time-sensitive therapies that we should say that anywhere where there's -- the access issues or workforce shortage or say a small hospital that has some -- maybe it's not rural, but maybe it's in an area where there's a deficit of specialist care where that's important.

The second is remote monitoring, and when we talk about what that looks like, that is a video arrangement. That is a synchronous type of telehealth. So the other

question, the other -- I guess the distinguishing thing we should consider is whether or not synchronous and asynchronous are equivalent in terms of substitution capabilities. So that's the other piece.

I think for dermatology, when there's a shortage of dermatologists and you need someone to look at a lesion right away to say, okay, this lesion is very suspicious, I want this one to go and have consideration for excision, moles procedure or whatever, I think that's an issue that needs to be addressed as well. So remote monitoring specifically for chronic co-morbid conditions, and I think that we should be -- we should be also prescriptive enough to say that these entities, like we did with the LTCHs with CCIs, these are the ones that take -- they rise to the top as being priority items that we should consider. And specialty-driven care as mentioned earlier, but there might be some other areas such as urology and neurology. And say a primary care doctor is in a position where he or she has a lot of Medicaid/Medicare patients and it's hard to get a specialist in the area, and you're limited by transportation for the beneficiary, that might be a prime opportunity for, again, a synchronous video type

arrangement. Whether it's in-source or out-source, I think those ideas, we can be flexible with that.

DR. CROSSON: Thank you, Alice.

Okay. Discussion on what's been presented, Craig.

DR. SAMITT: So I thought these were both great presentations, and, you know, I want to harken back to the discussions that we've had on prior meetings, and I think sort of the sticking point here is whether we envision telehealth is substitution or supplemental and the concerns about telehealth running rampant so to speak. And what I heard today kind of gives me reassurance that that isn't the case. Between the two presentations I heard, slow proliferation even in the commercial setting, so it's not like even when it's covered we're seeing high utilization.

The MDs that referenced it don't see it as a windfall opportunity. In fact, they're a bit more fearful of telehealth with the concern that it's supplemental work, not supplemental revenue. And there is some -- and I think it was the first presentation that talked about the reduction of readmissions and so there's a presumption that there is a cost of care savings that comes with certain

forms of telehealth. And then we most certainly heard that it's value-add to consumers as a convenience or to employers, and so it gave me comfort that in a controlled fashion, telehealth is not a luxury, that it actually adds significant value from a quality, service, and potentially cost standpoint.

And I sense the sticking point may be I think we're thinking of telehealth as all or nothing when I think we should think of it as little and more of, that we cover some telehealth and the reality is in a controlled setting with certain diagnoses and certain circumstances, we should explore freeing up sort of some of the regulations regarding telehealth so we can use this alternative modality more effectively than we have in the past.

DR. CROSSON: Okay. I saw David.

DR. GRABOWSKI: Yeah, so first, I enjoyed both of the papers and presentations. I wanted to pick up on Craig's comments there, about this idea that telehealth isn't just limited in Medicare but in these other settings as well -- traditional Medicare, Medicare Advantage, these commercial plans. I was actually surprised at how low it was, to be honest. You know, I think every one of these

pilot programs that we've seen is the result of an academic paper, and I've read every one of those papers. If as many people were using telehealth as publishing these pilot programs maybe we would have, you know, a much greater use.

I guess, picking up on Craig's comment about whether -- well, this is an indication that, you know, the flood gates are not going to open, another spin on that might be, you know, it seems really low, almost too low, lower than I would have expected, and I sort of wonder if these aren't Medicare issues but rather system-level issues, as to the low use of telemedicine to date. And going forward, if we are going to see an increase it's not just thinking about kind of changing payment policies in Medicare but rather there needs to almost be a culture change around this, because I'm really surprised that just kind of the low use across all these different payer types and systems. Thanks.

DR. CROSSON: Okay. Pat.

MS. WANG: This is really interesting reading. I was, you know, with the -- it's a given, it's always good for people to have more choice and more options for how they access care. That said, I do think, you know, to

David's point, telehealth might be a new enough modality that maybe there needs to be, in the introduction of it, a more intentional approach. You know, and I have questions around, you know, whether these were tested or they are used in sort of diverse communities, and, you know, multiethnic, you know, multilingual, just the utility of it.

That said, sort of seeing -- and I definitely have a concern about cost duplication as opposed to cost avoidance, so it's really encouraging that Craig's study showed that they were able to sort of control that and substitute. So that's encouraging.

What struck me, in terms of intentional deployment of telehealth, I was very impressed by the provider-to-provider use of telehealth, whether it was Telestroke or rural hospitals obtaining, you know, access to, you know, more specialized expertise in urban areas through telehealth, the hospital readmission efforts -- this seems really useful.

As far as direct-to-consumer, at least from the presentations and the reading, the one that I think is the most interesting is the use of telehealth for behavioral

health, because there are clear access issues there. It's not only -- we heard a report last year on behavioral health in Medicare, and, you know, there's clinician shortages, there are, you know, there's a shortage of behavioral health professionals who even take Medicare. It's really, really hard to get people access to clinicians, much less overcome some of the cultural inhibitions about going to see that. So I found those snippets very interesting.

I guess that I feel like, yeah, let 1,000 flowers bloom, and it's great if people have the option. I would be cautious about potentially creating a new cost escalation path without clear benefit, except where there seems to, from your studies, be something very, very useful that is clear, like the Telestroke, et cetera. But that's my perspective.

DR. CROSSON: David.

DR. NERENZ: Just a couple of things. I'm wondering if there is any room in this discussion for some of our site-neutral philosophies, essentially to say that if a certain body of clinical work is going to be done, the payment system can be indifferent to whether it's done in

person or whether it's done electronically. I realize that's easier said than done, and Rita is already shaking her head, and I'll be happy to provoke the discussion.

But I sort of couple that with another idea, that, you know, certainly one of the cautions about, you know, opening up avenues of payment for telehealth is the potential for overuse and expansion of budget. But a number of things that we've heard seem to say that that's not at least an obvious, imminent problem, meaning that beneficiaries seem somewhat reluctant to take it up, providers seem somewhat reluctant to take it up, you know, Craig's experience. You know, that just suggests to me that it may be possible, at least without overt danger, to open up some options.

And then as I think about, well, you know, how exactly do you do that? Do you create new billing codes? Do you create -- and then that led me to the site-neutral to say, well, you know, if you're going to psych visit that you would do in person, bill it the same way if you do it with telehealth. Fundamentally, the work is the same thing, and, you know, ditto on the stroke consults, ditto on a number of things.

So I will wait now for Rita to tell me why that's a bad idea.

DR. CROSSON: Well.

[Laughter.]

DR. REDBERG: Because, you know, I think about telehealth in our mission, you know, to improve value, to improve quality, and lower costs, and it's not clear to me it does any of those. You know, certainly Telestroke could be good, and, you know, clearly telehealth isn't the same thing. But what was lacking -- and the chapters were both great -- but there is no outcomes data at all, and the outcomes data I've seen was very neutral or negative on the benefits that I just talked about for telehealth, which is why I think -- and I think your focus groups were very telling, because, as I said earlier this morning, you know, I would like to preserve the reason that people go into medicine is because they like to see patients and help them get better, and not for all these other things.

And, you know, the patients you talked to in the focus groups said they like the hands-on approach better. I mean, I don't think my talking to a patient in my office -- and, you know, I hear a lot of things. I mean, when

people come to the doctor, as you know, they like to tell things that they don't tell everyone else. That's not going to happen in a telehealth visit. I'm really -- you know, from my point of view as a provider, it's much easier, but I don't think patients are getting -- and I think that's what they clearly said in the focus group.

You know, the examples that you gave, I think, are totally appropriate. It's much easier if I just have to give a test result I can do it. But I can do it now by my chart. I'll leave a phone message. I don't need a telehealth visit, you know, to give someone their test results when they're negative, in particular. And I think perhaps the reason the utilization is low -- because I looked at one of those plans. It was MDLive, because my -- I have an HMO kind of coverage, and my kids don't -- they live out of state now but they are covered because they are under 26, so I thought, oh, maybe they could use this.

Well, I could see why the utilization is low. First of all, there is a significant copay. I think it was the same as the doctor's office. But then there was all this other stuff about logging on, and calling someone, and then they might call you back. You know, it was like -- it

didn't seem as convenient as it might be. So I think there were other barriers that might have impeded the utilization, not that it can't be useful.

So I feel like this is one of those things. You know, if we had alternative payment models then we would know where it was really useful, because that's where we'd use it. But to put this into a fee for service, I think we're just going -- I fear we are going to have proliferation of low-value, unnecessary telehealth service without improving quality of care.

DR. CROSSON: Okay. Kathy.

MS. BUTO: Okay. So one of my concerns is that the analysis of what commercial plans are doing is not entirely transferrable to our consideration of whether telehealth services should be expanded in Medicare, partly because they are prepaid, for the most part, prepaid plans, partly and largely because the population is so different. I guess, after reading the papers, I felt that an argument could certainly be made to consider Telestroke treatment, very kind of targeted additional uses, mental health services, to some extent.

But because, like Rita, because Medicare is a

fee-for-service environment, I think the possibilities for proliferation are quite great. And so I think we would want to approach it that way, and not just assume, because the use has been fairly low in the commercial sector that that's what would happen if coverage was expanded in Medicare.

Having said that, I would like -- I think we have to consider the fact that none of them seem to have any restrictions about urban versus rural, and it's something that would defer to clinicians and hospital people, that it seems to me there might be good reason for even two urban hospitals to consult, or physicians in an urban area to consult with a given hospital in the same urban area to get the right specialist to consider some issue.

So I guess I wonder about the urban-rural thing, which I think was always looked at as a way to limit use to the most desperate situations. But we ought to at least consider that and the experience of the commercial sector.

The other area, and I know it's outside the remit, is Medicare Advantage. And I come back to something that I think was touched on in the first report, which was the fact that home health agencies have greater flexibility

to use telehealth because they are being paid under, you know, the episode. I don't understand why we don't give MA plans all the flexibility they want under the payment, you know, per-beneficiary payment amounts, to use telehealth services, and why we make them charge an extra amount, or use their savings to provide extra telehealth services. It just strikes me as an odd thing, particularly given that we have -- that the policy is different for home health agencies. I don't see why MA couldn't use the same flexibility.

So, anyway, that's, I know, outside the remit of this report but something that we should think about.

DR. CROSSON: Bruce.

MR. PYENSON: Boy, there's been a lot of great comments and I just wanted to pick up on David's comment, that I was surprised at the very low reported utilization. And I've seen data across a few states for a particular organization that was much, much higher, and, you know, in this sort of thing you're always wondering what the data reflects or what might be in -- I think the report mentioned market scan from a few years ago. But it seems as though this might be a benefit that is particularly

attractive to millennials and not yet baby boomers. So there might be a few more generations for Medicare.

But on the cost issue, it struck me that we might not want to think about, as David said, having a site-neutral payment. From an RBRVS standpoint, we might think of a telehealth reimbursement as having close to zero work expense, practice expense. And I suspect, from a business model, some of the lower-priced, ultimately the carve-out companies' business model, their expense is based on probably pretty low work expense overhead.

So we might want to consider that in thinking about the potential Medicare cost.

DR. CROSSON: Warner.

MR. THOMAS: I thought the report was helpful. I think that the comments I would make, I understand the concerns about fee for service and potential for overutilization, but I think there is a big opportunity for the replacement of certain care, specifically ER visits and fact that people have to travel for care. And I know, you know -- I think if we are really concerned it I think what we ought to do is potentially, then, pilot this and let the ACOs or MSSP entities, you know, be able to use this as a

tool and be able to even have it on a fee for service reimbursement, especially if they are taking, you know, some risk. Maybe it would also give incentives for organizations to go in that direction.

But I still think this is a technology that is going to fundamentally change our delivery of care and not supporting it is, I think, short-sighted, frankly. I can understand the concern about utilization issues, but, you know, frankly, we don't have utilization control on anything else in fee for service Medicare. So, you know, I just -- I have trouble understanding that when -- even though I hear the concerns, when we're not dialing in utilization controls in other areas, you know, whether it's home health or drug pricing or whatever.

So this is something that has the potential to replace high-cost visits and high-cost ER visits, and has a potential to make care of people more preventative. I do think there's application to people, you know, over 40, and I think we're on a very early phase here, and I think this is going to accelerate a lot. We've seen tremendous acceleration just in '17. So, anyway, that's just -- I would encourage us to be supportive of this technology and

not inhibit it, because I think it could be helpful for patients.

DR. CROSSON: Okay. Let's come up this way. Jack.

DR. HOADLEY: First of all, I really did enjoy both of these presentations. My guess is that we are probably not going to be drawing any broad conclusions or making any broad recommendations, given the scope of this particular mandated report and given some of the variety of thoughts we've had around the table. You know, we could make an exception on something like the urban-rural distinction. That might one where, you know, we could potentially get to the point of, you know, either a recommendation or at least a statement in favor.

But it seems to me, and this, to some extent, builds on my comments from last month, what we're really getting here, it seems like, is a really useful collection of information on how telehealth varies in a lot of these different service situations. So we've talked about the Telestroke care, the psych care, the inpatient follow-up, remote patient monitoring, the consulting with specialists, E&M. There's been maybe a dozen different sort of

categories of care that have been highlighted in the various presentations.

And it seems like if we can -- we could do a real service in this report by sort of walking through each of those, with respect to a number of the things that the research has dealt with. What are the Medicare rules that apply today? What's the private insurance use for that particular category? What's the value, in terms of is that something where patient satisfaction or if there is any outcome information, you know, kind of plays out? What's the potential for that particular category, for substitution versus new demand?

We're not going to be able to have definitive -- you know, this is not a table that has yes, a simple checkmark, because a lot of these are going to be nuanced. But financial implications, cost sharing -- it seems like if we walk through a set of six or eight sort of things for each of these 10 or 12 service categories we've talked about, we really will help to lay a framework, that we could go back to later, that Congress could use, that the broader community could use, to think about how telehealth may be more valuable in this category than another, as of

today. You know, that will easily change. I think Warner is right. This is something that if we look in two years could look very, very different.

But if we are just sort of framing it up where it is today in a way to use all the different information we've gotten from these different sources to organize that, it seems like that would be a way we could really make this report a useful one, given that I think we are unlikely to draw any broad, across-the-board conclusions or make some global recommendation that, yes, Medicare should, you know, open it up broadly, or, you know, try to keep it really limited the way it is today.

DR. CROSSON: Okay. Paul.

DR. GINSBURG: Yeah. A few thoughts. I am really struck again by how heterogeneous telehealth is, and, in fact, promptly early on in this report we probably should be very clear what people mean by telehealth, what we mean by telehealth. You know, basic questions like, does this include e-mails? From listening to everything we've said, I don't think we are including it, but we need to be very explicit about what's included, and why we are making these decisions, for the report.

I am concerned about, you know, the open-ended, fee-for-service environment of Medicare. I remember Craig telling us how focused and how supported by pilots Anthem's work in this area is, and just to throw it open in an unconstrained environment, that's something else. I think, like Jack, I think we should be thinking in terms of a number of discrete types of telehealth, to try to identify what seems particularly promising.

But I'm really concerned about, this is going to be very challenging for Medicare policy-making, because so much of it is made in legislation, and in a rapidly changing environment. What is legislated is going to be obsolete very soon, and maybe we should even, as part of this coax, point out that it's moving fast. This might be an area where Congress wants to give CMS a lot more discretion than it would tend to give, to avoid what's happened in a lot of other areas where the fact that there are no Medicare bills for years bring the program way behind.

I did like Warner's idea about thinking in terms of some of the risk environments in Medicare, like ACOs, like Medicare Advantage, allowing more flexibility in those

environments than outside of those environments. And that might be a good approach.

DR. CROSSON: Thank you.

Amy.

MS. BRICKER: A couple things. At my company, we have had some tremendous success in remote monitoring and the ability to intervene with a patient with respect to diabetes management as well as asthma and COPD, and so I think that -- I'm happy to share that with you, if you're interested, but I think that there is value in being able to take advantage of the technologies that are available and to intervene sooner rather than later in the hopes of preventing some sort of exacerbation if you will or presentation at the ED.

Agreed with Warner's comment around prevention of unnecessary ED visits separately from that comment in the hopes that if you can connect with a professional that can say, "You know what? You're okay. You don't need to go." I'm thinking moms, late at night with the kid, what have you, that is not sure and ends up at the ED and unnecessary costs associated with that. I think that it's just peace of mind.

And, you know, I'm also excited about the opportunity around behavioral health. Coming from a small town, I can understand the comments that were made in your interviews with people that say the stigma associated with me in the parking lot. I think that's real. I think that people don't want necessarily to have to face into that in their community.

So I think if it's not a widespread green light and supportive of what others have already said around allowing some flexibility in ACOs or MA plans -- love that idea -- if not that, then some pilots with behavioral health or in some way so that we can -- I think the conversations around hesitancy are all for the right reasons, as stewards of the program and not wanting to open the flood gates. But I'm not sure that this is the thing that is going to make the difference with respect to that, meaning maybe we're overly cautious here, given the information that you've presented and instead of embracing the technology and the advancements and where people want to be seen sort of in their homes, in the privacy of their homes, versus this revenue stream that we fear that physicians would take advantage of, so in support.

And thank you for the report.

DR. CROSSON: Dana.

DR. SAFRAN: So I'm also very much in support.

I do favor quite strongly doing a testing of this in ACO and Medicare Advantage environments as opposed to the fee-for-service environment. I really take to heart Warner and Amy's points: Is this really going to be the straw that breaks the camel's back?

But on the other hand, I think that what we are looking to do with this technology is to continue and accelerate transformation and to kind of clinical -- a physician friend of mine calls it "break the tyranny of the office visit," and I'd call it "breaking the tyranny of building-centered care."

But it feels like in the context of fee-for-service, it will be an "and," and we'll also have this struggle around the fees for this are the same or less than the fees for the in-person.

So I think there are a lot of good reasons to do tests, as folks have indicated, and I personally would confine those to the budget environment, where they're looking to find the lowest cost, best way to get care to

patients. And that may be much more often in things that don't have walls.

DR. CROSSON: Craig.

DR. SAMITT: I just want to jump onto the tyranny of the office visit comment. One of the things that I would say is I do believe that we need to be consistent when we talk about a desire to cover high-value and not low-value services, and I think we come in with a paradigm that the way we've always been doing things is high value. And anything new, we have to hold up against that, and the new things may be low value.

So, as we think about telehealth, there's admittedly an insufficient body of evidence, but at some point when we find that telehealth could be equally high touch, equally high quality and lower cost than existing services, then we have to be consistent in our own thinking about how we're defining high value and low value. And we just have to look at other industries.

We could argue that we should never use Uber and Lyft because Yellow Cabs have a licensing process and they're more easily and readily available, and so that's high value. But, obviously, the new generation is finding

high value in something different, which is technologically enabled. So I think we have to prepare for the likelihood that similar higher value, newer alternatives will exist in health care than we've offered to patients and members in the past.

DR. CROSSON: Okay. Thank you. Thank you.

This has been a good discussion. It's interesting. It's very balanced. As a matter of fact, it's so balanced --

[Laughter.]

DR. CROSSON: -- that I'm getting pretty curious about what you all are going to come back with in November.

No, seriously, it's been --

MR. GAUMER: Something bold.

[Laughter.]

DR. CROSSON: It's very good work. It's been very helpful.

I think we've got the Commission primed and ready for a discussion of the options, and I think having joked about it, I think you do have, I think, a little bit of a central tendency here that will prove useful.

So thanks a lot, and we'll see you back in

November.

Now we have time for public comment period. If there are any members of our -- any of our guests who would like to come up and make a comment, now is the time to do that. Please line up at the microphone if you want to.

[No response.]

DR. CROSSON: Okay. I think seeing none, we are adjourned until something like 8:30 tomorrow morning.

[Whereupon, at 4:26 p.m., the meeting recessed, to reconvene at 8:30 a.m. on Friday, October 6, 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, October 6, 2017
8:32 a.m.

COMMISSIONERS PRESENT:

FRANCIS J. CROSSON, MD, Chair
JON B. CHRISTIANSON, PhD, Vice Chair
AMY BRICKER, RPh
KATHY BUTO, MPA
ALICE COOMBS, MD
BRIAN DeBUSK, PhD
PAUL GINSBURG, PhD
DAVID GRABOWSKI, PhD
JACK HOADLEY, PhD
DAVID NERENZ, PhD
BRUCE PYENSON, FSA, MAAA
RITA REDBERG, MD, MSc
DANA GELB SAFRAN, ScD
CRAIG SAMITT, MD, MBA
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AGENDA PAGE

P R O C E E D I N G S

[8:32 a.m.]

DR. CROSSON: Okay. I think we can begin. Good morning, everybody. Welcome to our guests.

The first item for this morning is redesigning Medicare's hospital value incentive programs, and Jeff and Ledia are here, and it looks like Ledia is going to start. Thank you.

MS. TABOR: Good morning. For several years, the Medicare program has used four different programs to provide hospitals with incentive payments based on the quality of their care. Quality has been improving at least partly due to these programs. However, past Commissioners and the hospital industry have raised concerns that the designs of these programs are complex, overlap, and send different performance signals to hospitals. Also, aspects of the programs do not align with Commission's principles for quality measurement.

Today we'll discuss how the Congress and CMS can design one simpler hospital value incentive program that rewards hospitals for the quality and value of the care they provide to beneficiaries and aligns with the

Commission's principles for measuring quality. We are focusing on inpatient care today, but over time there are opportunities to expand this work to outpatient care.

First, I'll review the hospital quality payment programs and our concerns with their current design. Then we'll present a draft design, measures, and scoring methodology for a redesigned, budget-neutral hospital value incentive program, or HVIP. We then plan to use your feedback and current data to model HVIP scores and payment adjustment to present to you in the spring.

I'll now briefly review the current hospital quality payment programs.

In the Inpatient Quality Reporting Program, hospitals report about half of 60 measures to CMS (such as through medical record abstraction) while the other half are claims-based outcome or cost measures that CMS calculates. In 2016, nearly all inpatient hospitals met the program's requirements and received their full annual market basket update.

In yellow, the Hospital Readmissions Reduction Program reduces up to 3 percent of a hospital's base DRG payment if the hospital has excess Medicare readmissions

over a three-year period for selected conditions, such as pneumonia.

In blue, the Hospital Acquired Condition Reduction Program ranks hospitals on their total rate of preventable conditions in two categories: first, claims-calculated patient safety indicators such as pressure ulcer rates; and, second, hospital-reported health care-associated infections such as surgical site infections. The 25 percent of poorest performing hospitals receive a 1 percent reduction in all inpatient payments.

In orange, the Hospital Value-based Purchasing, or VBP, program uses a combination of measures from four quality domains to develop hospital scores: patient experience, safety, efficiency, and clinical care. The program is budget-neutral, so CMS redistributes a pool of dollars equal to 2 percent of base and patient DRG payments to hospitals.

Before moving on, I want to point out that Medicare is currently publicly reporting quality results from these programs to consumers and providers on CMS' Hospital Compare website.

In the past the Commission has expressed four

main concerns about the design of the current hospital quality payment programs. First, there are currently too many overlapping programs, which creates unneeded complexity in Medicare and for hospitals. For example, a hospital's payment is tied to their infection rates in both the VBP and HAC reduction programs.

Second, all-condition mortality and readmission measures are more appropriate to measure the performance of hospitals rather than the condition-specific measures that are currently used in the programs. Using all-condition measures would increase the number of observations and reduce the random variation that single-condition readmission rates face under current policy.

Third, some of the programs include process measures that are not tied to outcomes and are burdensome to report. Also, some of the provider-reported measures may be inconsistently reported, such as hospital-acquired infections.

Fourth, the program score hospitals using "tournament models," and not on clear, absolute, and prospectively set performance targets. Setting a fixed target would allow aggregate penalties to go down when

industry performance improves.

There is an opportunity to redesign Medicare's hospital quality payment programs to make a budget-neutral hospital value incentive program that will be patient-oriented and promote change in the delivery system. Since current hospital programs are defined in statute, Congress would need to create the new HVIP in legislation. But we believe that CMS has the authority to make some of our suggested changes to hospital quality programs without congressional action, such as using all-condition measures versus condition-specific.

For simplicity, hospitals should have their payment adjusted based on quality and cost measure in one program as opposed to separate programs. Medicare should seek legislation to combine the HRRP and VBP into one program. We would incorporate four measure domains from these programs into the HVIP: readmissions, mortality, spending, and patient experience.

Jeff will discuss how the HVIP would translate quality measure performance to payment using clear performance standards that account for differences in provider populations.

We assume that Medicare would publicly report results of the HVIP on a site like Hospital Compare.

In the new HVIP, the Medicare program would not pay hospitals and other providers for simply reporting measures. Therefore, the Congress could eliminate the IQRP and consider removing payment tied to Medicare quality reporting programs in other sectors where pay-for-performance programs have been implemented, like skilled nursing facilities.

Medicare can also seek legislation to retire the HAC reduction program, which Jeff will talk about in a few minutes.

The Commission believes that quality measurement should be patient-oriented, encourage coordination across providers and time, and promote change in the delivery system. Quality measurement should not be unduly burdensome for providers, and Medicare quality programs should include population-based measures such as outcomes, patient experience, and value.

Based upon these principles, we propose to include four largely CMS-administered quality measures in the HVIP. Providers may choose to use other granular

quality measures to manage their own quality improvement, but these would not factor into Medicare payment.

First, hospital readmission is a clinical measure of care that represents lack of coordination, where patients are put at risk for additional complications. Measuring and adjusting payments based on a hospital's readmission rates holds them accountable for ensuring that beneficiaries have the discharge information they need and encourages hospitals to coordinate with other providers. Since the implementation of the Readmissions Reduction Program, hospitals have taken action and improved readmission rates.

The second measure, mortality during or 30 days after a hospital stay, is an outcome measure that is important to beneficiaries and encourages hospitals to coordinate with post-acute providers. Like the readmission measure, this outcome measure can be determined with a high degree of accuracy. As suggested with the readmissions, we would use an all-condition mortality measure which will hold hospitals more accountable than condition-specific measures.

Third, Medicare spending per beneficiary is a

claims-based value measure that rewards efficient, effective hospital care, not volume of services, and reduces delivery system fragmentation. The measure describes whether Medicare spends more, less, or the same amount per Medicare patient compared to national spending. By pairing the spending measure with mortality and readmissions, hospitals have an incentive to maintain episode quality while reducing episode costs.

Fourth, since the Commission has expressed the importance of measuring patient experience, we propose to use the existing Hospital Consumer Assessment of Healthcare Providers and Systems, or HCAHPS, survey instrument for measuring patients' perspectives on recent hospital stays. The survey results are used to calculate ten core measures of patient experience such as communication with nurses and discharge information. For simplicity, the redesigned HVIP can score hospitals only on the overall hospital rating measure which is how many patients rated the hospital a 9 or a 10. Outside of the four measures I just described, hospitals can continue to use the other measures for their own quality improvement activities.

I'll now turn it over to Jeff to discuss the HVIP

scoring methodology.

DR. STENSLAND: All right. Now I will outline how the quality scores and value score Ledia just talked about could be translated into financial rewards for the hospital, and this could be refined over time.

As she said, quality targets will be prospective. So if a hospital reaches the target, they get full points. For example, if each domain was worth 10 points and a hospital kept its readmission rate below the target, it would get the full 10 points. If the readmission rate was 10 percent above the target, it would receive less than the full 10 points.

We would then sum the points over the four domains Ledia talked about. The hospital would just have one overall performance score, but they would still receive more detailed information on each domain to help them make actionable steps toward improving quality.

The one score would be converted into bonus points.

First, all hospitals would face a withhold, for example, 2 percent.

Second, hospitals would be divided into peer

groups. For example, peer groups could be deciles based on the hospital's share of low-income patients. This is consistent with the Commission's past principles on addressing SES.

CMS would prospectively set how much each quality point will increase inpatient payments, and they would do this so that CMS would expect to distribute 100 percent of the withholds as quality bonuses.

The net effect is that hospitals that outperform the benchmark for their peer group would receive more than their withhold. For example, if Grady Memorial outperformed the expected performance of Cook County and others in the low-income decile, it would receive more in bonuses than it paid in withholds. In contrast, poor performers would receive less than their withhold.

One thing we have not talked about is hospital-acquired infections, and everyone agrees that reducing hospital-acquired infections is an important objective. The question is whether the infection rates belong in the HVIP.

We propose requiring hospitals to continue to report their infection rates to the CDC and continue to

work with the CDC on reducing infections as a condition of participation in Medicare.

However, infection rates would not be in the HVIP and would not affect payment rates. There are at least two reasons why infections are less attractive than mortality and readmissions.

First, false negatives and false positive findings are more likely for hospital-acquired infections than for readmissions or mortality. We know with great accuracy if someone has died or if they were readmitted. In contrast, some infections that are reported may have been present prior to admission -- a false positive. In addition, some infections may develop during the admission that may not be detected during that admission, and that would be a false negative.

And, second, we don't want to place financial penalties on hospitals that make efforts to improve their detection of infections. Similarly, we do not want to reward hospitals that spend fewer resources on detection of infections resulting in biased, incomplete infection rates.

As I said, while hospital-acquired infections would no longer affect payment, hospitals would still be

required to work with CDC and try to reduce their infection rates.

So this brings us to your discussion. We are happy to answer any clarifying questions, and then we welcome feedback on refining the design, measures, and scoring. In particular the scoring mechanism will continue to be refined as we start to simulate the results.

Now I will turn it over to Jay for clarifying questions.

DR. CROSSON: Okay. Thank you, Ledia and Jeff.

We are open now to clarifying questions. Let's start over here with Jon.

DR. CHRISTIANSON: So based on your presentation, when you collapse the four domains into one score, you're weighting them equally. Or do you have any opinion about whether they should be weighted equally?

MS. TABOR: That would be a question for the Commission, but we did think an equal weighting would be simpler and, you know, kind of put less value judgment into the value incentive program. But the Commission should discuss whether they want to weight things differently?

DR. CHRISTIANSON: Yeah, I think we should. I

think weighting equally is a value judgment in itself, so I think we would need to talk about that, yeah.

DR. CROSSON: Dana.

DR. SAFRAN: Three quick questions.

So, one, on the HCAHPS I'm curious about your choice of just the global rating as opposed to the more sort of clinically meaningful and actionable composite measures and maybe compositing them.

MS. TABOR: So we went with just simpler, that one measure would be kind of easier for hospitals to track and score, knowing that they would still continue to HCAHPS and monitor those all individual measures. But, you know, that's another question for the Commission. You know, should we use the other ten measures or not?

DR. SAFRAN: Okay.

MS. TABOR: Yeah.

DR. SAFRAN: Can you say a little bit more about the exclusion of the HAC? You know, Jeff, maybe this is for you. I see a rationale there, but can you just say a little bit more about what's behind the concern? Because to me -- well, I don't want to get into a Round 2 value statement, so can you just explain a little bit more?

DR. STENSLAND: We'll welcome your value statement later.

[Laughter.]

DR. STENSLAND: But we were trying to keep it simpler, and we did look at some of the literature that suggested that there was some unequal reporting amongst different entities of their infection rates, and especially things like pressure ulcers also, and that some places had a better reporting of those on the claims than other places. And we did not want to reward poor reporting.

DR. SAFRAN: Yeah.

DR. STENSLAND: And the other ones are really clear. You know, it's kind of like any sort of model you're doing, the others we are very confident in the -- we got the dependent variable right, and then we have to get the risk adjustment.

DR. SAFRAN: Yeah.

DR. STENSLAND: But with the infection rate, we weren't always sure we got the dependent variable right, even before we start to get to risk adjustment.

DR. SAFRAN: Okay. Thank you. And then my final question is on the SES peer grouping. I think I understand

-- and, again, I'll save my reactions to it, if I do understand it, for Round 2. But I think what you're saying is that by doing the peer grouping, you are sending a different performance standard for hospitals based on their SES, not necessarily trying to provide additional resources to those who care for a lower SES population in order to assist them in being high performers. Do I understand that right?

DR. STENSLAND: Well, there is some past work that the Commission said that the QIO dollars could be redirected toward helping poor performers. So we have that kind of on the books. And I think we would still have everybody reporting their scores, so if you're looking at the scores, you could see the scores for the different entities. But when it comes to moving around the money, like say the people treating the poorest people would be just competing against each other, because we didn't want to disproportionately take money away from the hospitals treating the lower-income folks.

DR. SAFRAN: Yep. Understood. So let me ask it a different way. So when you talked about the absolute performance thresholds, by doing the peer grouping, that

absolute performance threshold will be different for those treating lower SES than it will for other hospitals. Is that what you're saying?

DR. STENSLAND: For the money distribution, it will. I don't want to make a value judgment saying that we don't have an expectation that in the long run they should be lower. It's just for distributing the money.

DR. SAFRAN: Thanks. Got it.

DR. CROSSON: Brian.

DR. DeBUSK: First of all, great chapter. Really love where you are with this. So my next hair-splitting question is certainly not a criticism of what you guys are doing. If you'll go to Chart 7 where you look at the CMS-administered measures, none of those four are adjusted for SES in and of themselves. What you're proposing is a composite score and then adjusting the composite score for SES. Well, that stratification is a very non-linear process, obviously. Have we considered -- and this is the question: Have you considered or played around with models that did the stratification prior to calculating the composite score, but because of that non-linearity they will be -- you will get different answers?

DR. STENSLAND: Yeah, I think you could get a different answer. But in the end, if our goal is to not disproportionately take money away from the poor hospitals, we thought we would aggregate them first and then do it. But --

DR. DeBUSK: Could you stratify each of the four domains --

DR. STENSLAND: You could do it that way, too.

DR. DeBUSK: Okay. You might want to run it that way just because you're introducing -- we can talk about it offline.

DR. STENSLAND: Okay.

DR. DeBUSK: But I think you're introducing a high variability data point, calculating a composite score, and then trying to stratify.

DR. STENSLAND: Right.

DR. DeBUSK: Some of those extremes in the raw data may actually skew the result.

DR. STENSLAND: Yeah, the only thing I thought of when we were going through this is we might actually remove some of that variability when we look at the composite measure, like some of the literature would say if you look

at mortality, African Americans tend to have lower mortality, higher readmission rates. And we could put those two things together and have the SES move the -- or the income quartiles might move the adjustment in different directions for those. But if we put them together, I think we might have less of a movement.

DR. DeBUSK: Well, you will get migration toward the mean.

DR. STENSLAND: Yeah.

DR. DeBUSK: I mean the average of an average. Okay. I was just wondering. Hopefully, if you'll at least keep one eye open on that --

DR. STENSLAND: Okay.

DR. DeBUSK: -- because I think we might get a materially different answer, depending on when we apply the peer grouping.

DR. STENSLAND: Okay.

DR. CROSSON: Paul.

DR. GINSBURG: Yeah, I'm also on Slide 7. When I look at the four measures, readmissions, I take it there's a target, a threshold. So what you get depends on how close you get to your target.

The other three, are they similar as far as having a target as opposed to continuous, the better you do, the more score you'll get?

DR. STENSLAND: I would say both. I think the one principle that I think people were generally on board here is we want prospective targets ---

DR. GINSBURG: Yeah.

DR. STENSLAND: -- so that the provider know in advance, "This is where I need to get to get all my withhold back," and so there would be targets for each of the domains.

But if you are below the target, how much you would lose would be -- it would be continuous. So it wouldn't be like a cutoff like it is for the hospital-acquired infections, where either you get 1 percent or nothing.

DR. GINSBURG: Yeah.

DR. STENSLAND: Like as I said, if you're 1 percent worse than your target, you'll lose 1 percent of the domain points.

DR. GINSBURG: Yeah.

DR. STENSLAND: So it would be continuous and

prospective.

DR. GINSBURG: Okay. Because, in a sense, if you did it, maybe you'd call this a tournament model, but if you took all four measures and they were all continuous, the better you do, the more points you get. And, of course, there would have to be a projection about performance to calibrate that. Wouldn't that engage hospitals more fully if the better they do, the more -- it's a problem I've always had with the readmissions policy, the fact that lots of hospitals are off the hook because they're nowhere near the score for penalty, whereas if you did it this way, everyone would be trying to reduce their readmissions.

DR. STENSLAND: So you want a continuous, going up, both up, down and below?

DR. GINSBURG: Yeah, just to think about it. Yeah. On all of them, I guess.

DR. CROSSON: Rita.

DR. REDBERG: Thanks. It's a great chapter, and I like simplification.

I just have a question. It's peripherally related on HCAHPS. Do you know what percentage of hospital

discharges actually fill out -- get sent the form, and then of those, what percent fill it out?

MS. TABOR: The national response rate is about 28 percent. So I'm not -- there is as methodology on kind of how many have to get sent out by each hospital to get the appropriate sampling, which I don't have offhand, but in general, to answer your question, 28 percent is the response rate.

DR. REDBERG: Twenty-eight percent of people that get sent the form and fill it out, but that's not all the discharges, right?

MS. TABOR: Exactly.

DR. REDBERG: Okay. Thank you.

DR. CROSSON: Jack.

DR. HOADLEY: So I just wanted to make sure I understand the scoring of the dollar flow.

So, in your example, it's a 2 percent withhold, so that when all is said and done, the worse a hospital would do if they were sort of at the very worst scores would be to be a minus 2 percent, right?

And then, generally speaking, your idea is that if you hit the targets, you'd end up back at zero; is that

right?

DR. STENSLAND: You get --

DR. HOADLEY: If you hit the various benchmarks.

DR. STENSLAND: Yeah, I think you --

DR. GINSBURG: I don't think so.

DR. STENSLAND: -- would be getting a bonus, if you got over it, because there's going to be -- there's going to be an expectation that some people won't -- they won't get their full amount.

DR. HOADLEY: So I'm trying to get a sense of it. So that some people would get like a plus 2? They would get more than the withhold back?

DR. STENSLAND: Right.

DR. HOADLEY: It's a budget-neutral distribution, I assume?

DR. STENSLAND: Yes. It would be projected to be budget neutral, but it wouldn't necessarily be budget neutral.

DR. HOADLEY: Okay. Projected to be budget neutral.

And is the notion to set a maximum amount that a hospital could get?

DR. STENSLAND: We could. We haven't dealt with the maximum, but you could put something in there.

DR. HOADLEY: Okay.

The other question I had is sort of similar to a question I asked in the MIPS discussion yesterday. Are there any particular concerns about the loss of some of the existing quality measures? I know you talked about the infections and so forth, and that seemed like a creative way to try to make sure that targeting isn't lost, but are there other concerns that you would have that even if the overall scheme makes sense that we're losing some information or we're losing some targeting on some of the other outcomes measures?

MS. TABOR: I think that that would, again, be a question for the Commission. There is the data right now, but the measures are not producing very valuable information. Everybody is kind of topped out on these process measures to kind of check the box, so --

DR. HOADLEY: And I'm thinking more the outcomes than the process, in any case.

MS. TABOR: Yeah. I think that we discussed internally that the kind of condition-specific measures

that hospitals may be using now for mortality and readmissions, that CMS could still play a role in kind of calculating those out so hospitals would have those. So you'd still have the measures in the area --

DR. HOADLEY: Okay.

MS. TABOR: -- but it just wouldn't be tied to payment.

DR. HOADLEY: Okay. Thank you.

DR. MILLER: Yeah. And this is something that we've talked about -- lots of measures where you're trying to simplify, give the hospital something to focus on.

There were some discussions between the hospitals and CMS about things that the hospitals had concerns about, and apparently, the four overlapping measures was one of the things that was high on their list to say this is a complaint.

To us, it seemed like yeah, and that's a direction the Commission is kind of going. Can we simplify this, put it on a non-tournament basis, kind of go forward?

Then the other thing to keep in mind is these are the measures to move money around and the exchange that you just had that if CMS were calculating other information

that they were collecting below this and disaggregated, it doesn't necessarily mean it has to disappear. But for the purposes of moving large blocks of money around, do you have something that people can see, kind of understand what they're working against? That's the question on the table.

DR. CROSSON: The other thing that struck me as an infectious disease physician, because I initially bridled at getting rid of the rewards or penalties for hospital-acquired infections, particularly was the fact that if, in fact, the hospitals are being held accountable for mortality and readmissions, one would have to think, if you were running a hospital, that if you didn't continue, as hospitals have been doing very well recently, managing infections, that would increase -- likely increase both your mortality rate and your readmission rate. I don't think we're abandoning that pressure completely.

DR. HOADLEY: Right. I think that makes sense, and I'll come back on Round 2.

DR. CROSSON: Jon, on this?

DR. CHRISTIANSON: Yeah. I'm still confused a little bit about the money flow based on Jack's comments.

You have the 2 percent withhold, which the closer

you get to the benchmark, the less of that you lose. Is that right? And so if you get to the benchmark, you get your whole withhold back? Is that what you're saying?

DR. STENSLAND: We can make it more like Paul wanted to make it, continuous up and down, but the way we originally had thought about it was CMS would project, based on past performance, where everybody would be, so that all the money would be disbursed. So people that are below the benchmark are going to get less than the full amount of the money.

DR. CHRISTIANSON: Less than the full amount of the withhold?

DR. STENSLAND: Less, because they're not going to get full point, so they won't get their full 2 percent back.

DR. CHRISTIANSON: Right.

What about above? That's the --

DR. STENSLAND: Well, then if you're at or above, you're going to get more than --

DR. CHRISTIANSON: Yeah.

DR. STENSLAND: -- more than your withhold back because the people that are at or above the threshold are

going to get some of the money from the people below.

DR. CHRISTIANSON: So what's the function that determines how much you're going to make above the withhold once you get above the benchmark?

DR. STENSLAND: I think that function would be a function of basically how much are we taking -- how much of the withhold is not going back to the people that are projected to be below the withhold, so then you have a pool of dollars that aren't going back to people. And that pool of dollars would be going to the people that you think are going to make the threshold, and you just compute what that percentage add-on would be for those people in order to spend all those dollars.

DR. CHRISTIANSON: Okay. That's the part that I'm confused about, is how you spend those dollars above the benchmark. And maybe that's to be determined.

DR. MILLER: Just a second. The other way to interpret his question is you get what you get above it and also how you perform below it is a function of the four categories and how many points you rack up on each of those and then are summed together. Is that what he's asking?

DR. STENSLAND: Well --

DR. MILLER: Like you're asking how does the money go -- so talk a little bit about, you know -- and I know you did it --

DR. STENSLAND: Yeah.

DR. MILLER: -- the four domains, equally weighted, Jon, which you've already raised is an issue, but just run through that.

DR. STENSLAND: So let's see if I can do this off the top of my head, but if we had four people in this or four organizations in this and two were below and between those two below, they only got a fraction of the points up to the benchmark, so they only got a fraction of their withhold back -- and let's say those two ended up losing $100,000 each because they didn't get up to the benchmark, so now you have $200,000 to work with. And you have $200,000 to work with for these two that met the benchmark. Then you kind of have a projection of what very impatient payments will be next year, and you say how much -- what percentage would we have to increase their payments in order to spend that full $200,000, and that's the percentage increase that they get above the full 2 percent withhold.

DR. CHRISTIANSON: So, basically, if you're below the benchmark, you have a pretty good idea about what you're going to lose. If you're above the benchmark, you don't have any idea ahead of time what you're going to get because it depends on how much people don't get to the benchmark.

DR. STENSLAND: Yeah. The way it's structured now is you know you're at least going to get your 2 percent back and something else. You don't know how much that something else is.

Now, we could also do it Paul's way where it's continuous. The farther above you are the benchmark, the more money you get.

DR. MILLER: But wait a second. There is some now -- and I don't want to deal with Paul's way yet --

DR. STENSLAND: Okay, okay.

DR. MILLER: -- because I think that's harder for me to think about.

But since this is being done prospectively, there would be sort of a notice, rulemaking, that type of thing, and what the hospital would have a sense of is if it hits the target where it is and then each point above that

target, what they would be likely to get.

Now, they may not know what they're going to -- how they're actually going to perform, but they would have some sense of what that would produce for them. Is that --

DR. STENSLAND: That is the idea, and I think I wasn't clear a minute ago, but that is the idea that there would be some -- some schedule up of -- you know, you get this many points. This is the percentage add-on you're going to be getting next year, and this would all be a projection that CMS would make. And CMS might get it wrong, and if people do better than expected, well, then they get more money out of the Medicare system than they put in on aggregate. If they do worse than expected, they get less money. It would work similar to the way the outlier system works with payments.

DR. MILLER: That's how I think about it.

MS. BUTO: But that's only if all -- I mean, if all of them in that cohort do better than expected, then they may not get better than expected in the bonus. In other words, what if everybody exceeds the standard? The standard is, it turns out too low or based on prior behavior, then you're at zero, right?

DR. STENSLAND: They would get -- still get more because CMS would set it in advance of saying if you reach this threshold, this is how much extra add-on you will get. And if people just happened to do better than CMS had expected --

MS. BUTO: Then it's not budget neutral, you're saying.

DR. STENSLAND: -- then it's not budget neutral.

MS. BUTO: Yeah. I gotcha. Okay.

DR. STENSLAND: So this is -- it's projected to be budget neutral, but it won't necessarily actually be budget neutral because there will be some error. It's like the outlier payments are projected to give back everything that we take in the withhold, but sometimes we give back more. Sometimes CMS gives back less.

DR. SAMITT: So now I'm a bit more confused than before, and I guess if I can ask some pointed questions to help clear it up, so this is --

DR. MILLER: Can I ask one thing just before you do that?

DR. SAMITT: Yeah.

DR. MILLER: Do you understand that, Jon, because

you started it -- [speaking off microphone].

DR. CHRISTIANSON: I think I understand what you're saying. I haven't processed whether I think it's a good way to go yet, but --

DR. SAMITT: So correct me if I'm wrong with my assertions. This is no longer a tournament. It is no longer a zero-sum game, which means that if everyone outperforms, then we will spend more than the 2 percent withhold.

DR. CROSSON: Remember, in the beginning, Jeff said "projected budget neutral," not mechanically budget neutral.

DR. MILLER: Yeah. And understand if they do the projection one year and they get it wildly wrong, then they're going to fix the projection for the next year. So that the notion isn't that, oh, we're going to spend all of this out or we're not going to spend any of it out because the projection is so far wrong. The idea is to make a projection based on behavior, set a standard that everybody can see. If I'm above it, I'll get this many dollars. If I'm below it, I'll lose this many dollars. And then, in a sense, it's almost like rough justice through time. You

might get it a little off. You get it a little under, and it kind of moves through time that way.

If there's one wild year where everything is wrong, then their projection has to change.

DR. CHRISTIANSON: Kathy's comment helped clear it up for me because we're not budget neutral year by year, so I was wondering whether there would be some sort of clawback or something. There isn't, as Mark just said.

DR. REDBERG: And it would depend a lot on where the performance targets are set.

DR. CROSSON: And also -- and I want to throw this complexity into it, but as I was thinking about what Paul said, we're assuming here that both on the upside and the downside, there's a linear relationship among the points. One point is worth one point. Two points is worth two points. It doesn't have to be that way. It could be non-linear, which could -- Paul, I think could get perhaps a little bit to what you were thinking, or not?

DR. GINSBURG: I think non-linear is good.

I was also thinking the harnessing behavior like economics. Rather than it being completely continuous, it might be like five different thresholds, in a sense. If

you get to them, you get greater bonuses, as opposed to a more -- because that gives people targets to shoot for.

But the thinking behind the overall suggestion of continuous was let's make it so that all hospitals get rewarded if they do better as opposed to hospitals being able to say, "Oh, we already do great on this measure. We don't try it, try to improve any further."

DR. CROSSON: Well, we're wandering around here. I'm not sure where we are, in 1 or 2.

Craig, did you get your point?

MS. THOMPSON: I just want to say --

DR. CROSSON: I'm sorry.

MS. THOMPSON: -- but keep in mind if every hospital performs above the threshold, what have we done? We've reduced readmissions, and we've reduced the Medicare spending per beneficiary. So I wonder -- measuring process, we are measuring outcomes.

DR. CROSSON: Completely outrageous.

[Laughter.]

MS. THOMPSON: And so I think this question of whether or not it's going to cost the program more, if we're doing what we're saying we're doing here --

DR. MILLER: Yeah. Nicely done.

[Laughter.]

DR. MILLER: That was a good comment.

DR. CROSSON: Craig, did you get buried in here somewhere?

DR. SAMITT: Yeah. How can someone follow that?

[Laughter.]

DR. SAMITT: I'm going to go back to a clarifying question.

DR. CROSSON: Thank you.

DR. SAMITT: Can we go to Slide 3? Have we sort of assessed the collective downside and upside with the new value-based program versus the old program? So when we look at -- if I am a lower performer in the old method versus a high performer, what is the potential span of gain or loss from a risk perspective versus the new program? So the new program is obviously just 2 percent down. The old program seems as if it's far greater than just 2 percent down. So I'll come back to this in Round 2 because, again, it's the question of magnitude.

Have you done that assessment so that we can compare and contrast?

MS. TABOR: So our plan is to do that as part of our analysis for the spring, so we won't have to take kind of the concepts of which measures to use and how do we score in general. We'll play it out and do comparisons about how people performed currently versus how they perform in this new program, so to be determined.

DR. SAMITT: Thank you.

DR. STENSLAND: And just part of --

DR. CROSSON: Okay. I'm sorry.

DR. STENSLAND: I was just going to say part of the reason we've having this discussion now is we're going to try to simulate this. So we want to get your feedback now on what the parameters should be like and how it should be structured, so then we can simulate that as opposed to simulating it.

DR. CROSSON: Reinstituting Round 1 discipline. Clarifying questions?

Bruce.

MR. PYENSON: I was going to say if Jon keeps making this more complicated, the hospitals are going to need actuaries to certify the receivable.

DR. CROSSON: All right.

MS. BUTO: You're all for it.

MR. PYENSON: I'm all for it.

DR. GINSBURG: [Speaking off microphone.]

[Laughter.]

MR. PYENSON: Okay. I very much like the direction this is going.

Back to -- if we could, back to -- I think it is Slide 5. On the measures on the right, it seems as though mortality is -- under this is all-cause mortality, I think. Is that how you're viewing it?

DR. STENSLAND: I think it could be either one. That's kind of what I would call maybe a third-order concern.

I think our first concern is we wanted outcomes. The second concern is we want it to be all conditions, so we wanted to spread across all conditions to get a big N. As David would say, we want more signal to noise there.

DR. NERENZ: One doesn't imply the other. Don't go there.

[Laughter.]

DR. STENSLAND: All right. I just unleashed David, a big mistake.

[Laughter.]

DR. MILLER: Too late. It's on the record.

DR. STENSLAND: And then if we go down to the next one, is to say is it going to be all cause, kind of more the Yale-type measure where it's not exactly all cause, because it's all cause but not planned, or would it be something that makes some judgment call on what's potentially preventable and eliminates some things that are deemed not potentially preventable? I think you could go either way in that sense, and assuming whatever metric comes out, it would be a metric in the public domain that would go through CMS, notice and comment, and people could comment whether they thought it was an appropriate measure.

MR. PYENSON: A question. I think one of the slides, you suggested a 30-day readmission, or was it 30-day mortality? As you know, PPCI has up to 90 days, and most of the action, in fact, happens in the first 30 days. But what do you think the pros and cons of a shorter period or longer period are?

DR. STENSLAND: I think it could be either way. The longer the period, the more you're encouraging the hospital to look out what's happening later. But the

farther you get away from the discharge, the less it's actually in the hospital's sphere of influence. And 30 days is kind of what we're using now, and it seems reasonable.

DR. CROSSON: Kathy.

DR. NERENZ: That's the signal, the noise issue.

[Laughter.]

MR. PYENSON: I'm not sure.

DR. NERENZ: It is.

DR. CROSSON: Kathy.

MS. BUTO: I just wanted to go back to the hospital infections issue. Slide 11 and I guess page 6 in the report, in the reading materials, we talk about the AHRQ study that reported between 2010 and 2015 a reduction of HACs per discharge of 21 percent, and I guess projected savings of $28 billion. And I realize -- and I understand the rationale for wanting to move away from that. But I wondered if you had looked -- because I'll save for Round 2 my thoughts about reporting to CDC, which sounds fine but no payment penalty, I just -- you know, I'm skeptical. So I'm wondering if you looked at or could look at a way to sharpen or make that measure more robust or more, I guess,

something that we could actually validate through claims data in a way that gives us more confidence. And I'll just say that false negatives do not bother me as much because even if a person comes into the hospital with an infection, that person's in the hospital; the infection is potentially dangerous to other patients. Your title is reducing hospital infections, and that strikes me as such an important part of quality and safety in the hospital that not to have it at all just -- I just raise the question of is there a way to somehow capture a piece of that and continue to have that in the measure.

DR. CROSSON: Okay. Pat.

MS. WANG: I think you partially answered my question in responding to Bruce, but to the extent that there are some measures that overlap with other programs, like ACOs and MA, so let's take readmission, is the thought to use the same measure and the same specifications? Or is it possible that you're thinking of using something completely different?

DR. STENSLAND: I think exactly the same measure and exactly the same specifications, and the idea would be that if some -- if there's a physician-owned ACO, we want

their incentives to be aligned with the hospital, so we both want to reduce exactly the same readmission measure.

MS. WANG: Okay. So this is just sort of like a factual thing. How is the data that's reported validated? Or is CMS going to calculate something like the readmission measure based on like a HEDIS specification or something like that?

MS. TABOR: So CMS would calculate the measures.

MS. WANG: CMS would do it.

MS. TABOR: Minus the HCAHPS would be survey-administered, but it's still basically CMS-administered.

MS. WANG: Okay.

MS. TABOR: They run the program.

MS. WANG: And on a similar vein, are you thinking that in setting targets, for example, for readmissions that they would somehow align with what is recognized as target performance in these other programs? For example, that a target readmission rate that even -- or above target qualifies a hospital for a bonus in this program does not equate to two stars in Medicare Advantage, let's say? That's a moving target because it is a tournament model in the case of MA, and it won't be here.

Have you thought about that issue? Because that would send mixed signals.

MS. TABOR: That is something we'll have to keep in mind that I think CMS should consider all providers when setting the targets and that they should be consistent across the providers, so we can spell it out more, if that's what the Commission wants.

MS. WANG: Okay. The other question that I had had to do with the stratification for SES. You know, the example of proportion of duals is mentioned, and this is just a question. Is there variability across states, whether it's -- or is the standard for who is a dual identical?

DR. STENSLAND: Eric? Where's Eric? I ask him this question about three times a year.

MR. ROLLINS: [off microphone].

DR. MILLER: And I think in response to a few of your questions, but starting with the last one, I think our preference has been income, but that has some availability issues, and also the world in general talks about duals a lot more than income. And so I think the Commission has generally taken the position of, fine, you know, if duals

is the way people want to go, or duals or DSH, that type of thing. But there is some variability in that, as Eric is saying. But, you know, again, it's sort of what you want perfectly and what you want in terms of practically.

Your point about, well, how does this link to other programs, again, it's a few years back, but, you know, we talked about this notion -- and, by the way, this conversation should sound a lot like the MIPS conversation yesterday. I hope people are making that connection. It is -- well, no, I didn't mean that --

[Laughter.]

DR. MILLER: -- apparently the way it sounded. I didn't mean it. We're trying to -- we said a few years back, you know, the ideal situation is to have comparability across the fee-for-service, the ACO, and MA environment as much as possible so that all the signals are going in that direction, and fewer and outcome was part of what -- that's part of what drove us to fewer measures and outcome types of measures, plus the burden issue, which, you know, I think is pretty obvious. And we're trying to systematically work our way through -- you know, the MIPS had an immediate feel to it because that's being

implemented. This is a complaint from the hospital industry, and it's a legitimate one, and it's consistent with our principles, trying to deal with that.

We've said a bit about MA, but we've probably not gotten quite up to, you know, that point yet. But you can think of yourselves as working through the continuum and trying to bring a unified vision to the whole thing. But, you know, as always -- unfortunately, Warner is not here. Instead of putting all of it in front of you, we're trying to put it in front of you, you know, systematically so you can deal with it.

DR. CROSSON: Okay. Sue.

MS. THOMPSON: Well, thanks, Jeff and Ledia. As you can tell, I am quite enthusiastic about this focus on outcomes and simplicity.

In that spirit, as you think about mortality and maybe the push-pull that exists between readmissions and mortality for hospitals, and the work in palliative care, and into hospice but even more in terms of the care of the chronic patient who's in a palliative program, any thoughts on exclusions or how to address that piece of the continuum?

DR. STENSLAND: I think that would be a pretty complex thing that CMS could talk about who's going to be excluded and who isn't. But I don't know, I -- I think that's more could than I'd want to get into.

MS. THOMPSON: Okay.

DR. STENSLAND: I'll take this -- just to go back to what Jay said, because he said something I thought was interesting about the HACs. You know, if we're giving -- the hospital infections, there's already some other incentives to reduce your infections in the program, as he says, mortality and readmissions. But also your costs because you're likely to have higher costs within infections, even inside the hospital, and the patient satisfaction score overall. So the idea is if you're getting an infection, probably all four of the other things are going to look worse. Sue would probably have a better idea on that.

DR. MILLER: And can I - I agree with Jeff that I don't want to deal with it on the fly because it sounds very complex. But would you just run it one more time for me so I make sure I know what I'm thinking about after the meeting's over?

MS. THOMPSON: Well, I think between mortality and readmissions, it's that decision of do I keep the patient in the hospital? Do I send them home with the risk that they're going to come back? So if I've had the conversation with the family and we all agree, we're in a chronic here, and we've entered into a palliative program, but there may be a point in time where the patient needs something, pain can't be managed in the home or in whatever setting they're in, they've got to come back into the hospital. So does that then mortality maybe end up being a mortality, or is that an exclusion?

DR. MILLER: Right. So you might not be saying this, but are they brought back to die in the hospital?

MS. THOMPSON: No, they're not. They're likely brought back for some procedure. Maybe there's a --

DR. MILLER: I see.

MS. THOMPSON: -- pain procedure, an intervention that has to happen to control the pain.

DR. MILLER: Okay, so --

MS. THOMPSON: They're not being brought back to prolong life. They're being brought back to manage a symptom that cannot be managed in another setting.

DR. CROSSON: So hospice would not -- would hospice cover that? I know it doesn't completely cover palliative care where you're sort of in between --

MS. THOMPSON: Now you're getting into a benefit question I don't know.

DR. MILLER: I wanted to get a sense of what you were --

DR. GINSBURG: Yeah, I guess there are a lot of ways. You were thinking about coming back for pain relief, but I was thinking that the patients in the palliative program may not live as long and it's 30-day mortality. So in a sense, entering into the palliative care may make the hospital's mortality performance look poorer, and we wouldn't want that to happen.

MS. TABOR: And hopefully the risk adjustment --

DR. CROSSON: Well, we don't want to --

MR. PYENSON: On that point.

DR. CROSSON: Yes, Bruce

MR. PYENSON: There's also evidence that palliative care prolongs life and hospice prolongs life. So it could go either way on that.

DR. MILLER: But at least I understand what

you're getting [off microphone]. Okay. Thank you.

DR. CROSSON: David.

DR. GRABOWSKI: Thanks. Thanks, Jeff and Ledia, for a great report. I wanted to come back and ask again about the peer groupings. I think Mark started to answer my first question, which is what are the candidates here, and it sounds like dual status, DSH payments, you thought about income but that's not there. So I'd like to learn a little bit more about that, and then how are you thinking about validating -- you know, it's critically important that we're comparing apples to apples in each of these deciles. I just want to learn a little bit more about how you're thinking about those groupings, because I think that's going to be a place that you get a lot of pushback. Thanks.

DR. STENSLAND: When we first did it with readmissions, we used the share of the Medicare individuals on SSI, and that was a consistent measurement across all the states, unlike, as Eric says, there's a little bit of inconsistency with the duals. And when we talk about duals, it's important to say that we mean full duals, not like partial duals, because we think that that's really the

indicator of low-income people. And in terms of validating a measure, you know, we'll look at some -- like try to describe who is in these deciles and try to get some validation that way. But if you have any other ideas, we'd be open to it.

DR. GRABOWSKI: As a follow-up, it would be interesting to look at the other payer mix at these hospitals as sort of making certain they're like providers, and it will be interesting to see whether they're largely doing commercial or Medicaid and what are the other payers, as well as a variable.

DR. CROSSON: Okay. More questions? David and then Bruce.

DR. NERENZ: I wasn't going to ask, but it was prompted by David. On this grouping, you know, the illustration is one variable with deciles or whatever. What if it turns out that as this plays out, there are three or four or five variables, all of which matter, all of which are independent from each other? Do you then anticipate a matrix of groupings with a hundred cells? Or what happens?

DR. STENSLAND: I think we might get into -- a

hundred different cells might get into too few of competitors that you're working with to setting these benchmarks. You have a hundred different benchmarks. But if -- and I think this is the most straightforward thing, is to use these income deciles. And at least with readmissions, when we looked at it, it was very monotonic. As your SSI share goes up, your readmission rate went up, risk adjusted. And so that gave us some comfort there.

But if we ended up finding that there was a new SES, something that was much better than income and people all agreed that, yes, this is the way that you should really -- you know, some sort of an index of difficulty of the patients due to SES criteria, if someone came up with one of those, you could just use that index rather than just a simple ten decile.

DR. NERENZ: I'm just raising the question. What if there are four others that are independent but they're equally good? What do you do?

DR. STENSLAND: Then I think you create an index and see if the index really does perform better.

DR. NERENZ: If they're independent, they just make a mess. But, anyway, that's -- I was just asking for

clarification [off microphone].

DR. CROSSON: Bruce.

MR. PYENSON: There's a MedPAC measure that I really like, healthy days at home, and I'm wondering if that's a measure you thought about in this context.

The second question is on the socioeconomic status of people who are receiving long-term-care services in the community have more intense needs but are hard to identify. and I'm wondering if there's a way that you know about that CMS can identify those.

MS. TABOR: I'll take the first question. So the healthy days at home, unfortunately, I think the sample size wouldn't be large enough for the measure to use at the hospital level. We have to kind of use it at more of a market level, which is how we've been testing it.

DR. MILLER: And on the second question, I'm not sure we have a way of knowing that, right?

MS. TABOR: Yeah. I don't...

DR. STENSLAND: No, but if I was looking into that, I might call up David Grabowski and ask him how good of an indicator is the full dual for somebody that's in

long-term care and has these needs.

DR. GRABOWSKI: I would answer it's mixed.

[Laughter.]

DR. CROSSON: Okay. Good questions. We're going to move on to Round 2. I'd just point out that we kind of did a little bit of Round 2 already, so I would sort of ask, you know, let's not -- if you can manage it, let's not repeat the same points. We've got about half an hour, so, Paul, do you want to start?

DR. GINSBURG: I think this was an excellent piece of work and an excellent proposal. I'm very enthusiastic about it. I like the fact that it's simpler, reduces burden on hospitals, it focuses on outcome, and it fosters coordination of care. I stated before I do believe that we should find a way to have the rewards and penalties engage all the hospitals, including the ones that are doing well, as well as the ones doing poorly, so that they all can have a financial incentive to improve their outcomes.

I'd like the financial incentives to be larger as we evolve working on this because I think we have a lot more confidence that these measures are meaningful than the old measures. So in a sense, we should be willing to put

more money behind it.

I love Measure 3. That's the spending, the total Medicare spending per admitted beneficiary, and I like it because it really is fostering coordination of care. And it occurs to me that just one idea to think about is whether to pull it out of the budget neutrality. You know, this is prompted by what Sue said. This is the area where, you know, if we give a lot of rewards for reductions of spending for care, you know, the Medicare program can afford that because its spending is really being held down by those actions.

I'll stop here.

DR. REDBERG: We just weight it higher instead of pulling it out? I worry about pulling it out.

DR. GINSBURG: Yeah, you know, that's a good point. We definitely should discuss the weighting. I'm really glad Jon brought that up. That might be a good way.

DR. CROSSON: Okay. So let's go on to the comment period. I think maybe we'll start over here this time with Pat -- sorry, Craig, did you --

DR. SAMITT: No, I think this was a wonderful piece of work, and I'm very much in favor of an incentive

program that is more simplified, because I think from that perspective it will be more effective. And I'm comfortable, actually, with the measures that have been selected as well. I think that they collectively represent value and they interrelate well.

My only concern about the program, again, is whether the incentive collectively in replacement for all of the other incentives is material enough to really bring attention to the imperative for hospitals to be accountable for each of these measures and whether volume will trump value or fee-for-service will trump quality and cost if the incentive that we're linking to this program is not material enough. So that would be my only concern here.

DR. CROSSON: Pat.

MS. WANG: I would also commend the work and the thinking. The direction is really good, simplification, fewer measures. The elimination of the tournament model I think is really, really important.

I would again recommend, echo what I was asking about before. I think it's very important to the extent that there are overlapping measures to other programs, ACO and MA, to not just align the measures but also to align

the targets so that you have the same signal going. So, you know, a target plus performance, and this program is not the equivalent of two stars in MA because that will be a very confusing conversation for people to have.

The one thing that I should have asked about before, but I would just put on your radar screen in spending per beneficiary, for duals who are receiving long-term care through the Medicaid program in the community or what have you, it's possible that there will be a false positive that Medicare spending is going down because it's being shifted to the Medicaid program. I think that's a phenomenon to be aware of.

I am concerned about the hospital-acquired conditions, the infection rates as well. I take your point about, you know, the unreliability of the current program, but I do hope that there is a way to continue to try to capture that information and at least have it on fully display for the public. I think it's important information.

Thank you.

DR. CROSSON: David.

DR. NERENZ: Thank you. I like this a lot, and I

do plan to support it. I like the simplicity. I like the moving away from double and triple jeopardy that exists in some of the current programs. I'm happy with the outcome focus. I like this a lot. Thank you.

I just want to take a couple minutes just with a cautionary message about the reliance on outcomes, and it's going to be a bit of a sermon, but it won't be long.

It's good to look at outcomes, but if we go to Slide 4, I think around this table, but at other groups as well have -- the third bullet point. When we observe some sort of statistical disconnect between process and outcome, I think we and others have come to the point we say, well, the process measures are suspect, but the outcome measures are fine. And, you know, we're not explicitly saying that, but I think we act as if we thought that sometimes.

Here is my little sermon. One of the great privileges of my professional life was to meet and know and interact with Avedis Donabedian at the University of Michigan who gave us the structure-process-outcome dichotomy. I just want to read you a couple things. I went looking for this after our July meeting.

This is Avedis. Outcomes do not directly assess

quality of performance. They only permit an inference about the quality of process of care, so the essence of quality is in the process, not the outcome. If outcomes are good, we cannot say for certain that care was of high quality. All we can say, that care is more likely to have been of high quality than not, okay?

So I'll just get one other one. To the extent that there are doubts about causal linkage between elements of process and outcomes, the use of the process elements as indicators of quality is of dubious value. Okay. That's kind of what that says.

But for the same reason, the value of the use of the outcomes as indicators of quality is compromised to an equal degree. Okay. So how do I say that? This is my signal to noise thing.

Now, our little interaction here reminded me that the signal noise thing can be used in two different ways, and I should clarify. There's a purely statistical reliability sense. Let's say you look at a number for readmission. There's this question of is that number truly the readmission number, or is there some kind of weird -- okay. Sample size speaks to that. That's okay.

I am using it in a different sense, and I am channeling Donabedian in this. I am focusing on this idea that when you look at outcome, you're not seeing quality directly, and my sense of signal noise is if the essence of quality lives in the processes, what's done or not done, what's done well or not well, to what extent does the outcome truly reflect the quality of the process? That's the sense I'm using it.

And from that, I observe that the readmission measure, for example, particularly in the medical conditions, that's where we see evidence by several independent sources that it's 5 percent signal and 95 percent noise, and we have to wonder is that good enough.

Now, it may be the best we can do. It's okay, but we really have to worry about if part of that 95 percent is systematic bias and not just random error, and we know there's bias. The safety net hospitals, there are different sorts of biases in different areas. Okay. So I'm not saying anything new. It's just kind of a reminder, but where do I take this?

As David pointed out yesterday in the other context, risk adjustment is just crucial here. If this is

going to go forward -- and I'm happy if it does -- we really have to point out the need for better risk adjustment than we have now. There are risk adjustment elements in some of these, as we currently find them, but it's got to get better because not all the biases are removed by the current risk adjustment models that exist. And I think more work needs to be done, and we should recommend that more work be done to make the risk adjustment models better.

So the 5 percent number goes up and the 95 percent number goes down or whatever it is in some of these other domains, and most specifically, the biases are removed. If we know they're systematic biases that advantage or disadvantage certain kind of hospitals, we've got to get that out.

That's why I say what I say about the social factors. I won't belabor that. I've already used up my air time on that point, but my point this morning is more general. That if we go this way, the risk adjustment has got to be better than it is now.

DR. REDBERG: Dave, I see your point, but can you give us an example of a process measure that you think is

so -- in that category of more important than an outcome?

DR. NERENZ: I didn't say that.

DR. REDBERG: Or whatever.

DR. NERENZ: No, no. And I --

DR. REDBERG: What kind of process measures you are Donabedian had in mind?

DR. NERENZ: Well, let's take --

DR. CROSSON: I'm sorry. I don't want to do this dialogue thing. Rita, if you have a point, that's fine, but I don't want to --

DR. REDBERG: I'm just trying to understand that point.

DR. CROSSON: Yeah. No, but arguing back and forth, I don't want to do, okay? I'm sorry.

Kathy.

MS. BUTO: I want to go back to hospital-acquired conditions or infections and just say that I do understand the limitations of the data and our concerns about it. I see that we are pointing to some modification to the conditions of participation as well as reporting to CDC.

My experience is that unless payment is somehow tied to an expectation, it's very hard to move the dial on

something, and at least based on some of the work that AHRQ has done, it appears that there has been real reduction and some real savings associated with the existing measure.

So I come back to I would like to see us take another crack at that. I even compared that to the readmissions reduction program. It looks like they're comparable in terms of impact on spending and overall safety and quality.

One thing we could consider -- I'm not crazy about this, but another way to go at this is -- I guess I call it the shaming factor, which is if there were some way to make available information about infection rates in a way that -- and this is the tough part -- isn't challenged because of the limitations, as you've already pointed out, I think that's another way to go at it, and I think that would have an impact on behavior.

But as a patient or consumer beneficiary, I think the information about infection rates at a given hospital, that information is pretty critical -- I think more interesting to most people who are contemplating a surgery than say what the readmission rate is.

So, again, I'd just ask you to take another look

at that.

DR. CROSSON: Bruce.

MR. PYENSON: I also strongly support the direction we're going in, and thank you for putting it together so clearly.

I want to talk a little bit about why I think an all-cause measure is really needed here. The all-cause measures as opposed to something that might be called potentially preventable extends the responsibility of the hospital to things that are outside the domain of the hospital, but that's exactly what we want to incentivize and cause.

I think the all-cause measures -- rather the potentially preventable measures are often associated with black-box dynamics. They don't have to be, but they've been branded, to some extent, by 3M Corporation. And they create an environment where organizations are thinking about "Am I responsible for this, or am I not?" Given the currents that say we are an accountable organization and we're responsible for whatever it takes, which could include food programs or home assessments or other things like that, I think that broader approach of all-cause is

superior and moving in the right direction.

And those are metrics that are in broad use today. We see those pretty broad all-cause readmissions for bundled payment for care improvement program and the current readmission program for the six conditions.

So I'd like to move not just this program but our other discussions, for example, the examination that we had last year of readmissions from long-stay beneficiaries in nursing homes, to move all of those to an all-cause basis.

I find myself agreeing with several of the Commissioners who think this is really important and important enough to have more money at stake and is 2 percent enough.

I think to David's excellent points about signal to noise, I think there's, unfortunately, a ton of noise in the system today. I think if we're successful, that noise will go down, and I don't think we want to -- and one way to get the noise to go down is to make the incentives more direct and more powerful.

So I think that's the measure of our success, whether the noise and the chaos in the system starts to go away, because I think a lot of that is inherent in the

chaos of the delivery system.

Thank you.

DR. CROSSON: Thank you.

Comments?

Jack.

DR. HOADLEY: So, again, like others, I think we're working in a good direction. I think this has been very helpful in focusing us on that.

I want to make three comments. One is a little bit overlapping with what Kathy was saying, but maybe a little more general, that we kind of know, at least anecdotally -- I don't know if there's a specific literature on this -- that the existence of measurements with payment consequences forces attention on whatever is being measured, and I think it's important to at least go through the exercise.

Even if we think that focusing on the broader measures will ultimately get us better results to go through the exercise of saying are there things like infections where we're going to lose some attention if we take the payment consequence away. Maybe it's only certain measures. Maybe it's just making the case that that's

appropriately overcome by the potential on the broader measure, if you do these things, the mortality will come down, so we're okay. But like at least make sure we've articulated that through and thought that through.

The second point goes to this issue of what we were talking about in Round 1 of sort of how committed we are to taking the tournament model out of this, and I think the way we ended up, the clarifying questions got us to the point where we are pretty thoroughly moving away from it. But it may be, then, in laying out options sort of are there variations of how far; in other words, how much more, how many dollars are at stake? How much more above getting your withhold back can you go?

Paul's points about is it a bunch of thresholds, is it some kind of a continuous things, I think it would be interesting to see some variation, some options for how to do that.

The third point, I guess is a smaller one, but it's about the peer grouping and the duals measure. As I was thinking about it, it strikes me that there are both differences among states in their eligibility standards for duals at least for some states and then there's also the

question of take-up differences, and there is some information known about that.

We should make sure to have that if we're going to go as far as specifically saying duals is the measure we're going to use -- obviously, there was some talk about maybe there are other options -- and then think about are there ways we should or could adjust for some of those state variations. I'm not quite sure what that means. It's just a thought, but at least we should be aware of how much of a difference that is.

I think for full duals, there's less variation in at a least the take-up side than there is with some of the partial dual programs, but at least if we understand what the amounts are and how much that would put hospitals in certain states at an advantage or disadvantage.

DR. CROSSON: Alice.

DR. COOMBS: I like the direction we're going.

A couple of issues, as I sit here. Thinking about Slide 5, in terms of whether or not to have a hard cutoff or a graduated kind of trend, some of the things that we really -- I guess of all these things we have prioritized, two of them actually track each other. The

spending and readmissions actually track each other because the spending is obviously going to be higher with the readmissions, but the question I have is if we weight them, the weight should correlate with whatever prioritization we have for what we think is the most valuable element.

In terms of the peer grouping, I think it's a good idea, but there's some other things that are going to track with the peer grouping, such as the CAHPS scores. So the CAHPS scores may actually be lower in low-income areas. The response rate may not be the same, and I think that in and of itself may yield itself to a different kind of experience, i.e., I remember one of our executives telling us at a medical staff meeting, "Be nice to the patients so our HCAHPS can improve."

And it's contingent on so many other factors in terms of the results you get from the HCAHPS scores. The patient experience is very important, but I'm wondering how we should weight that.

The other questions regarding infections, I think hospital-acquired conditions should track with your spend per beneficiary because those patients with C. diff, with MRSA infections, with a lot of the acquired infections will

require a post-acute care setting when they leave the hospital, decubiti, that kind of thing.

You may not pick it up on this. I don't think we're going to pick that up on here, right? The PACs. So if they go past the 30-day, that's an additional cost, say, for instance. So if you go past the 30 days, you wouldn't include that in the total spend per beneficiary.

DR. STENSLAND: If they left the hospital and needed post-acute care, that post-acute care, at least for the first 30 days of it, would be included in the spending measurement.

DR. COOMBS: Okay. And if they needed more than that, you would eliminate that; is that correct?

DR. STENSLAND: It would cut off at 30 days.

DR. COOMBS: Right.

So some of these patients may be at a post-acute care setting for even longer.

So I think the infection issues is germane. I think what Kathy says resonates with me in terms of hospital-acquired condition. So that an infection, a decubiti, something that requires a PAC stay is an important piece of this that rises to that level.

I'm actually interested in a lot of other things, which it would be a benefit to the beneficiaries to know about. As a beneficiary, I would want to know if there were hospital-acquired conditions in this hospital that has this prevalence of C. diff infections. I would want to know that, and to what extent are we responsible for the public knowing that kind of information and making wise choices and shared decision-making?

So those are my comments.

DR. CROSSON: Okay. Rita.

DR. REDBERG: I want to join my fellow Commissioners in complimenting you on the record, and I really like, as Paul summarized, I think, the simplification, the focus on outcomes and spending.

The only one which I alluded to in my Round 1 question is I think it's important to capture patient satisfaction, but it's so difficult. The things that patients are able to assess and get asked about, the cleanliness of the room and things -- and the response rate of whatever percentage -- and I don't know what it is either, who gets sent the survey. The response rate is so low that there's short of being very inherent bias and

people answer because they're either very upset with the care or they're very happy with the care, whatever. I don't know how we can address that, but I just have a little trepidation about that particular measure. So I think the idea is good, but overall I think it's a great -- and certainly, the other measures, I think are much simpler, will relieve the burden on hospitals and really help us to achieve high-value care.

DR. CROSSON: Brian.

DR. DeBUSK: I had one brief comment on the peer grouping. I'm a strong advocate. I really like what you're doing in peer grouping, and I recognize there are a couple different criteria that we can use.

What I would encourage you is to pick your criteria that can expand different measurement systems; for example, the voluntary value program that we discussed yesterday. So if you find yourself running up against something like DSH, well, there will be domains that we don't have DSH available in. Whatever you choose, I would encourage you to choose something that can go across those domains.

The other thing I would encourage, I know there's

some concern over do you do quintiles, do you do deciles. Maybe we have a low resolution, which would presumably be quintiles, and a high-resolution stratification. But, ideally, say a year, two years, three years from now, it would be really nice to see -- if I saw in the reading material where we said we use the MedPAC peer grouping method at fine resolution or at high resolution, I'd like to immediately know, well, that was based on SSI percentage, and because you said it was high or fine resolution, it was 10 deciles. But, again, ideally, I'd like us to have one tool that can transcend multiple systems because I don't want to get into what Bruce talked about earlier where, well, is this 90-day readmission, or is this 30-day readmission, or is this all-cause, or is this potentially preventable? Is this condition-specific? You know, I dream of a day where I don't have to read every footnote when we deal with something.

So I'm sure we'll revisit that, but that's my one point.

DR. MILLER: You're still going to read the footnotes because what you do.

[Laughter.]

DR. CROSSON: Yeah.

I have to admit to being shocked by that comment.

DR. MILLER: Yeah. I know, very shocked.

[Laughter.]

DR. DeBUSK: I was faking it.

DR. MILLER: There you go.

DR. CROSSON: Dana.

DR. SAFRAN: Thanks.

I completely agree that the direction here and the substance is superb, and I have a number of comments and suggestions that really grow out of my own experience working in this area. I know we're almost at the end of time, so I'll try to fit this content in quickly.

First is the idea of aligning across different programs the way that I think it was Mark who pointed out -- somebody over here pointed out that we're doing is really a great idea, and we have used that and really have seen that for the kind of measurement approach that we're trying to take that extends beyond the walls of the setting that's being measured, it does cause the system to have to actually act like a system and integrate and work together, so fully in support of a direction that has some deliberate

redundancy in the things that are being measured for ACOs and hospitals, for example.

Second, really like the move away from tournament to absolute thresholds. We've done that, and I would love to offline talk to you about the methodology we've used because we have done something, I think, along the lines of what Paul was suggesting, where it's not linear. It's graduated.

But the key point I wanted to make is that by having a range of performance targets and having it be continuous across them, even though not linear, it's very, very motivating to provider organizations because every increment of improvement is worth additional payout, and they know that. And depending on where you set the beginning of that target, you can avoid demoralizing those who are too far away from making it at all, so I would to think with you about that and share what our experiences and methodology have been because I think it works very well.

And it's also transparent on our part to providers, like here is the expectation, and so it's all good things.

I would really like to see a rethinking about how to approach the peer grouping on the SES. So that rather than having different peer groups have different performance standards, which I know even saying out loud makes us uncomfortable to say, well, we're going to set a lower performance standard for patients who are going to a facility that serves lower-income people, that we would enhance what the payment potential is for those facilities.

So to add resources in -- and, again, I know because time is short, I don't want to take the time here, but I would love to share what our experiences has been. That has been our approach. I think I've said that before in our meetings. Set the same target for everybody, but the rewards are different depending on the population mix that you have. And what we've seen is providers from our lowest SES groups going from behind the PAC to leading the PAC in their performance, and that's good for everybody.

On HCAHPS, I would urge you not to use the global measure but to use the more clinically relevant measures. Just because I used to make my living on patient experience, I'll correct some facts here. Lower-income people actually score their care more favorably than higher

income, and people who have a better assessment of their care are responding more than people who have a low. It's actually the farther out you go trying to get more respondents, the more your scores go down because people, I guess, believe what their mother has told them, to not say anything if you can't say something nice, especially that generation.

So I would urge you to use things like how clear discharge instructions were, how good the communication was, how responsive the nurses were. There are a lot of good measures there that we would want to improve.

I also agree with some of the comments you've heard about really taking another look at the ability to keep the hacks in there. I take the point that -- I think it was Jay who made that by reducing -- with accountability to reduce readmissions and mortality, you have to focus on infections, but I think there have been some other points made, including the transparency point and what we'd want beneficiaries to know. That would urge us to include them.

And I do understand the challenges of the differences in data quality that have led to the questioning of those measures, but I just wonder whether

this isn't the time to actually try to solve that problem. Maybe by some auditing function or something. I'm not sure what it looks like, but try to improve the quality of the data so that we can actually use these measures.

If we can't have them here, then maybe they can remain prominent in the Medicare stars work, which I know is getting reassessed right now.

Just a couple final things. On resource use, it brought me back to the conversation yesterday about post-acute care, and I just wondered if one of the measures we would include in the resource use domain might be that idea of creating accountability for the hospital of the total cost of care for post-acute care, that sort of bundling all post-acute care and the hospital owns it and gets rewarded if they're succeeding there. That just occurred as a way to connect those two conversations.

On mortality, I would urge us to do a little bit of research in qualitative to understand how provider organizations are working to improve on the all-cause versus condition-specific because I think some important issues have got brought up here today about the pros and cons. All-cause has some real benefits to it, but I do

worry about how we deal with the challenge of patients for whom we want them to get palliative care and definitely be the right outcome. And it is true that the literature shows that hospice sometimes prolongs life and not always.

So I think looking at condition-specific may be a good thing to do. I know clinicians, clinical leaders in hospitals that I work with have told me that accountability for things like cardiac procedure mortality have caused them to change their behavior and not operate on any patient who walks through the door and, in fact, be really careful if a patient is very high risk. Maybe it's not a good idea to do the procedure, anyway. And I think that's the incentive we want to strike, so I just would want to be sure that gets preserved if we move to an all-cause.

And then, finally, just really agree with the points about making sure that payment here is adequate to transformation, because I think transformation for the hospital under payment reform to date has been least visible, right? Physicians and physician organizations are responding to the move to value-based payment. For hospitals, it is still primarily volume and complexity, and this feels like the moment to set a signal that's strong

enough that starts to really change some of that incentive and behavior, so thanks.

DR. CHRISTIANSON: Wow. Those are great comments. Thank you.

So I also agree with the general approach that we're trying to take here. I like the measures you've chosen.

I agree with the idea that we don't want to move money around based on infection rates, but that it's important to keep them out there and very visible. I think we do need more money on the table.

I agree with your lecture, David. I've given similar lectures myself, even though I don't know Donabedian personally -- or didn't know him personally.

I would say in this context with respect to the variables that are chosen here as outcome measures, they are aware we want to see the beneficiaries go. We want to see this kind of improvement in beneficiary health, and we want to see cost constraint on the part of the Medicare program. So I think they're a good set of measures.

And I think in this context, we want to see hospitals change processes. We want to see them improve

their processes. We want to see them innovate, and we want to make sure, to your point, Dana, that we have the ability to convey that information to everybody. So when we find out a way to do something better that improves one of these measures, all hospitals find out about that.

So I understand the arguments you're making about process. They're very clear. I would want to have incentives that this provides to improve processes, change processes, not reward necessarily existing processes, but really encourage hospitals to do better.

So I think this is a good set of measures, and as I said before, I think this is a good direction to go.

DR. CROSSON: Last point, Rita.

DR. REDBERG: Very quick. I like the measures, but when Dana was talking about how important it was -- and you did -- measuring infections, it just occurred to me that a better measure for that if we were looking might be how much antibiotics the hospital is using, because that would contract pretty carefully. And we know actually there's a lot of overuse of antibiotics, but certainly, it's kind of a marker in an infection rate or concern. That was all.

DR. CROSSON: All right. Thank you.

Dana, particularly, thank you for your comments. I'm sorry you had to wait until the end, but that was very good, as were everyone else's.

Ledia and Jeff, you've got us set on the right compass heading here for sure, and I think you got a lot of support as well as a lot of, I think, very constructive ideas that will enrich this, and we look forward to you coming back with the next iteration, so thank you very much.

And we will move on to the next presentation.

[Pause.]

DR. CROSSON: Okay. Let's proceed with the last presentation and discussion for the month of October, and we're going to take on, I think by Commissioner request, a look at the Part D exceptions and appeals process. And Jennifer and Emma are here to present to us, and, Jennifer, you've got that look like you're starting.

MS. PODULKA: I'm just eager.

[Laughter.]

DR. CROSSON: I'm wrong. All right. Emma.

MS. ACHOLA: Good morning. In this session,

Jennifer and I will review the Part D exceptions and appeals process and discuss the role electronic tools can have in drug prescribing. We've touched on these topics in recent Part D work, and today we're following up with more detail in response to your interest and questions. We would like to thank Rachel and Shinobu for their help on this project.

First, here's a quick overview of our presentation. I will begin by providing a review of the exceptions and appeals process. Next, Jennifer will walk through data on exceptions and appeals outcomes and summarize stakeholders' concerns with the process. Finally, I will discuss the role electronic tools, such as e-prior authorization and real-time prescription benefit check, can have in mitigating concerns with the appeals process.

Medicare beneficiaries enroll in a stand-alone prescription drug plan or Medicare Advantage prescription drug plan in order to obtain the Part D drug benefit. These plans create and manage formularies, which are lists of covered drugs -- which is a list of covered drugs that comply with Part D law and regulation. Plans must also

establish an exceptions and appeals process so that enrollees can request a formulary or tiering exception.

If the plan decides that the requested drug is medically necessary, they can approve the exception request. If an enrollee's request for an exception is denied, they may proceed through the appeals process.

The exceptions and appeals process is complex and involves multiple levels. I will walk through each step of the process, which typically begins with the enrollee's prescription being rejected at the point of sale or pharmacy counter.

Next, the enrollee and their prescriber may request an exception. Once the request for an exception is received, the plan must issue a coverage determination.

If the plan's coverage determination is adverse, or not in favor of the enrollee, the enrollee or their prescriber may request a redetermination from the plan.

If the enrollee is dissatisfied with the outcome of their redetermination, they may ask for a reconsideration from an independent review entity.

Next, to proceed to an administrative law judge, the enrollee's case must be at least $160 in 2017. The

final two steps are the appeal to the Medicare appeals council and a judicial review in federal district court.

I would like to point out that the decisions in the appeals process must be adjudicated in specified time frames. For example, for a coverage determination, the plan has 72 hours in a standard review and 24 hours in an expedited review to notify the enrollee of their decision.

Now I will turn it over to Jennifer to discuss data on the outcome of these steps.

MS. PODULKA: Part D plan sponsors are required to report data on pharmacy claims that are rejected at the point of sale and the outcomes of the coverage determination and redetermination steps of the appeals process. CMS also reports on the decisions in the IRE step.

The plan-reported and IRE data are incomplete, and they should be interpreted with caution. Not all Part D plan data must be reported, and some that is does not pass data validation requirements. CMS specifically warns that data may be incomplete and/or incorrect.

So while we are very happy to have the exceptions and appeals data to share with you, we ask that you keep

these caveats in mind and interpret the trends we're about to present as broad brushstrokes in a somewhat blurry picture.

Part D plan sponsors report data on pharmacy claims that are rejected at the point of sale for six reasons. I'll show you those six reasons on the next slide.

While reported rates vary by plan, overall very few prescriptions are rejected at the point of sale at the pharmacy. This means that in 2015, about 4 percent of reported pharmacy transactions were rejected for these reported reasons.

Then roughly 9 percent of rejected pharmacy transactions went on to request a coverage determination from a plan. A similar share then requested a redetermination from the plan. And about 5 percent requested review by the independent entity.

Notice that as we're moving through these steps, we're talking about fractions of fractions so that by the time we get to the IRE step, there are roughly just 33,000 cases compared to more than a billion Part D pharmacy claims.

As I mentioned, plans must report on pharmacy transactions that are rejected for six reasons. Those non-formulary status, prior authorization requirements, step therapy requirements, quantity limits, and high-cost edits for compounded and non-compounded medications. These last two are very rarely cited as a reason for a rejection.

Among pharmacy transactions that were rejected for reported reasons, the most common reason was non-formulary status, which affected 1.9 percent of total pharmacy transactions in 2015. The overall share of reported rejections was about 3 percent in 2013 and about 4 percent in 2014 and '15. Plans must also report how many coverage determination decisions they made in response to enrollee requests.

So looking at the far right side of this graph, the overall rate of coverage determinations per 1,000 enrollees increased by about 35 percent, from 147 per 1,000 enrollees in 2013 to 199 per 1,000 enrollees in 2015.

This increase may indicate that enrollees and prescribers are more aware of or more willing to make use of the Part D exceptions and appeals process, or it may mean that their prescriptions are increasingly subject to

formulary, tiering, and utilization management requirements.

Looking at the bottom row of the table, in 2015, 64 percent of coverage determination decisions by the plan were fully favorable to the enrollee's request, 0 percent were partially favorable, and 36 percent were adverse. Employer, MA-PD, and PDP contracts followed a similar pattern. In comparison, Medicare-Medicaid plans had a higher share of fully favorable outcomes at 73 percent and lower share of adverse outcomes.

Plans must also report data on redeterminations, which is the final appeals step that happens at the plan level. Looking at the far right on this graph, the overall redetermination rate more than doubled from 8 per 1,000 enrollees in 2013 to 17 per 1,000 enrollees in 2015. In 2013, PDPs had the highest redetermination rates, but in 2015 employer plans surpassed them.

And now looking at the bottom row in this table, 70 percent of redetermination decisions were fully favorable to the enrollee, 1 percent were partially favorable, and 30 percent were adverse. Employer plans and PDPs followed a similar pattern while MA-PD and Medicare-

Medicaid plans had the lowest rates of fully favorable outcomes and, correspondingly, the highest rates of adverse outcomes.

Finally, if the enrollee is dissatisfied with the plan's final decision, they can appeal to the independent entity. Because the number of actual IRE appeals for each plan is low and there are issues found in some of the submissions, reported data are not available or not validated for the majority of plans. This was 71 percent in 2013 and 74 percent of plans in 2015. When data are reported and validated, the IRE agreed with the plans' redetermination decision most of the time -- on average 74 percent of the time in 2013 and 82 percent of the time in 2015.

Now, outcomes at the determination, redetermination, and IRE steps vary at the plan level. To explore this variation, we grouped Part D parent organization by plan type, into MA-PD, PDP, Employer, and Medicare-Medicaid Plans, and focused on the 20 parent organization plan type combinations that accounted for the largest number of pharmacy transactions in 2015. Together, these 20 account for more than 80 percent of reported

pharmacy transactions, rejections, determinations, and redeterminations. There's a large, detailed table included in the mailing materials.

To very briefly summarize, we found variation in reported pharmacy transaction rejections as well as determinations, redeterminations, and IRE outcomes.

In our discussions with stakeholders, all have noted frustrations with Part D exceptions and appeals. To quickly review key highlights from each stakeholder:

First, plans must resolve determinations and redeterminations within specified time frames that Emma mentioned earlier. They cite challenges in reaching prescribers and getting needed information in time to meet deadlines.

Second, CMS audits have found that several Part D plan sponsors have failed to comply with regulations in areas such as formulary requirements, coverage determinations, and exceptions and appeals processes.

And, finally, beneficiary advocates have recommended giving enrollees information about the reason for a plan denial at the point of sale. The current notice given to enrollees by the pharmacy when their transaction

is rejected notifies them of their right to request a coverage determination and instructs them or their prescriber to contact their plan.

In comparison, following an adverse coverage determination or redetermination, plans are required to send enrollees a standard form with detailed information on why the plan arrived at the adverse decision, as well as a specific explanation about what information would be needed to approve coverage.

Now I'm going to turn back to Emma to discuss an alternative suggested by stakeholders.

MS. ACHOLA: Multiple stakeholders have suggested that electronic tools such as electronic prior authorization and real-time prescription benefit check may reduce pharmacy rejections at the point of sale and thus the need for enrollees to use the exceptions and appeals process.

You can think of electronic prescribing tools along a continuum of increasing features and capabilities. I'll describe key features of each tool, but actual tools on the market do vary.

Beginning on the left-hand side of the continuum,

regardless of whether they do it routinely or not, most clinicians have the ability to e-prescribe or send a prescription to the pharmacy electronically.

Most also have some way to check enrollees plans' formularies. Again, they may or may not routinely do so. You can think of formulary look-up as a one-way flow of information, meaning that plans provide the formulary data and clinicians can review it.

Real-time prescription benefit check and e-prior authorization are more advanced and have more features than e-prescribing and formulary look-up. Both allow a two-way flow of information as they enable clinicians to exchange data with plans. Clinicians enter specific information about the enrollee and the medication, and if the benefit check and ePA are integrated in an electronic health record, some of these fields are pre-populated by the software.

The clinician then receives an affirmative response that the drug is covered, including the estimated cost-sharing amount. Or they get a negative response that includes the reason for the denial and may include product alternatives along with their expected cost sharing.

ePA is the most complete option along the continuum. It allows for multiple rounds of data exchange between clinicians and plans and can even enable clinicians to initiate an exception request and submit required supporting information.

Ideally, clinicians use ePA during an office visit with the enrollee. They can reportedly receive a response in a matter of minutes. If necessary, they can discuss and select medication alternatives with the enrollee. And the enrollee can leave their appointment with less worry that they'll face a rejection at the pharmacy.

While the use ePA may be ideal, there are obstacles to its full adoption. By law, Part D plan sponsors must support e-prescribing, but it is optional for prescribers and pharmacies. There are also no statutory requirements for ePA.

Second, there are hundreds of EHR and ePA vendors, making integration of ePA software with current EHR systems technically challenging.

Third, there are multiple actors involved in the ePA process: prescribers, PBMs, plans, and pharmacies.

ePA developers must find a way to address varying use capabilities so that ePA can still function when one or more of these actors does not use ePA for a transaction.

Finally, clinicians can directly or indirectly bear the costs for ePA packages and must embrace practice pattern changes to use it routinely.

In summary, few pharmacy transactions are rejected for reported reasons. Also, few cases are appealed to plans for coverage determinations and redeterminations. The plan's decision is usually in the enrollee's favor. Additionally, few cases are appealed to the independent review phase of the process. Where data are available, the independent entity typically upholds the plan's decision. Beneficiary advocates have requested that enrollees be provided with detailed information when their pharmacy transaction is rejected at the point of sale.

Finally, ePA and similar tools may reduce the need for enrollees to use the exceptions and appeals process, but there are obstacles to its use, most notably, clinicians' willingness to embrace practice pattern change.

Thank you, and we look forward to your discussion.

DR. CROSSON: Thank you. Thank you very much. Jennifer and Emma.

Let's have clarifying questions. Let's start with Pat here.

MS. WANG: Just very basic information. What proportion of pharmacy claims are coming through e-prescribing at this point?

MS. PODULKA: You know, that's actually a very good question, but I'm going to have to get back to you with a number.

MS. WANG: Okay. Is your view that e-prescribing is prerequisite to do e-prior auth?

MS. PODULKA: Not --

MS. WANG: It is.

MS. PODULKA: Oh, actually I'm getting some various head gestures.

MS. WANG: I assume that it is because it's the next step in e-prescribing, so the foundational question would be how much actually go through e-prescribing at this point.

DR. MILLER: So I'm probably the least educated, so you two will want to follow what's about to happen here

fairly carefully. I recognize on your continuum that it's generally viewed that e-prescribing is kind of more out there and lots of people are doing it. But the way I have it organized in my mind -- this is the part you'll want to listen to, you two -- is we're talking about something different where it's e-prior auth, where the physician is in the office and says, "I'm going to prescribe something here," and during that process the physician can query or the office can query the plan specifically, find out this is a problem, not on the formulary, you don't have prior authorization, you have a quantity limit -- I'm definitely way off the end of the pier here -- whatever it is, and then make a decision at that point to either redirect the prescription and then I would see that falling into the electronic prescription process or not, as the case may be.

MS. WANG: My --

DR. MILLER: Well, hold on. You might want to see if any of that was correct.

MS. PODULKA: Right. We did say this kind of quickly, but there's both the ideal and the standards, and then there's what can happen in the marketplace.

So, ideally, the ePA software allows the

clinician to enter the information, exchange any information needed with the PBM, arrive at a final decision, and then the script is electronically transferred to the pharmacy. But that's the ideal when all the actors are engaging in the ePA.

There could be a situation where all of those actors except the pharmacy are currently participating in the ePA for that transaction, and so everything might happen within the ePA tool, but then at the end, the physician has to jump out and submit the script in a more traditional manner to the pharmacy.

And, also, you know, many clinicians' offices have e-prescribing capabilities now. Having that tool currently in the office does not really impact in any way your choice and ability to install the ePA or EHR integrated with ePA tool software within your practice. So they can be completely separate, but ideally they're integrated.

DR. SAMITT: And correct me if I'm wrong. The complicating factor here is that the ePA software is like to be linked with the plan, not the provider. So at the provider level, if I see a patient with Plan A and then I

see a patient with Plan B, then I'm not using a singular ePA system.

MS. PODULKA: Again, this is where we get to the ideal and then what's happening with a thousand flowers blooming. Ideally, ePA software is developed by a software developer, and it is also ideally integrated with the EHR. And it is transferring information between multiple plans, and ideally all the plans. But that is probably, again, asymptotically an ideal.

You could have fewer plans integrating the information. Back at the other end of the continuum are more like I'm checking as a clinician with the plan. That's not the full ePA software suite.

DR. CHRISTIANSON: [Presiding.] Let's see if Pat --

MS. WANG: I just -- I guess as a practical matter, how likely do you think it is that a prescriber who does not do e-prescribing will actually use ePA, even though there are separate tools available for that?

MS. PODULKA: If you're a clinician and you use that little white pad every single time you submit a script, or every single time you prescribing something to

your patients and you're using your little white pad, you're probably not the clinician who is going to embrace and adopt ePA.

DR. CHRISTIANSON: Amy.

MS. BRICKER: Just a couple of things. So to your question, Craig, the two big players, Surescripts and Cover My Meds, in the ePA space, attempt to contract with all plans, PBMs, so that they're a single repository. There are many others -- Express Scripts has their own -- but very low utilization of that. But that one you would only be linked, obviously, to Express. But the bigger players, their goal is to be one-stop shop for you to link in with.

And I agree with your point, though, Pat, on adoption.

DR. CHRISTIANSON: Craig, did you -- you were in this conversation. Okay. Other clarifying questions?

MR. PYENSON: Thank you very much, Jennifer and Emma. I noticed a section on transitional scripts in the document, and I'm wondering if the thought there is that if we had a better appeals process that we could do away with the rule of transitional scripts?

MS. PODULKA: We didn't necessarily make that linkage. We did want to include the information about transitional fills. We think they are an important safeguard. I'm not sure that if there was full EPA that that would obviate the need for that safeguard, but it was something I need to think more about.

DR. MILLER: Yeah, I feel like all our internal review and conversations, we did not implicate this point, and so --

MR. PYENSON: Maybe it was subliminal.

[Laughter.]

DR. MILLER: Certainly unintentional.

DR. CHRISTIANSON: Does anybody else have any subliminal clarifying comments?

[Laughter.]

DR. CHRISTIANSON: Jack.

DR. HOADLEY: I don't know if it's subliminal or not. You mentioned that in the real-time, the RTPB, check that you would get back some kind of cost-sharing information, and I guess I'm wondering, is that always the case? Does that seem to be a universal characteristic of those plans? And, if so, is it sort of a full information

like you would get at the pharmacy, which is I'm still in the deductible so in this case it's full cost, or I'm in a coverage phase where it's a $10 copay?

MS. PODULKA: This is one -- I'm sorry. I'm going to give very unsatisfying answers to many of these. There are the ideal situations, where if everyone is participating and there is full information then yes, you do have the full cost-sharing information for both the approved one, or if it's not approved and it shows formulary alternatives, it shows the cost-sharing amounts for those.

However, there's the ideal and there's a not-for-profit association called the National Council -- or NCPDP, for standards. They have specific standards, which are -- you can think of as specifications for how software developers should develop and implement these tools. But it is an open market and there are many -- hundreds and hundreds of tools out there. So real-time prescription benefit check, which is a horrible acronym to trip off your tongue, hopefully shows that cost-sharing information, but we don't know that all packages do, and certainly it depends on how linked in it is to all the plans and how

updated all the information is.

DR. HOADLEY: So in practice, we don't really know, for a given physician doing that, what's the chance they're getting that more complete version or a less complete version?

MS. PODULKA: Yeah. Unfortunately, we don't have that kind of data that allows us to see into that.

DR. HOADLEY: Yeah, that's what I thought . Thanks.

MS. BUTO: I just wondered whether given the, you know, I guess extensiveness of the adoption of ePA that you're sort of thinking of in the ideal world, whether, in a less than ideal world, if the pharmacy and plans had ePA. So the doctor actually prescribes, the patient brings the script to the pharmacy, the pharmacy at least looks at it and if there is an issue where they know immediately it's not covered by the plan they could activate ePA, just to see whether -- I mean, is that -- do you see any of that behavior, because that would at least simplify some of the doctor part of this, which could be, you know, a real obstacle if everything had to be in place.

MS. PODULKA: Absolutely, and according to the

research we were able to find, capabilities for EPA are much greater take-up within plans and within pharmacies than they necessarily are within clinicians' offices. And so, absolutely, if the plan and the pharmacy are linked in the ePA, the pharmacy can see information, and it's possible that the pharmacy can know this, you know, wasn't on your formulary, here are alternatives. We also understand there are very different practices among plans and PBMs about how much information gets fed back to the pharmacy at that point. And at that point, you know, pharmacists often, anecdotally, will talk to their patients. They will often try and call the prescriber. But in the end, in this country, only clinicians can prescribe, so the pharmacist can help but at the end of the day the patient either needs to get back with their prescriber in person or by phone or somehow, to get it cleared up.

MS. BRICKER: Yeah. The majority of the delay, though, is because if it is non-formulary, even if you knew the formulary drug, you still have to call the physician, and so it's in that kind of, or if it's a prior auth or a step therapy, we tried this or that drug, that's usually

required to come back to the physician. So the pharmacist -- the pharmacy does play an integral part because they have the relationships, typically, with the physician and they can call and say, "Here's what you need to do," but you still rely so heavily on that physician engagement. So the ideal path is for it to be resolved at the point of prescribing, the e-prescribing, versus having to get the pharmacist involved, really.

DR. REDBERG: Right, because then the doctor can just redo the prescription. It's a pain.

DR. CHRISTIANSON: So this is a quick question, I hope, maybe for Jack as much as you guys. So the overall picture is not a lot of beneficiaries are involved in this process and you keep funneling down to fewer and fewer as you go through the review process, and so the impression is this is not a major issue for Medicare. But I'm wondering if there are any research studies that have been done around how discouraging the process is to beneficiaries. So we have a lot of beneficiaries -- do we have a lot of beneficiaries that are sort of even discouraged from being in this process? Jack, maybe you know the answer to that too. So maybe the issue is bigger than the numbers, which

you qualify appropriately all the way along the line, would suggest.

DR. HOADLEY: Yeah, I mean, my sense is that we don't really know and it's this -- it's always hard to observe the, you know, the situations where the person gets discouraged at the pharmacy, never goes back, and even to distinguish that between situations where, you know, maybe they figure out that they don't really need that drug or, you know, why they don't follow up. You know, and when I get to my round two comments I'll say more on this point.

MS. BUTO: But, Jon, isn't the rejection rate really low? It's like 4 percent or something like that.

MS. PODULKA: The rejection rate is very low, and we know the reported six reasons. But we know the transactions. We don't know if those are concentrated amongst certain beneficiaries. Presumably it's not 4 percent across the board for any given beneficiary on each transactions. It's beneficiaries with specific types of drugs are probably more affected by it than the general population.

DR. HOADLEY: I mean, if we could -- if we had the data to do this, if you could think about, you know,

all the prescriptions that are just refills of the last prescriptions, they are extremely unlikely. They are probably 0.00-something. And so, you know, it's a 4 percent of that total universe but what percentage is it of the new prescription, the ones where, you know, the engagement of this question probably is more relevant.

DR. CROSSON: [Presiding.] Amy.

MS. BRICKER: Are you able, or do you have access to commercial comparators? So I saw the comprehensive review within the Medicare benefit and over time, but comparing the experience of Medicare to that of the commercial space.

MS. PODULKA: We don't have terribly detailed data. We did see a somewhat comparable abandonment in pharmacy transaction rejection rates, maybe even slightly higher, maybe a point or two higher in the commercial market than in Medicare. So at least we didn't look at the Medicare data then and go, oh, Medicare seems greatly skewed from commercial experience. But we don't have a lot of like detailed comparative data to look at.

DR. CROSSON: Okay. It looks like we've finished with round one and now we'll move on to round two, and I

believe Jack is going to begin.

DR. HOADLEY: So thank you, and I really do appreciate you providing us this information. I'm glad we are giving some attention to something that is very important. We have said, in some of our recommendations on Part D, you know, that doing something with regard to, you know, X or Y implicates the fact that we need a good, effective exceptions and appeals process, and it's important to have this as a check. And I fully appreciate the fact, the data limitations you talk about, and, you know, I haven't looked extensively at these data, not nearly as extensively as you have, but, you know, it's very hard to really make sense of what these data are telling us.

You know, can we understand why the 2015 numbers are higher? You know, is that a good trend? Is that a bad trend? You know, we can't even really say is that good news or bad news. The variations across plans, it would be great to be able to say that tells us -- you know, that's a quality measure that this plan has a high number and that's bad. But a high number can be bad or good, depending on, you know, sort of what gets you to there.

You know, to this point of the 4 percent rate, and I started to say this before, you know, I don't take a lot of comfort in that rate. Again, it's hard to know what to make of it, and I think, you know, the issue of what's the appropriate denominator is part of that. But it's also, you know, from a patient's perspective, when you get a prescription -- and we could separately -- I asked the question of whether all the prescriptions are appropriately prescribed -- but to the patient at that moment, that's their doctor's prescription. That's something that they feel they need to be filling, and they're just taking the steps to get the drug to take it, and then they're hitting this obstacle.

And again, some of the obstacles are for good reasons. They're formulary design and so forth. But, you know, I think we need to try to really think about how to get -- both make sense of the data, and there's limited ways we can do that, but also then to see how to fix it.

So I come back to this ePA and e-prescribing and I think that it does feel to me that that is a route towards improving this situation. Now the question is, how do we get there. You know, this struck me as thinking

about the adoption in the 1990s of electronic point-of-sale systems, and when that was called for in legislation, I think it was in 1990, my recollection is that that was quite a hue and cry of, you know, how you're telling us we've got to be able to do all these transactions at the point of sale. Before that you took your drug to the pharmacy, you may have paid the full amount up front, and you waited for the paper transactions to follow and the insurance to figure out, you know, what you actually owed, and got some of that money back. And there was a concern at the time that we would never be able to really implement this broadly.

Well, it happened. It was law. It was done through Medicaid, and we now are routinely used to the fact, and when we go to the pharmacy, unlike what sometimes happens in a doctor's office where you really don't know how much you're going to owe until all the insurance paperwork clears, you know by the time you walk out of the pharmacy that this is the copay you owe, and unless you're in one of these situations where something is rejected, that's it. There's nothing further.

So we got there somehow, 20 years ago or 25 years

ago, when that seemed hard. It seems like we can figure out a way to get here on this. And as Amy said, you know, you really need to do this at the point of prescribing, because if the person is going to the pharmacy, you know, they've seen their doctor at 3 in the afternoon but by the time they get to the pharmacy it's 7 at night. Well, there's no ability, probably, to have an immediate transaction with a physician at that point, so that's already the next day, a second trip to the pharmacy, and all the other things that follow.

So it really does seem to me that we should figure out how to make a win-win out of this by getting this kind of system in place, and I think you've given us a lot of the reasons that's not easy to do, and I think to the extent that we can continue to figure out what are the most important obstacles, is this just a matter of saying it has to be done in a provided amount of time and then the rest of the obstacles will work out, that didn't work so well for electronic health records. You know, I think people thought those would be -- you know, it would be a struggle to get in place, but in a few years it would be there, and I don't think we have quite the same comfort we

do with the point-of-sale transactions.

So I think, you know, that's just something that, you know -- unfortunately, I don't see an obvious recommendation that we could put on the table to say here is the path to get there, but to the extent that we can continue to try to think of that it would be nice to be able to do that at some point.

Two other ones I just wanted to mention. One is on the point-of-sale notice. It still seems like that's another important part of the piece, even though if we had the full electronic prior auth and all that kind of stuff we would have less of that situation. But it is an extra step for the beneficiary to be able to figure out, okay, why did I not get this, and if we could provide more information at that, I think that is valuable.

And one that you didn't mention that I wanted to raise was an issue of auto-escalation to the IRE. As I understand it, in the Medicare Advantage, if there's an adverse determination for the beneficiary it's automatically escalated to the IRE for that redetermination, whereas in Part D, which otherwise mostly follows the Medicare Advantage system, you don't have that

auto-escalation. And I know there are some in the beneficiary community who think that that would be a value to be able to make sure that there is that chance to get an independent review on top of what the plan does. So maybe that's something we could take a little more of a look at in the future. There are many fewer, from the data I've seen, IRE reviews in the Part D world than there are in the Part C world for that reason.

So those are the points I wanted to make.

DR. CROSSON: Thank you, Jack. So let's have further discussion. I see Amy.

MS. BRICKER: So picking up on a thread that Jack mentioned, I actually think that the recommendation could be a requirement around electronic prescribing. It's not just for this process but in the fraud that exists within the pharmacy space. We all know too well, in practice, that you can pick up the white pad and forge prescriptions, and, you know, with electronic prescribing there are greater controls. There is a, you know, a check that it's a real patient. I mean, there's just another safety net there. And with the proliferation of fraud in this space, it's widespread, requiring electronic prescribing is

something that I would support and am interested in the other Commissioners' point of view of that. Yes, there is an expense. Got it. But I think it's well worth the push, and figuring out how we, you know, provide incentives or some date in the future where it's a requirement, I would like to consider.

And I'm also a big proponent of electronic prior auth. It's a great way for -- you know, it solves many of the issues that you've outlined, from a delay, from, you know, potential frustration from a beneficiary, from the physician's workload or their staff. Being able to resolve those issues with the patient there is ideal. It's ideal also from the PBM's perspective, for all the administrative costs associated with faxing, and, yes, that's really the goal standard, faxing still of this information. So I'm in support of that.

I was able to look at, in our own experience, appeals and denials in the commercial space versus the Medicare space, and in our experience, there is a much higher -- it's a vast difference -- of denials of appeals in the Medicare space. And when I dug a little bit deeper, it's because of these 72-hour timeframes. So many, many,

many, a disproportionate share, will get that initiation of prior auth, maybe from a pharmacy, and the clock starts ticking at that moment. And if you don't have all of the information from the physician in that 72-hour period, you must deny the claim.

So the claim is not able to be pended. Like in the commercial space we can pend the claim and continue to work the claim. We have to deny it, close the book, send the notice to the beneficiary, which probably causes them to say, "What the heck? I thought, you know, my doctor was working on this." And then -- but so much higher denial rate in Medicare but much higher overturn rate in Medicare.

So the information is there. We eventually do get it for those that continue down the process. So you have to really look at what's the rationale or the reason behind these statistics. And while I understand the spirit -- we want to try to resolve these things quickly -- it's because we're still working in this fax environment and not an electronic environment, that I don't know that 72 hours is necessarily in the best interest of the beneficiary. I think it just causes confusion and additional sort of headache. But just to give you additional context.

DR. CROSSON: Good. Thank you.

Other comments? Start with Kathy.

MS. BUTO: So ePA sounds very appealing, and I thought Amy's comments were really interesting.

I was kind of coming at it from the same perspective without the data that she has, which is, wow, it really looks like persistence pays off in the end. You'll get your claim approved in many cases.

But it sounds like some of that is because of the inefficiency of early denials because of the time frames, so that's not such a good thing.

I guess what I'm wondering is how ePA actually helps with the appeals process. It does cut down on the initial frustration that the beneficiary, not realizing the drug, wasn't on formulary, but is there a potential to build in at least the first appeal if the physician feels very strongly that that drug for that patient is what's needed? So rather than have to go through -- after you've got the initial prior auth and you're told, well, it's not on formulary, is there the possibility of doing the additional steps to really streamline the appeals process, which I think was part of the objective here?

MS. PODULKA: Yes. And, actually, everything in this field is somewhat ineptly named because while it's called e-prior auth, the tool can actually address other utilization management tools. So while you're using an e-prior auth tool, it could address -- if there are quantity limit requirements, the clinician can go ahead and submit documentation for why their patient needs to exceed the quantity limit and potentially get it approved within the EPA software for this exception.

So it's almost literally as if you are taking the very first step of the appeals process and putting it at the point of care during the office visit. So that means that some share of cases right now that end up having to walk through each of these steps with the delay and the time requirements would instead be resolved initially with the prescription.

Potentially, some share would continue. They wouldn't be resolved then, but then that might also help in the sense that there would be fewer cases. And AMA has reported that office staff time and clinician staff time spent on resolving all these requests that come later through fax and phone call take up a significant chunk of

their time. If there are fewer cases that would make it through to exceptions and appeals, that would presumably reduce the clinician office workload.

MS. BUTO: I think that's a real improvement if that's the case.

Thanks.

DR. CROSSON: Okay. Bruce, and then well come back up here.

MR. PYENSON: I would recommend a look in this context at the transitional fills, which are significant cost items for some organizations. In particular, whether those would be -- could be eliminated with a faster, more efficient appeals process.

DR. CROSSON: Jack, on that point?

DR. HOADLEY: On that point.

It seems to me that one of the issues that transitional fills is somebody is just getting a renewal of an existing drug, that now they are on a different plan, and therefore, it's not covered. They haven't had a new doctor's appointment that gives the opportunity to consider the new thing. So that's some of the situations where the transitional fill just gets you to the point where your

doctor can reengage to say now is it okay to switch to the new medication.

So it might reduce the number of cases where transitional fills would be necessary, where a new doctor's visit is involved, but some of these that are just renews might not have a chance to come up through the electronic system.

MR. PYENSON: Just on that point, I understand what you're saying. There is a different business aspect of this which involves rebates paid to intermediaries who are deciding that. So I think there's some other aspects that are driving some of the business that falls into the transitional scripts.

DR. CROSSON: Okay. Pat.

MS. WANG: I think that e-prescribing is foundational for ePA. ePA is the right way to go, and I think everybody would like to see that process work better. Whatever the number is of rejections, I mean, I think it's not a burning platform, but I don't think that -- I think everybody would like the process to run better.

I think the tools are available, and the issue is sort of clinician preference and convenience.

To me, the only way to really get full adoption or more uptake on ePA is to make is easy for the prescribers so that they don't have to click around to different systems, right, because we know they're busy, so that's a pain in the neck.

And my understanding is at least that the issue is sort of integration of -- I mean, you have to integrate plan formularies' rules, et cetera, into an EHR, so that when you are e-prescribing, it's going out in one signal and one transaction. The information could come back to the clinician. They could have that conversation wherever.

I don't know how to do that. I think the tools are all available, and as you know, I think plan sponsors employ those tools and make them available. It's just a question of what capabilities a prescriber has and what capabilities exist to -- within the EHR vendors actually integrate that information, so that it's more seamless.

I don't know how to overcome those. I don't have a suggestion here, but I think that's really what the goal is. And I do think that e-prescribing is foundational because if you're not e-prescribing, you're not going to look up in a -- even if there's freestanding EPA system, I

don't see that happening.

DR. CROSSON: Craig.

DR. SAMITT: So given my remarks yesterday about telehealth, you won't be surprised to hear me voice my opinion in favor of e-prescribing and ePA. Technology is good yet again in this regard, and it's been pretty clear from this presentation that finding a method to shift and incent or mandate e-prescribing at a minimum, if not ePA, raises multiple boats.

I think when we talk to providers about the complexities of health care, one of the biggest areas of angst is prior authorization, and the somewhat manual and time-intensive and costly process that we put providers through, not to mention beneficiaries and members, that is just excessive, costly, and frankly unnecessary, and that automation would very much help simplify.

In fact, on your Slide 7, even though we call it an ePA program, you would argue that automation would resolve a lot of the drivers of appeals if that exchange occurred at the point of prescribing as opposed to the point of sale.

My question is, What do we do about it as MedPAC?

From a Medicare payment policy perspective, what is it that we can do to influence this? I am at a loss to really understand what our recommendation would be in this regard, but I do think that we need to find a way.

My only suggestion -- and I don't know whether that points to an answer -- is have there been any subsets of our system that have solved this. So I guess I'd point to provider-sponsored plans, where they've been able to figure out sort of how to drive higher levels of e-prescribing and the use of ePA, and is there a business case there that really stems from those type of environments that suggests that there is a way to do this? And it would point to potential suggestions for how we could recommend policy in that regard.

DR. CROSSON: Okay. Dana and then Rita.

DR. SAFRAN: Just a very quick comment.

In following up on Craig's, I am very much in support of moving in the electronic direction, and that's somewhat informed by the experiences that Blue Cross Mass has had in doing that.

I don't have the data at the top of my mind, but when I was coming into the company 11 years ago, we were

just starting e-prescribing requirements with our physicians and doing it by actually giving them the tools that let them do e-prescribing, like paying for the tools and putting it in their hands. It was extremely well received. I don't have more current information, but over time, we did track that it improved safety as well, which I think is well documented in the literature, but we saw it in our own data in terms of adverse drug events.

And then the way we incentivized it was we began to make it a gate, that you had to be using e-prescribing in order to qualify for some of the incentive payments for some of our other performance-based incentive programs. So I don't necessarily recommend that here, but it does bring me back to, gee, repealing MIPS and like what do we have out there for the individual doc, and maybe this is one little piece of something.

MS. PODULKA: There is currently a requirement in the meaningful use quality measures for physicians that they e-prescribe once for one patient.

[Laughter.]

DR. CROSSON: Rita.

DR. REDBERG: First, thanks for a really

excellent chapter and presentations. I think it's a challenging area, and you made what's going on as clear as can be.

I will just comment just on the process itself. It is, I think, a very small percentage of transactions. The ones that go to ALJ, you even have a judge who I think probably has no expertise in plan formularies or prescribing, so those I think are not the best way to resolve any of these issues.

But speaking as a clinician about e-prescribing, I cannot endorse your experience at all, Dana. It is a pain in the neck. It takes me five times longer to do an e-prescription because half the time you put it in, it doesn't recognize what you've typed in. It doesn't have the right pharmacy. So I'm not saying we shouldn't do it. I'm just saying it is a pain, and it's like Epic. Doctors, I think uniformly were four years into it, and it takes us about 30 percent longer to see patients now with our electronic record, and the electronic prescribing takes a lot longer. It's definitely in there, and I think it should be at the point where the doctor prescribes, because at the point I'm writing the prescription, I already have

in the record what insurance that patient has and where they're going to fill that prescribing. So it seems like it should already tell me if it's not going to go through.

So, certainly, it could be, but I really hesitate to make that requirement because I think doctors, you know, who even are a little older than me, they'll just retire if you force them to do this because it is really a pain. I do it, but it wouldn't be my choice.

In terms of the prior auths, in terms of things that I would want to address in Part D plans, I feel like the much bigger issues are drug pricing and appropriate drug prescribing. I think what patients want to know is how much their out-of-pocket is going to be, which I still can't tell them, even though I e-prescribe and have all this information there, and how much the drug is going to cost.

So that's the kind of things that I feel are much bigger issues for our beneficiaries. I think this is important, and I think e-prior authorization would help, but I just, unfortunately, don't think our electronic systems have really kept up with -- they're not user friendly at all.

DR. CROSSON: Jack, final word?

DR. HOADLEY: Yeah. I just wanted to add a couple of thoughts.

I mean, I think one point, back to what Rita was saying and as Jennifer pointed out, the ePA softwares are more than just the prior authorization. They should address some of those other issues.

The things that I've heard about when I've talked to clinicians are the kinds of situations where they don't really care which of several competing products they're going to prescribe. They're happy to prescribe the one that's recommended by that formulary, if they knew, but they don't want to go through a complicated process of figuring that out.

Many of the prior authorizations that the PBMs and the plan put on are perfectly reasonable or they're for various administrative reasons -- is it a Part B versus a Part D use? -- that are quickly resolved, and they expect a lot of them to be said yes to. And so I think what we're talking about here is a way to keep a lot of these routine decisions out of an exceptions and appeals process and figure out a way to get them done up front.

I'm encouraged by the notion that there's some ideas that we could push forward. It won't be as simple as just putting a mandate that says you have to do it, but some mix of requirement of assistance and maybe some effort by CMS or others to encourage better software development so it doesn't have some of the problems that Rita talks about.

So I think if we can get this -- if we can get a lot of this business out of being called exceptions and appeals and just be routine ways to direct the correct prescribing and get us out of this sort of fax mentality, which really does feel like an antiquated way to process, it seems like this really can be a win-win. But we've got some obstacles to overcome to get there.

DR. CROSSON: To one of your points, Jack -- and this is based on some prior work that I did -- I think looking backward or looking back at the progression of the development of EHRs, there was a number of different priorities that many of these companies could have brought forward as let's work on this first, let's work on that second.

The priorities that seemed to have evolved had a

lot to do with payment, particularly now with physician-based EHRs, with getting the payment system right, and then getting the regulatory requirements in order, including some of the meaningful use requirements.

And I think there's a sense among physicians, which is backed up by data, that physician usability, the front end of whatever you want to call it, for many companies, including some of the largest ones, was not one of the principal priorities. And that has had the effect that Rita talked about.

And I think for -- again, based on my own experience, for some of the larger practices that had more resources and actually IT infrastructure, who could reconstruct the front end and customize the front end for physicians, that problem has been addressed. But for many doctors around the country who don't have that capability, it has not been, and it's not a trivial issue because it drives resources. It drives cost, and it drives resistance to policy changes like moving forward to the prior authorization idea.

Well, this has been a good discussion. Thank you very much, Jennifer and Emma.

This is the kind of thing that we do. We don't always move to a hard recommendation. I don't think I hear one coming out here, but this is very valuable, I think, as time goes by, as this issue comes up, as it will, both in legislation and regulation, to understand the sense of the Commission. And I think this discussion creates a sense of priorities and tools that the staff will be able to use going forward, and we may very well -- based on changes that come forward, we may well come back to this again.

Thank you very much.

And I think we will move now to the public comment session. If there are any members among our guests here who would like to make a public comment, please step to the microphone now, so we can see who you are.

[No response.]

DR. CROSSON: Seeing no one approaching the microphone, we are now adjourned, and we'll reconvene for the November meeting.

Thank you very much, Commissioners. Safe travels to everyone.

[Whereupon, at 11:06 a.m., the meeting was adjourned.]