PUBLIC MEETING

Reserve Officers Association
Top of the Hill Banquet and Conference Center
One Constitution Avenue, NE
Washington, D.C. 20002

Thursday, March 1, 2018
9:31 a.m.

COMMISSIONERS PRESENT:

PENNY THOMPSON, MPA, Chair
MARSHA GOLD, ScD, Vice Chair
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CHARLES MILLIGAN, JD, MPH
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WILLIAM SCANLON, PhD
PETER SZILAGYI, MD, MPH

ANNE L. SCHWARTZ, PhD, Executive Director

AGENDA PAGE

P R O C E E D I N G S

[9:31 a.m.]

CHAIR THOMPSON: I'll ask everybody to take a couple of minutes to finish up conversations, and then we'll get started.

[Pause.]

CHAIR THOMPSON: Okay. We're going to kick off this morning with Chris and Rick, moving through a review of our June chapter report and recommendations relating to the operations of the Medicaid drug rebate program.

REVIEW OF DRAFT JUNE REPORT CHAPTER AND RECOMMENDATIONS: IMPROVING OPERATIONS OF THE MEDICAID DRUG REBATE PROGRAM

* MR. PARK: Thank you, Penny.

Today we'll present an overview of the draft chapter for the June report. This chapter builds on our prior discussions and focuses on discrete changes to the rebate program. It provides an overview of the rebate program, discusses some of the issues with authorized generics and CMS oversight and enforcement and lays out our future agenda to research and analyze the levers and challenges states have in managing the drug benefit that we

heard from the panel in December.

We will then present three recommendations and accompanying rationale for your consideration.

Two of these potential recommendations were presented at the December meeting. Those are excluding authorized generics from the calculation of brand drugs', average manufacturer price, or AMP, and strengthening the authority of CMS with regard to misclassified drugs.

The third potential recommendation presented in December on correcting a prior drafting error in the line extension rebate was included in the Bipartisan Budget Act of 2018. So it doesn't make sense to make that recommendation now, but we have -- there was some discussion at the December meeting, and some of the Commissioners expressed some interest in allowing states to share in the line extension rebates. And so we've drafted a recommendation around that option for you to consider today.

During today's session, we would appreciate any feedback you have on the draft chapter, as well as any feedback you have on the draft recommendations and rationale.

We have scheduled a second session in the afternoon to finalize the recommendations and have a vote, so we do have some opportunity to incorporate any comments you have today.

The draft chapter starts with background information on the Medicaid drug rebate program. This is information you're familiar with and has been previously published in our issue brief on Medicaid payment for prescription drugs. Just at a high level, the general thing to know about the rebate program is that drug manufacturers must provide a rebate to Medicaid. In exchange, states must generally cover all of the manufacturer's drugs.

This chart is just a quick summary of the rebate calculations. There are different rebates for brand drugs and generic drugs. The brand drug rebate is higher. Both brand and generic drugs now have an inflationary rebate that adjust for price inflation over time, and if the drug’s increase in price exceeds that, the Medicaid program gets a rebate on that.

There's a rebate for line extension drugs that I mentioned earlier and we'll discuss a little bit later.

And then another thing is that there is a federal offset on certain rebates that were changed due to the Affordable Care Act, and the Federal government receives 100 percent of the rebates associated with those changes.

The chapter discusses the treatment of authorized generics and the calculation of a brand drug's average manufacturer price. As a reminder, an authorized generic is a generic version of a brand drug made by the brand manufacturer. The brand drug manufacturer may license the authorized generic to secondary manufacturer.

Statute requires that a manufacturer that has an authorized generic blend the price of the authorized generic with the brand drug's price when calculating the AMP for the brand drug.

Because the authorized generic is cheaper than the brand, this blending effectively lowers the AMP for the brand drug and, thus, lowering the rebate for the brand drug.

Sometimes there may be a corporate relationship between the brand drug manufacturer and the secondary manufacturer, and transfer price between entities could be artificially low and intended to reduce the rebate

obligation of the brand drug.

The next section of the chapter discusses CMS' oversight and enforcement of the rebate program. Under the drug rebate program, manufacturers have the responsibility to classify their drugs as brand or generic. Because the rebate amounts of brand drugs are higher than those for generic, a misclassification can reduce the rebate amounts collected.

CMS has limited authority to address cases in which it deemed the product to be misclassified. It's an all-or-nothing authority right now. CMS may terminate a manufacturer's rebate agreement, which would exclude all of the manufacturer's products from coverage. This option is seen as disruptive to beneficiaries, and CMS has been reluctant to take this action.

CMS may ultimately discuss the issue with manufacturers and request them to amend the classification, but because they do not have like an intermediate sanction pathway, it's ultimately a voluntary response on the manufacturers to make a change.

After our meeting in December, the Office of Inspector General released a report on misclassification

drugs in the Medicaid drug rebate program and found that approximately 3 percent of drugs are potentially misclassified. In this report, the OIG has two recommendations -- that CMS pursue a means to compel manufacturers to correct inaccurate data, and this could be either legislative authority to compel manufacturers to submit accurate data or authority to suspend potentially misclassified drugs in the rebate program until a correction is made.

As mentioned earlier, in December we discussed a drafting error in the calculation of the alternative rebate for line extension drugs, and that correction would have given the line extension -- the basic rebate plus the greater of the line extension's inflationary rebate or the highest inflationary rebate for any strength of the original version.

The Bipartisan Budget Act of 2018 included this correction, and the corrected formula goes into effect for rebate periods beginning October 1st, 2018. The CBO scored this as $5.7 billion in federal savings over 10 years.

The federal offset remains in place, so the Federal government will receive the entire amount of rebate

dollars associated with this correction.

In December, we discussed how most states supplemental rebates are calculated, and that when federal rebates increase, supplemental rebates decrease proportionately. Because of this, some Commissioners expressed interest in potentially making a recommendation to allow states to share in the line extension rebates and asked the staff for more information on how the supplemental rebates for states could be affected.

We do not have direct access to supplemental rebate amounts because these rebates are considered proprietary, so we discussed this issue with a contractor that negotiates supplemental rebates on behalf of several states. While they cannot predict how rebate agreements might change in the future if the line extension rebate is changed, they did estimate that about 10 percent of the supplemental rebates currently are for line extension drugs, and assuming if those all went to zero, kind of upper bound of the impact, then that would kind of represent maybe a potential loss of 10 percent in supplemental rebates.

The chapter concludes with a brief discussion of

our future work on prescription drugs. Much of the work over the next year will focus on some of the issues we heard from the panel in December on how states can manage the use and mix of drugs.

For example, we heard about the challenges that states face in having to cover a new drug as soon as they hit the market and how states don't necessarily have time to develop coverage criteria, and the Commission expressed some interest in maybe a potential grace period to allow states to develop the appropriate coverage criteria, and we'll continue to explore that option.

Additionally, several states have expressed interest in having more flexibility in determining coverage and managing the program. Massachusetts submitted an 1115 waiver amendment, and Arizona has submitted a letter to CMS wanting to offer a close formulary similar to those offered in commercial payers.

We plan to research how Medicaid's current ability to manage the use and mix of drugs compares with other payers, and we'll monitor state activities such as Massachusetts and Arizona to see how those develop.

We also heard from our panel that Medicaid has

had success in managing the traditional drug classes, but there are particular challenges unique around high-cost specialty drugs. So we'll continue our research to see if there are additional tools needed and monitor the development of value-based contracts in both Medicaid and other payers.

And I'll pass it over to Rick to go over the draft recommendations.

* MR. VAN BUREN: Thank you, Chris. Good morning.

I'll now discuss the draft recommendations, the rationale behind them, and some considerations for Commissioners.

The first draft recommendation reads: "To ensure that manufacturer rebates are based on the price of the drug available to wholesalers and pharmacies, Congress should remove the statutory requirement in Section 1927(k)(1)(c) that manufacturers blend the average manufacturer price of a brand drug and its authorized generic."

This recommendation would close a loophole in the current law that allows drug manufacturers to reduce the AMP and, therefore, the rebate obligation on certain brand

drugs.

CBO estimates this would result in savings to the Federal government of less than $1 billion over five years. We expect that would come in the form of higher federal rebates.

Similarly, we expect this proposal would increase rebates to the states as well.

If Congress were to pursue this recommendation, it's possible that drug manufacturers will ask that the best price of the authorized generic no longer apply to the brand drug in order for the two metrics to be treated consistently.

We don't have data and we don't know if any brand drugs are currently paying a best price rebate based on the best price of the authorized generic.

Finally, it's possible that this recommendation would increase the federal upper limits paid to pharmacies on certain drugs, which could result in increased provider payments to pharmacies.

EXECUTIVE DIRECTOR SCHWARTZ: And, Rick, just to clarify, when you say CBO says less than one $1 billion, it means it's somewhere between zero and a billion dollars and

they're just not able to provide us with a point estimate.

MR. VAN BUREN: That's correct. It's not a fancy way of saying zero dollars.

EXECUTIVE DIRECTOR SCHWARTZ: Okay.

[Laughter.]

MR. VAN BUREN: It's just that's the way they score our recommendations.

The second draft recommendation is: "Congress should give CMS authority to reclassify drugs that it has determined that a manufacturer has classified inappropriately for the Medicare Drug Rebate Program, or give CMS authority to suspend individual drugs from participating in the rebate program until the manufacturer has corrected the drug's classification."

This recommendation, as Chris mentioned, is intended to address a gap in the current oversight regime. As we heard earlier, CMS can terminate manufacturers for noncompliance but lacks intermediate sanctions to go after individual noncompliant drugs.

I'll note this recommendation combines two enforcement authorities, the authority to suspend and the authority to reclassify. These don't need to be combined.

If Commissioners want, they can recommend either authority or both.

This recommendation would also preserve all of the current enforcement authorities and would not relieve manufacturers of potential liability for misclassifying their drugs. It would merely give CMS more targeted enforcement authority over the rebate program.

Some considerations on this recommendation, as Chris mentioned, the OIG found that the overwhelming majority of drugs in the rebate program are correctly classified. Only 3 percent were potentially misclassified.

In terms of score, there is a potential for increased rebates as a result of these changes, but the CBO estimates that this proposal would achieve no savings over the current baseline.

In terms of CMS, the process for determining if a drug is misclassified can be administratively complex.

CMS has also made changes, both regulatory and in its systems to make it more difficult for manufacturers to misclassify drugs.

There is the potential for litigation from drug manufacturers if they disagree with CMS' decision to

reclassify or suspend a drug, and there is a potential that suspending individual drugs from the rebate program could be disruptive to beneficiaries who rely on those drugs.

Finally, as Chris mentioned, these recommendations are consistent with want the OIG recommended in its December 2017 report.

Turning to the third recommendation, it reads: "Congress should amend Section 1927(b)(1)(c) to allow states to share in the rebates for line extension drugs under the alternative rebate formula."

As we heard earlier, the intent of this, the rationale behind this recommendation is to ensure that states don't lose out on rebate dollars as a result of the technical fix to how the line extension rebate is calculated.

As we heard in December, the supplemental rebates are often negotiated based on the manufacturer receiving the guaranteed net price after all other rebates are taken into account, so an increase in the line extension rebate would result in a decrease in state supplemental rebates on those drugs.

Since states share in the supplemental rebates

but not in the line extension rebates, the result is that states would lose out on some rebate dollars from those drugs.

We don't have -- well, we're still waiting on a CBO score of this provision. We did a back-of-the-envelope based on the CBO score they assigned to the legislative fix of the rebate formula. So assuming that saved $5.7 billion over 10 years and assuming an average federal share of 63 percent, we estimate that this recommendation could increase federal spending by $2.1 billion over 10 years. Again, that's not an official CBO score. That's just Chris and I looking at the numbers and making an educated guess.

I'll conclude by saying there's no discernible policy rationale for why the Federal government retains all the savings from this provision. It was included in the Affordable Care Act likely as a saver to reduce the cost of that legislation.

That concludes our presentation. We now welcome Commissioners' feedback on these recommendations and are happy to answer any questions you may have.

As we heard earlier, there is a second session this afternoon to finalize the language, review any

changes, and vote.

Thank you.

CHAIR THOMPSON: All right. Great.

Let me go ahead and kick us off. First of all, thank you for coming back after our initial conversation a couple of meetings ago, I think, on these subjects. I think there was a lot of interest on this, and I think the Commission is definitely desirous of taking some votes on some specific recommendations.

We'll claim victory on the line extension change contained in the budget, and I want to come back to that in just a second. But let me just ask a few questions covering all of these recommendations.

So, first, with respect to Recommendation 1, we are providing a rationale here that talks about this as addressing a loophole that basically has to do with manufacturers and their related corporate entities.

In doing this, are we also bringing in something bigger than the particular problem that we're identifying, and is there a way to narrow the recommendations so that it's only addressing the particular situation in which we have concerns?

MR. VAN BUREN: I think in terms of trying to target this recommendation -- so if you were to try and carve out to say this only applies to manufacturers that have a corporate relationship, let's say, that was something -- I think it's very hard for us to capture the entire universe of corporate relationships and licensing agreements that could exist that could allow this same dynamic to persist.

So any attempt to narrow it may inadvertently fail to capture what we're trying -- what this recommendation would be intended to prevent.

CHAIR THOMPSON: So it's not that from a policy perspective, you wouldn't have a way of doing that. It's from an implementation perspective, we don't know how it could really get executed in that way. Is that right?

MR. VAN BUREN: That's fair. I think it's hard to conceptualize how to draft -- how this would be drafted to only target, you know, bad actors, for lack of a better word.

CHAIR THOMPSON: Yeah. Sure.

EXECUTIVE DIRECTOR SCHWARTZ: So I think as sort of a general point that we consider ourselves not -- lucky

not to be drafters, and so to the extent that you want to talk about what the Commission means and the rationale --

CHAIR THOMPSON: Right, the rationale for that focused on something which could potentially --

EXECUTIVE DIRECTOR SCHWARTZ: -- we can do it, and I think that's the appropriate, you know, cautions about this, what we mean, but, you know, Rick is the only attorney on staff. And I think he's glad he's not a drafter too.

CHAIR THOMPSON: And on the other side of that, by not narrowing the recommendation to the specific circumstance that we're concerned about, are we capturing some other situations which don't cause us concern or where there is actually a positive policy outcome?

MR. VAN BUREN: So we spoke to some of the staffers who actually worked on -- the requirement to blend the AMPs was part of the Deficit Reduction Act of 2005, and we spoke to some of the staffers who worked on that. And I think the intent of the provision was to -- part of the intent may have been to create a disincentive for manufacturers to introduce authorized generics. Part of the intent may have been to create a measure of AMP that

could be publicized in some sort of public reporting database.

Neither of those -- based on our conversation, the language regarding the transparency and the public database fell out of the final draft, and in terms of the other issue around authorized generics, there's an FTC report that looked at this issue and didn't see a measurable effect on authorized generic -- well, the FTC essentially said the business decisions that manufacturers make regarding whether or not to introduce an authorized generic are complex and multilayered, and tracing it to one policy change would be very difficult. So I think that's a long-winded way of saying that there's, you know --

CHAIR THOMPSON: Okay. All right.

MR. VAN BUREN: Yeah.

CHAIR THOMPSON: Let me ask a question about Recommendation 2. So Recommendation 2 is about taking action basically because there isn't manufacturer cooperation. So the way that I read this recommendation, we're saying -- earlier we talked about whether we needed more resources to do more audits, to find more situations, but I'm presuming based upon the OIG -- was it the OIG

report? Yes. That given their analysis, we're no longer thinking that we need to necessarily invest more on the audit side of this in a substantial way, such that we would want to make a recommendation about resource levels.

So now we're doing audits. We're doing reviews of the classification of these drugs. We find a small percentage, as you noted, that may be misclassified.

So we're making a recommendation about CMS taking action because we believe that if they write the manufacturers or call the manufacturers and say we believe this is misclassified, the manufacturers will not adjust their classification on their own. Is that correct?

MR. VAN BUREN: That's possible, yeah.

CHAIR THOMPSON: And have there been circumstances where that's happened, where CMS has said, "We think this is misclassified, and the manufacturer has failed to make the proper adjustment"?

MR. VAN BUREN: Yes. The most notable instance of that was with EpiPen.

CHAIR THOMPSON: Yeah.

Although maybe there was some question about how clear -- right? -- that communication was?

MR. VAN BUREN: Yeah, that's fair.

CHAIR THOMPSON: Okay. And we say maybe misclassified. Presumably, it is possible that the manufacturer has information or has a counter-argument that could be compelling to the government, correct? And so that when the government comes and says, "We've got a problem here. We don't think this is correct," and the manufacturer comes back and says, "No, we think you're wrong," the manufacturer may be right in that instance. And there may be a need to exchange some information for that to be adjudicated in a proper and fair way, correct?

MR. VAN BUREN: Yes.

CHAIR THOMPSON: And our concern here in this recommendation is those instances where even after the exchange of that information, there is not a method to require the manufacturer. In other words, if there is a process by which an identification of a possible problem, an opportunity to respond and support with additional documentation results in a decision by the government that the drug is misclassified, now we're sitting in that situation. What are the available remedies at this juncture that are not embedded in this recommendation,

which would have the government just make the change or the government suspend the drug? Right now, what would be CMS' next step?

MR. VAN BUREN: At that point, CMS could terminate the manufacturer from the rebate program if they found that they had good cause to do so. That would remove all of the drugs of that manufacturer from the rebate program.

In terms of other governmental authorities, the Department of Justice could initiate a claim under the False Claims Act against such a manufacturer, but that would be up to the DOJ. It's not CMS' decision.

CHAIR THOMPSON: But there are CMPs too, right?

MR. VAN BUREN: There are CMPs, civil monetary penalties. The OIG -- and that was a -- in the December report that we discussed, one of CMS' comments in its response to OIG was that the OIG should use its oversight and enforcement authority to compel manufacturers to correct inaccurate classification data.

OIG specifically responded to that point by saying it believes it lacks the legal authority to affirmatively pursue penalties for the submission of

inaccurate drug classification data. So OIG believes that the CMP authority doesn't extend to this instance.

CHAIR THOMPSON: Okay.

I mean, I do think that -- and I want to allow the other Commissioners to jump in here, but it's one thing to say we may have concerns about suspending a drug because of beneficiary impacts, and others can jump in and comment on that point.

Although we could always say that CMS doesn't have to use the authority that way -- right? -- and they could take things into account, as they do in other program integrity areas, where they consider impacts on beneficiaries and access and networks as they determine what kind of enforcement action that they want to take on different issues.

But in terms of just reclassifying the drug -- and I made this point earlier in our conversation about this at the prior public meeting -- I am concerned about whether manufacturers, if they improperly misclassify a drug, if the government is fixing it for them, does that actually incentivize them in the wrong direction? Which is I'll put it in a certain classification, and then if the

government calls me on it and I can't convince them of my case, then the government has a way to just fix it and we move on. So what's the penalty in that instance for a manufacturer who has misclassified that drug?

MR. VAN BUREN: So the current penalty -- all the current penalties would still -- I'll say a manufacturer could conceivably do that now, and all of the current enforcement authorities and penalties that they would be subject to would still remain, so termination from the program and liability under the False Claims Act.

Currently, whenever CMS discovers that a drug may be misclassified, it goes through kind of an iterative process with the manufacturer, similar to what you describe, where they each present their arguments. Depending on the specific facts of that, of that individual cases, CMS may ask for back rebates in that instance. It's not a given, but it can occur.

So we could certainly include something in the rationale about instances of intentional -- it sounds like you're talking about intentional noncompliance or --

CHAIR THOMPSON: Not even intentional noncompliance. I mean, I think people respond to

incentives, and people take care where care is required. And they act promptly when it's important to act promptly, and then they give themselves a little bit of leeway where they think they can take some leeway. So I just think that that's human nature.

And I'll see if any other Commissioners have points of view on this, whether or not we want to try to first ensure at least in the rationale in the discussion that we anticipate that the decision for the government to reclassify the drug would not be taken without an opportunity for a manufacturer to be heard on the issue; and then secondly, whether we want to suggest that there ought to be some way, in addition to reclassifying the drug, to either go back and collect past rebates to the time that should have been classified properly or have any other administrative penalties available in order to ensure that people are taking proper care.

I do want to come back to the third recommendation, but let me just stop there for a second and invite other comments from Commissioners. We have Kit, Chuck, and Martha.

COMMISSIONER GORTON: So, Rick, first a question.

Under the current process -- or rather under this recommended process, is there due process for the manufacturer? Is there an opportunity, an administrative process or something that exists that CMS would -- if all this came to pass, would use its new authority to reclassify the drug, and then are there administrative procedures that the manufacturer could use to say, "No. CMS, you're wrong, and we need a neutral adjudication"?

MR. VAN BUREN: I think in the current process, it might be fair to say the default setting is to work -- is for CMS to work with the manufacturer because that's their only kind of avenue of achieving this.

COMMISSIONER GORTON: Right.

MR. VAN BUREN: I think in anticipating how CMS would use its authority, it's conceivable that they would take the same approach they currently do in reaching out to the manufacturer first and then kind of trying to work to an agreement. These authorities would obviously give them greater leverage in such a situation.

If they go through that and the manufacturer still disagrees with their position, I don't want to speak out of school. I think they would probably be avail

themselves of the courts if that comes up and certainly can litigate.

COMMISSIONER GORTON: Right.

So my thoughts on this would be that there needs to be -- I like that they default now to alternative dispute resolution, and I think we shouldn't discourage that.

I do think at the end of the day, though, sometimes dispute resolution doesn't get to the right answer, and I don't think necessarily we should give CMS the trump card to say, "Okay. This is it." There ought to be some avenue to push back on that. I don't think it needs to be the Supreme Court or anything, but I do think that we ought to give them some administrative avenue.

A second thing is I'm concerned -- and I suspect other people are -- suspending the drug holds the providers and the members hostage, the patients hostage, and it may have very limited financial impact on the manufacturer. And what we're talking about here, if a sin is being committed, it's a financial sin, and so there ought to be a financial penalty. There shouldn't be a clinical outcome.

And so if OIG believes that it lacks authority to

do civil monetary penalties, then maybe part of the solution is to give them the opportunity to impose civil monetary penalties because I hear what you're saying. The fact that CMS under the current framework cannot compel the manufacturer to reclassify the drug, then I think if we give them the tool that says, "Okay. But it's going to be really expensive as long as you keep this misclassification there. We can't make you do that, but you're going to pay for it." And if we think that the motivation for the misclassification is, in fact, monetary, then having a monetary penalty would seem to me to offset that.

So I would be interested -- and it may be, to Anne's point, that we're not drafters. It may be that we just want to say should -- they should seek authority for a full range of intermediate sanctions, and we don't have to define what those are. But if you want to give some examples, I would certainly prominently highlight CMP.

And I'd like to talk less about -- first of all, suspending the manufacturer ain't going to happen, except in the most egregious behaviors, and that's going to be probably something criminal.

And suspending the drug hurts providers and

beneficiaries, and so I would like to deemphasize the idea of suspending the drug and just talk about other intermediate sanctions, of which there are many available.

CHAIR THOMPSON: Chuck, Martha, Sheldon.

COMMISSIONER MILLIGAN: Nice job, Chris and Rick, and Nice job, Kit.

Rick, I had just a -- I was going to focus on Recommendation No. 2 as well. Has CMS suspended a manufacturer; in other words, using the tool now, just broadly suspended a manufacturer for misclassification of drugs -- for a misclassification of a drug?

MR. VAN BUREN: Not for misclassification. They have terminated manufacturer rebate agreements for submitting inaccurate data.

COMMISSIONER MILLIGAN: So with respect to misclassification, CMS has not taken the major sanction available to them of terminating the manufacturer?

MR. VAN BUREN: That's correct, and they actually cite in the OIG report that has been getting a lot of attention that they're cognizant of the potentially disrupt -- that that would be significantly disruptive to

beneficiaries.

COMMISSIONER MILLIGAN: I wanted to come back -- I think I heard you say when you were doing the presentation about Recommendation No. 2 that CBO scored it as not really a saver?

MR. VAN BUREN: That's right.

COMMISSIONER MILLIGAN: Okay. So I think the question I wanted to put -- my last question on Recommendation No. 2 -- is if CBO doesn't score it as a saver, if in general, compliance is increasing, if there is the risk of litigation and there is the risk of beneficiary losing access to the drug, could you state the rationale for having Recommendation No. 2? Because I'm not seeing savings. I'm not seeing the -- I'm seeing the risk of litigation. I'm seeing the fact that CMS has -- is achieving better compliance about classification.

So what is the -- I think there is a rationale, but I think that it hasn't' been directly stated about the basis of the rationale for Recommendation No. 2 in the case of -- like what is it going to fix that isn't fixed now and if there isn't potential savings, et cetera?

MR. VAN BUREN: So I think the CBO score,

notwithstanding the OIG did identify that there were some savings that could be achieved through this recommendation, they weren't significant. I think reading between the lines, if you take EpiPen out of this, they were obviously responsible for a lot of the costs associated with intentional misclassification.

There is a level of just ensuring overall -- giving CMS the tools to ensure compliance with the law, and right now, they don't have those tools. They seem to exist in other parts of the program. This is one where they're lacking.

In terms of future noncompliance, CMS has changed its systems to make this more difficult; that is, they're not required to do so by the law. They're not required to do so by regulation. So while it's currently the case that this is difficult, it's not a certainty that this -- that it would always be the case. It's hard for us to kind of see what's coming around the bend, but this just ensures that regardless of what happens down the road, CMS does have some level of sanctions between asking the manufacturer to voluntarily comply and kicking them out of the program entirely.

COMMISSIONER MILLIGAN: And I guess my final comment is I do want to align myself to what Kit said about, I think, one of the remedies that would be beneficial here is creating access to civil monetary penalties.

Thank you.

CHAIR THOMPSON: Martha.

COMMISSIONER CARTER: I think I'm sort of fine-tuning what Kit said, understanding that the current -- I'm sorry. I'm looking at Recommendation No. 2, the second part of it, the ability to suspend drugs from the program until the misclassification has been corrected, just making sure that we protect the beneficiary.

I understand that this is less draconian than what's in place, and that's probably why it hasn't been used, but perhaps we could add some rationale that states we are concerned for preserving access for the beneficiary as well, the expected appeals processes is going on.

CHAIR THOMPSON: Sheldon.

COMMISSIONER RETCHIN: Since I was out last meeting, do I get extra minutes?

CHAIR THOMPSON: No.

[Laughter.]

COMMISSIONER RETCHIN: Well, I actually did have two. So, first, for Rick, since you mentioned it -- so first question for you would be on the Mylan EpiPen misclassification. How does the recommendation change or close that loop? They were fined, I think, and had to provide remedy for the rebate and the misclassification. So that would be my first question. I'm sure I'm being naive about that.

The second one, though, I guess is for Chris on the line extension and actually a little confession, and I don't want anybody to pull my college transcript. I didn't do real well in math.

So if you go to page 8 on the recommendation for the line extension, I'm just having a hard time trying to put together and follow the CBO scoring and then what you found on PBM. It almost doesn't even directionally seem the same thing, how they could get to $5.7 billion and then the PBM estimates. They're so far apart, or am I missing something?

MR. PARK: Sure. I don't know which question you want answered first, but --

COMMISSIONER RETCHIN: Oh. Well, let's go reverse because I can't remember the first.

[Laughter.]

MR. PARK: Okay. So the line extension correction that the CBO scored will significantly increase the rebates overall, the total rebates for those particular drugs, because the way the existing formula worked, very few line extensions were actually falling into this alternative rebate situation. And so that's why there's significant savings, is that the inflationary rebate on those line extensions is going to go up dramatically, so that's how they're getting the $5.7 billion over 10 years.

The reason why that supplemental rebates may not be affected as much is that the increase in the line extension rebates may go far beyond what that guaranteed net price is right now on those line extension drugs. It could potentially wipe out the supplemental rebates but also go way beyond what they're currently negotiating right now.

So there is a chance that the supplemental rebates will go down to zero because of that situation, but only about 10 percent of the supplemental rebates are

affected because there aren't that many line extension drugs. It's not like an overwhelming percent of the drug utilization.

And, again, that's kind of an upper bound, is the 10 percent assumption. Manufacturers still have some incentive to negotiate supplemental rebates for those particular products because they do want the market share, and so it's not necessarily the case that they would all go to zero. And so it's hard to kind of predict where that will fall, but overall, the total rebates will go up more than they are now. It's just some portion of that increase in the rebate dollars, the $5.7 billion that they're projecting, may be offset with some losses on the state side because their supplemental rebates go down.

MR. VAN BUREN: And then to answer the question about Mylan and how this recommendation to it addressed that specific instance, over a period of several years, you had EpiPen. So, first of all, I think it's very unlikely -- I think the manufacturer knew it was very unlikely they were going to get terminated from the program, given the breadth of drugs they produce.

So, secondly, there's a history of agency

publications, sub-regulatory guidance over several years that essentially said, "Manufacturers, if you have this type of drug, you should be classified as a generic drug," and that didn't move the needle in terms of the EpiPen classification. So this would be a way for -- this would have given CMS kind of a way to split the difference between putting out guidance and hoping and doing nothing.

COMMISSIONER RETCHIN: Can I just follow that up, Rick? And maybe this gives -- I don't know. Again, it may be apples and oranges, but it just gives Kit's point and Martha's point some legs.

EpiPens were actually -- even though classified as generic or misclassified – were the sole -- almost the sole drug for anaphylaxis. So had that been removed or the manufacturer suspended, that would have been a dramatic impact on patients or beneficiaries.

CHAIR THOMPSON: Let me go to Bill and then Darin.

I want to jump back in, and then I want to do some public comments. And then I want to come back to sort of figure out what we want to direct the staff to do in terms of any changes in wording to the recommendations

before we vote later today.

So, Bill.

COMMISSIONER SCANLON: Okay. I actually am supportive of the recommendation, but I'm not sure I understand it. And it's whether or not we're telling the Congress to choose between these two options or to enact both of these options, and then if they were to enact both of these options, if I'm CMS, sort of how do I sort of then approach a problem like this.

And in some respects, if CMS has the knowledge to be able to determine a drug has been misclassified, then it would seem like the first part completes the job. Due process needed to be sort of factored into this, but at the same time, they will reclassify the drug. Patient can still receive it. There's no sort of disruption that's involved.

That breaks down a bit if CMS doesn't have enough information to decide sort of whether they should reclassify the drug. They've made a request to sort of manufacturers, and they, in some respects, have no stick to sort of make sure that the request is satisfied, that they get the information to actually sort of make the

classification.

So I'm thinking in that case, if CMS were to reclassify a drug, then they would be vulnerable in a court when someone came in and said you didn't have a basis for doing this. So there's this issue of how can they get the information that is necessary to do that.

And I think something like civil monetary penalties or some other sanction would be better than suspension in terms of sort of having that kind of leverage, but I'm still questioning whether I would only want to do the first part of this recommendation as opposed to both.

CHAIR THOMPSON: Darin.

COMMISSIONER GORDON: So I agree with what's been said about giving adequate authority for CMPs and having a sufficient due process set out for this.

But still the question is a little bit like what Bill is saying. If CMS has the ability to determine that a drug has been classified and not knowing how that process is done, why doesn't CMS at the point that a manufacturer is applying to be part of the Medicaid drug rebate program make the determination on the classification on the front

end, and then we don't have this discussion?

MR. VAN BUREN: That's how they changed their system to operate currently, your conversation about the front-end determination.

So now when a manufacturer registers a new drug, if it was approved by the FDA under an abbreviated new drug application, it can only be classified in the system as a generic. But if it was approved by the FDA under a new drug application, it can only be classified in the system as a brand drug. So going forward, that's kind of their system.

COMMISSIONER GORDON: This is just dealing with past drugs that are already on the market on the drug rebate program?

MR. VAN BUREN: Yeah.

COMMISSIONER GORDON: Okay.

MR. VAN BUREN: Yeah, it would be pre-Hatch-Waxman drugs primarily.

COMMISSIONER GORDON: Okay. That's helpful.

CHAIR THOMPSON: So I want to make a couple of comments in response to the conversation and then make a comment on Recommendation 3 and then, as I said, open it up

for the public so we can see if there's any additional points that we ought to hear about as we discuss and finalize a direction to the staff here.

So one is I do think it seems clear that we prefer the financial sanctions to the participation sanctions, and I'm interested in sort of thinking about whether we can pick up on Kit's language about intermediate financial sanctions and kind of not prescribe, as we would never do, right? If it's a CMP, what is the CMP, and is it per instance, or is it per day, or is it per drug or those kinds of details, which I think are best left to further discussion and elaboration among the staff drafting the provision?

I also think it sounds like we want to be sure that there is an opportunity for informal resolution and an opportunity to be heard, for the agency to express its argument for why it believes the drug is misclassified, for the manufacturer to have an opportunity to respond and potentially to take advantage of something like a departmental appeals board process or something to resolve disputes.

And again, I don't think that we would

necessarily have to prescribe the exact steps and timelines and order in which such things are resolved, but simply to say that such a process should be part of imposing these kinds of intermediate sanctions, which is not at all unusual.

I would make a note that sometimes there's also an issue about getting a response, and so, to some extent, some intermediate sanctions may be useful to apply in order to generate a response back.

But, again, I don't think that we have to necessarily dive into all of those details.

I would like to say something about Recommendation 3 and my concern about that recommendation, which is when we initially have the conversation in the prior public meeting at which we first discussed some of these ideas, we were talking about sharing rebates with states in the context of a larger recommendation around the change to the line extension drugs alternative rebate formula.

And so we were talking about making a formal recommendation that had a potential large savings attached to it and then saying as an adjunct to that recommendation

that we would make an argument that those savings ought to be shared with states.

We'll take credit for at least in part the conversation that we had generating some of the action up on the Hill to actually make that fix, but now we don't have a larger savings figure to attach that sharing line too. And I think that if we were to have a discussion about in what way states ought to share in certain kinds of savings associated with the rebate program or not, I'm not sure that we would have honed in on this particular provision as the one in which to recommend a different formula for sharing state savings.

So I find it a little awkward to promote this idea, which now is a coster instead of part of a larger saver, and I think that perhaps we've just missed our opportunity on that one. And if we want to take up the larger question of how states share in rebate savings or how states share in savings more generally, I think it's better deferred to a different context and a different framework for that conversation than this one.

Toby.

COMMISSIONER DOUGLAS: Just thinking this through

the lens of the states, the concern with the ACA changes as well as this change, the idea of the drug program of states as well as Federal government driving efficiency within the drug program, sharing in the savings, and these changes changing that, I don't think honing in on this one specific is the answer. But for future discussion about assessment of how to create the right incentives between the state and Federal government on the drug rebate program or overall, I think that's the right venue to take this up and what policy rationale is it to now shift this approach within the drug rebate program, both with the ACA and here that it's all federal savings is something that could be brought up in the future.

CHAIR THOMPSON: And which is not to say, in my view, that we would not want to have that discussion in the chapter, that we would not want to discuss what we had thought would be a construct for a recommendation around the line extension rebate, alternative rebate formula and how we thought we could potentially promote the idea of sharing those savings back with the states.

But given OBE, that we are now deferring that kind of a conversation to a different context in the

future, should that be the desire of the Commission, rather than making that as a recommendation here.

Darin.

COMMISSIONER GORDON: Yeah. I totally agree. I mean, in the context of what Sheldon was talking about or asking about in the supplemental rebates, when you do things such as the 8 percent in the ACA or in this particular instance, it does have a ramification on supplemental rebates, which then has a negative impact on a state. They were getting a supplemental rebate, they get a portion of that rebate, and now they don't. So these all are inextricably linked.

But I agree with what you all have said. This isn't the particular place to make that point, but I do think we do need to make room for that broader discussion because it is about incentives.

CHAIR THOMPSON: Right.

Chuck. And then I'm going to open it up for the public.

COMMISSIONER MILLIGAN: Yeah. I might help with that segue. So I'm in agreement, Penny, and so what I'm hearing you say is this is not going to be voted on. We're

going to withdraw this from consideration as opposed to have a vote on it, and so --

CHAIR THOMPSON: That's right.

COMMISSIONER MILLIGAN: -- for the public comments, I wanted just to make it clear that it's not likely we're going to be voting on No. 3 at all.

CHAIR THOMPSON: Thank you, Chuck. Yes.

All right. Let me just pause here and open it up for public comment so we can take that in.

Go ahead. Approach the microphone, and just say your name and where you're from.

PUBLIC COMMENT

* MR. GRIFFITH: Thank you. Fred Griffith. Thank you for moving it closer. I'm only two blocks away, but I got to leave right away to go back over.

CHAIR THOMPSON: We knew we made a lot of people happy.

MR. GRIFFITH: So thank you very much for doing that. I appreciate it very much.

I have a very simple question. If you're a dual eligible in a Medicaid expansion state, are there any extra benefits or coverage attributable to such a status? I'm

not talking about the income limits or anything like that. I'm talking about are there any coverage benefits that would be attributable to such a person?

CHAIR THOMPSON: I'm sorry. This is not a question specifically on the topic that we were just discussing. This was just a general desire for some information?

MR. GRIFFITH: Correct.

CHAIR THOMPSON: Does anybody --

VICE CHAIR GOLD: Yeah. I think if I understand you, the answer is no. But if you're a dual eligible, a fully dual eligible --

MR. GRIFFITH: Yes.

VICE CHAIR GOLD: -- your benefits already are quite comprehensive, and your cost sharing is low. So you'd in fact be better off than in a Medicaid expansion plan.

MR. GRIFFITH: Right. Well --

CHAIR THOMPSON: Well, if you're a dual eligible, Medicaid expansion status is irrelevant.

VICE CHAIR GOLD: Right. It's irrelevant.

CHAIR THOMPSON: Yeah.

MR. GRIFFITH: Okay.

CHAIR THOMPSON: Okay.

MR. GRIFFITH: Thank you very much.

CHAIR THOMPSON: Thank you.

Any other comments on this subject before we proceed?

[No response.]

CHAIR THOMPSON: Okay. I'm going to make -- does any other Commissioner want to weigh in before I try to give the staff some direction about drafting?

COMMISSIONER CERISE: Can I just make one -- because I've heard a lot on No. 2 about civil penalties and other kind of administrative solutions, but I do think what I'm hearing from the recommendation is, on top of all of that, there should be authority -- not require, but the authority to say we'll exclude this drug and not every drug from the manufacturer. And to the extent that that adds something, I would certainly support leaving that option in.

CHAIR THOMPSON: Well, let me test that proposition because I think what I heard most of the Commissioners weigh in is that we think that we could get

to where we need to go by purely talking about an intermediate sanction list that is totally financial, so that we would say that CMS could have the authority to redress the classification error itself without the cooperation of the manufacturer or without relying on the manufacturer's action, supported through a process of discovery and due process that ensures that CMS knows what it's doing. I mean, we won't put it that way.

And then that there could be in addition to that, some penalties through civil money penalties that could be also constructed to ensure that manufacturers have the proper incentives to take care, to be responsive to CMS when it asks for the information that's necessary in order to draw the proper conclusions about classification, and to, in fact, incentivize the manufacturers to address these issues themselves, which would be everyone's preference.

Go ahead, Rick.

MR. VAN BUREN: I just wanted to clarify on CMPs too. The decision to issue CMPs is not made by CMS. It's made by the OIG. So part of the rationale for -- the thought process on our recommendations was to give CMS specifically some intermediate sanctions. I just wanted to

make sure that was obvious.

COMMISSIONER CERISE: I guess that was my question, is does that -- the ability to exclude, does that provide any added leverage in these discussions, or if you can get at it totally a different way, fine, but my understanding is you've added that because your concern is you can't get -- you potentially cannot get to the proper classification without that potential leverage point.

CHAIR THOMPSON: But I think that goes exactly to where Bill was, which is if you can just fix it yourself, then you don't ever need to go to an exclusion of the drug, right? You can just -- and again, assuming that you've gone through the proper process, which you would want to do in either case, to assure yourself that you feel confident in your conclusion, that if we give them an opportunity to just correct the financial error, which is the classification for the purposes of the rebate, then we never have to reach a question of whether or not the drug is available or not to beneficiaries. And I think that's everyone's preference, and it seems sufficient.

So what I would ask Rick and Chris is for us to see a little bit of a drafting, and again, I think that

it's the view of the Commission that we don't need to prescribe the exact nature of all of the details of the sanctions that would be available, but rather through example and discussion underneath, you know, talk about the fact that we are focused on financial sanctions. We would say that in the text and body of the recommendation as well, intermediate sanctions, sanctions that could be under the authority of CMS as well as the OIG, and I think that would be -- and then I think in the rationale, we need to just acknowledge that there needs to be a process supporting that, which provides for proper levels of evidence to be developed, an opportunity for manufacturers to respond, a desire to resolve without first through the voluntary action of the manufacturer.

COMMISSIONER CARTER: And then underlying concern to preserve access --

CHAIR THOMPSON: That's right. Thank you, Martha.

COMMISSIONER CARTER: -- too on the medications that may be the only option for beneficiaries.

CHAIR THOMPSON: That's right. That's right. Thank you.

So we will leave it to you, and then we will vote on the first recommendation, the second recommendation. We will not vote on the third recommendation, okay?

Super. Thank you very much. We'll look forward to seeing that later in the day again.

All right. Let's go ahead and move on to our next session, which is a review of the June report, chapter, and recommendations about substance use disorder confidentiality regulations.

Why don't you give us a moment to settle in as people get a coffee refill for one second, just so we are attending to you from the get-go.

[Pause.]

CHAIR THOMPSON: Okay. Why don't we go ahead and get started.

REVIEW OF DRAFT JUNE REPORT CHAPTER AND RECOMMENDATIONS: SUBSTANCE USE DISORDER CONFIDENTIALITY REGULATIONS AND CARE INTEGRATION IN MEDICAID

* MS. MINOR: Hi. Good morning. As part of exploring Medicaid's role in substance use disorder treatment, MACPAC has identified the need for improved

integration of behavioral and physical health care services, and the Commission has noted that the Federal 42 CFR Part 2 regulations, which govern the confidentiality of SUD treatment records can act as a barrier to health record exchange among providers that treat Medicaid enrollees.

And you most recently highlighted these issues in January and discussed potential ways to address these concerns; in particular, the wide-ranging confusion among stakeholders about the current regulation's application.

So reflecting this previous work, we today present an overview of the draft chapter for the June report as well as draft recommendations, and we look forward to your feedback at the end of the presentation. We want to ensure that the content clearly details Part 2's effect on SUD care and integration in Medicaid, and that the proposed recommendations correctly capture your thoughts and provide sufficient supporting evidence.

In drafting the chapter, comments submitted in response to federal rulemaking on Part 2 provided us with many insights on the views of state Medicaid directors, health care providers, plans, and patient advocates, and we also relied on information we gathered during a MACPAC-

convened expert roundtable back in November of last year.

The chapter begins with a discussion of the need to protect SUD-related information from potential harmful disclosures. We provide examples of how having an SUD can expose individuals to negative consequences, such as criminal prosecution or a loss of child custody, housing, or employment. And discrimination in the health care system is possible as well since some health care providers have negative views about individuals with SUDs. And the stigma of SUDs and fears about their potential exposure can prevent individuals from seeking needed treatment.

The Part 2 regulations, which implement laws passed in the 1970s are intended to address these concerns.

The chapter then goes on to summarize the Part 2 regulations. SUD treatment providers subject to Part 2 generally need to secure patient consent before they can disclose information related to SUD prevention, diagnosis, treatment, or referral. And this includes disclosures to other providers for treatment referrals or to Medicaid MCOs for payment. The recipient of any of that protected information generally can't share that information further unless there's new and separate patient consent.

And the required consent must capture several pieces of information, including how much and what kind of information may be disclosed and with whom it is being shared, and you'll hear more about this later from Erin.

The chapter discusses -- and the slide here also lists some of the limited exceptions to when consent is required; and payers can re-disclose information without consent to contractors for payment and health care operations purposes but not for treatment purposes.

SUD information subject to these consent requirements when it's delivered by a provider subject to Part 2 -- and the regulation defines this as a provider that is federally assisted and meets the definition of a program -- and a program in the regulation is an individual or entity other than a general medical facility or an identified unit within a general medical facility that holds itself out as providing and does provide SUD care.

It could also be a staff in a general medical care facility whose primary function is SUD care and who is identified as providing such care.

The chapter than briefly compares HIPAA and Part 2. As you know, HIPAA governs the disclosure of most other

individually identifiable health information. Generally, under HIPAA, consent is not required for providers to share information for payment, treatment, and health care operations. However, for SUD-related records, Part 2 takes precedence and permits disclosure without consent in far fewer circumstances. Law enforcement access is also more limited under Part 2.

So the next few slides provides some scenarios illustrating how information sharing without patient consent is generally more restricted under Part 2 than under HIPAA.

So, in this slide, you see the different requirements for sharing between a patient's individual health care providers.

The next slide shows the different requirements for sharing information between a patient's provider and a payer. It also shows sharing between a payer and a payer-supported program or activity that includes a treatment component. In this case, it would be the use of a care manager employed by an MCO.

And finally, the last slide illustrates when consent is needed for an MCO to re-disclose information to

a contractor for health care operations purposes, so the difference between the previous one and this one is -- the earlier slide showed re-disclosure for treatment purposes, whereas this one focuses on re-disclosures for health care operations purposes.

And I'll turn it over to Erin to discuss the remainder of the draft chapter.

* MS. McMULLEN: All right. Thanks, Nevena.

So I'm going to run through the challenges related to Part 2 that were highlighted in the chapter. The first relates to limitations on sharing information.

So there's widespread agreement about the importance of sharing information, but stakeholders disagree about the extent to which that information should be shared without patient consent.

Consent requirements can make it difficult to coordinate care, manage care transitions, and follow up on patient referrals.

Stakeholders often say Part 2 restrictions could result in inadequate or even dangerous care. That could include prescribing multiple medications that might have dangerous interactions with each other.

Some also express that separate privacy regimes just reinforce stigma that individuals with a substance use disorder face.

In instances where a patient has given their consent for disclosure within the health care system, there are additional barriers that exist. Those include the last two bullets on this slide, and we talked about those in a little more detail at our January meeting.

The chapter goes on to provide examples of how Part 2 impacts Medicaid delivery systems and places limits on data sharing. They make it challenging to assume financial risk or actively manage high-cost patients who might have a substance use disorder.

In your handouts, you should have a single sheet that has a box -- it's called Box 1 -- that provides example scenarios of how Part 2-protected information can or cannot be shared without consent in the health care system, and unless you have any objections, we'll go ahead and include that in the chapter.

In response to these challenges, the most recent update to the regulation does permit sharing without consent in certain circumstances. State Medicaid agencies

and MCOs can re-disclose information without patient consent for the purposes of payment or health care operation activities. However, they're not allowed to re-disclose for treatment purposes, and that would include care coordination as well as case management.

So plans and state Medicaid officials have argued that those activities should be considered patient safety activities, which SAMHSA does consider health care operation. If care coordination and case management were classified this way, payers would be able to re-disclose that information without additional patient consent.

So the chapter goes on to highlight confusion about Part 2's application, and that confusion influences the rationale for the draft recommendations.

The first area of confusion relates to who is considered a treatment provider subject to Part 2. SAMHSA has not offered guidance that clearly defines which providers and what settings are subject to the regulation. Key concepts such as holding one's self out as providing substance use care are largely left open to interpretation.

It's also unclear whether certain providers meet the definition of a program, especially for those that are

federally authorized to prescribe buprenorphine.

In the most recent updates to the regulation, SAMHSA has stated that prescribing buprenorphine does not necessarily make a provider fall under the definition of a Part 2 program, but because of this ambiguity, providers must use their own judgment to determine whether part or all of the medical records they keep are subject to the regulation.

The second area of confusion is which patient and what part of their records are subject to Part 2. It's not clear how the regulation applies to records for unrelated medical care delivered in conjunction with substance use treatment, medical care for illnesses resulting from a substance use disorder, or a medication such as buprenorphine that is used to treat substance use disorder.

So just as an example, a patient in a substance use treatment program may have liver disease that's directly attributable to their substance use disorder, but it might be unclear if the treatment for that illness falls under Part 2 or HIPAA. And patients may also be unsure whether Part 2 applies to their records because of this ambiguity.

There's also confusion about when information can be shared within a Part 2 program. There's certain instances where substance use information can be shared without patient consent, and that communication without consent is allowed between program personnel or between program staff and staff at an entity that has direct administrative control over that program.

Providers requested the term "direct administrative control" be further defined, but SAMHSA has declined to do so and advises stakeholders to consult with legal counsel to ensure compliance with that portion of the regulation.

Another area of confusion is what information must be captured in patient consent. The most recent update to the regulation attempted to make data sharing easier for patients whose information is shared within a health information exchange. Patients can make a general designation now of an individual or entity who would be the ultimate organization where the information is shared, so long as that person or entity has a treating provider relationship with a patient.

However, organizations representing providers and

payers assert that there is additional confusion regarding this general designation provision.

When providing consent, a patient must also specify how much and what type of information can be shared. While the consent form may include an option to share all their substance use health information, it must also provide a patient with specific granular options, which allows the patient to select only the information they want to share.

So SAMHSA has suggested that one way to present these options is to use information categories that would generally be found in a health record such as medications and dosages, but stakeholders have advised that this requirement is ambiguous and has requested that SAMHSA provide additional subregulatory guidance, including sample consent forms, that would comply with this granular requirement. However, at this point, nothing has been issued.

So that wraps up the challenges, and with that, I'll turn it back over to Nevena to discuss the recommendations.

MS. MINOR: So the first recommendation says,

"The Secretary of Health and Human Services should issue additional subregulatory guidance on 42 CFR Part 2 that includes clear definitions about which providers and which patient information Part 2 applies to, when information can be shared within a Part 2 program, and sample consent forms."

This recommendation would help lead to more consistent application of Part 2 by resolving ambiguities, which may cause providers and payers to misinterpret the regulations. MACPAC is concerned that confusion may lead to unnecessary self-imposed restrictions on information sharing, affecting delivery of whole-person care to Medicaid enrollees with SUDs.

And SAMHSA has acknowledged the need for certain clarifying guidance, but it's not issued any such guidance to date.

In your discussions, you recognize that there are disagreements among stakeholders about whether consent should be needed for SUD information to be shared inside the health care system, but absent any underlying regulatory or statutory changes, clarifying Part 2 should help promote more information sharing as is currently

permitted by the regulation.

The guidance should provide clear and consistent definitions of which providers are subject to Part 2, including whether it applies to buprenorphine prescribers or addiction specialists in multispecialty practices; what information Part 2 protects, for example, whether it applies to non-SUD medical care delivered in SUD treatment settings or care for illnesses associated with SUDs; and who within a Part 2 program can share SUD information with each other and whether it must be segregated in EHRs, accessible to providers in a Part 2 program. HHS should also issue sample consent forms that specify the granularity required by Part 2.

We don't think that this recommendation would have any direct effect on federal Medicaid spending. For states, any increased information sharing as a result of clearer guidance has the potential to improve care coordination for individuals with SUDs and coordination with other health care and support related Medicaid delivery system and payment reforms.

Beneficiaries with SUDs could also benefit from better care coordination and ensuring appropriate and

consistent application and health system compliance with the regulation could alleviate concerns that sharing of SUD information may cause patients harm.

Similar to the effect on states, better plan and provider understanding of Part 2 could foster more consistent and potentially increased data sharing, which in turn could improve patient care and consideration of SUDs in delivery and payment system reforms.

The second recommendation is contingent on the adoption of the first recommendation. It reads, "The Secretary should direct a coordinated effort by the Substance Abuse and Mental Health Services Administration, the Office of the National Coordinator for Health Information Technology, and the Centers for Medicare & Medicaid Services to provide education and technical assistance on compliance with Part 2 regulations. Such efforts should be targeted to state Medicaid programs, health plans, primary care and specialty providers, patients and their families, and other relevant stakeholders."

It would be the Commission's view that education and technical assistance is needed to ensure that

providers, plans, beneficiaries, and others know their rights and obligations under Part 2 and related subregulatory guidance.

To increase the reach of education and TA efforts, federal agencies should partner with relevant national and state stakeholder organizations to develop and disseminate information tailored to each constituency.

HHS should also provide additional education to patients and families about why consenting to disclose SUD treatment information to other providers can improve care coordination and health outcomes. The participants in MACPAC's roundtable noted the importance of conducting such activities to further disseminate any clarifying guidance.

The recommendation's effects are similar to those of the first recommendation. It would not have a direct effect of federal Medicaid spending. A better understanding of Part 2 could help states, providers, and plans better share patient information within the regulations' current parameters, potentially improving care coordination and the use of claims and quality data for various delivery system innovations.

And for beneficiaries, education can improve an

understanding of privacy rights as well as the potential benefits of providing consent for information sharing with a patient's entire treatment team.

So I'll close here, and we look forward to your comments and thoughts on the chapter. We're interested to hear if you think this addresses the major points. Do we strike the right tone, and have we characterized your concerns and views appropriately?

Likewise, for the draft recommendations and the rationale, have we captured your views accurately?

CHAIR THOMPSON: Okay. Thank you.

I think that we have given you the direction previously to come back with these two recommendations primarily because in terms of thinking about Part 2, we said to ourselves, well, we need to understand it better as well as does the entire community. And only through that additional understanding and actual application of the rules can we determine if there is still an issue that needs to be addressed, understanding all of these balances that need to be struck, which I think you do a great job in the chapter doing.

So I'll just make a couple of comments and then

open it up to the other Commissioners.

One is I'm not suggesting that we get more specific in the recommendations themselves, but when we talk about additional subregulatory guidance, that can take many forms and fashions.

And I think to the extent that we have suggestions -- I mean, you mention sample consent forms as an example, but to the extent that we can, through the feedback that we've gotten from the roundtable and the panelists and the research that you've done, identify other kinds of sub-regulatory guidance that might be useful, whether it's use cases, it sounds like people would like there to be some avenue for advisory opinions.

I don't know if there's anything from the HIPAA experience that we could apply. When HIPAA first came into being, people had lots of questions. There was lots of confusion. Was there anything that we can pick up there as productive suggestions to make for the Secretary to consider as what kind of subregulatory guidance will be most helpful to people? FAQs. Should there be a place where people can send in their questions and those kinds of things? So, again, not suggesting that be elucidated in

the recommendation itself, but in the body.

The second thing is that I think in the chapter itself, there's a lot of statements about this is not clear, and I always worry about that statement because it may not be clear to a lot of people, but it might be clear to some people. And so I think that we should just be emphasizing the point that the community of plans and providers -- and our interest, of course, being in the Medicaid and CHIP programs, coming from that perspective -- don't feel like they have command of these topics. So I would take it from that standpoint rather than from sort of like the general standpoint of this is just murky. It's murky to the people that we depend upon to deliver these important services to their patients, and I think we can stand on firm ground when we make that statement.

So Sheldon, Kisha, Marsha, Kit, Chuck.

COMMISSIONER RETCHIN: This is a very important area, and I think you did a terrific job, so thanks for your presentation and the recommendations.

I think I'm going to be very supportive. I just will say in the world of unintended consequences, HIPAA is probably in the top five. There are books written on that.

And as I follow this, I must say Part 2 confuses me.

Let me just ask you this. So there's a whole taxonomy of substance use disorders, but there are those who get prescription drugs and abuse prescription drugs, and then there are those who get illicit drugs, perhaps on the street, whatever.

But for those who abuse or get prescription drugs and have a substance use disorder, tell me how does a state prescription monitoring drug program get around that? There are 37 states, and as a provider, I can get on there. I may not have any therapeutic relationship, but I could find out what somebody is taking. How do they get around Part 2?

MS. MINOR: So if a patient is being treated for substance use disorder by somebody who falls under the Part 2 program definitions, so they're getting buprenorphine, which is a controlled substance, that Part 2 program provider is prohibited currently from reporting that information to the PDMP. So if a primary care provider is trying to access any other drug prescriptions that their patient has, they would not be able to see that their

patient is receiving buprenorphine.

Maybe I didn't completely answer your question.

COMMISSIONER RETCHIN: Let's say they're getting oxycodone and they're getting it through maybe five different prescribers or whatever.

MS. MINOR: I mean, that should be -- I mean, that would be accessible.

COMMISSIONER RETCHIN: That's automatically in PDMP.

MS. MINOR: Correct. Yeah.

COMMISSIONER RETCHIN: Okay. How do they do that? I mean, that seems like that would -- in setting that up, somebody must have addressed Part 2 in even setting up the PDMP. No?

MS. MINOR: No. Because in that case, Part 2 wouldn't apply. I mean just for the prescribing of like opioids for pain management, that kind of thing, Part 2 would not apply unless it was a Part 2 provider, I guess, potentially prescribing that, which wouldn't generally be the case.

CHAIR THOMPSON: Kisha.

COMMISSIONER DAVIS: Thank you for clarifying. I

mean, this was really helpful. Especially the comparison between HIPAA and Part 2, I found to be really helpful and the examples that you set out, because even with that, to really be able to identify where it comes into play and where it doesn't, I have concerns about Part 2 and HIPAA and them going in different directions.

So you have HIPAA which is complicated, but I think we at least in the provider world have gotten to a point where there's good understanding of it and how to protect patients.

And Part 2, which has actually been around longer, I am concerned about putting so much emphasis into creating a completely separate regulatory guidance for Part 2 that takes us further away from HIPAA. And so in the effort to educate the public and create guidance, you actually create more stigma around substance abuser, more separation, and I think in the end, more confusion about how can I treat this patient.

I think I found it very interesting that for Part 2, you can disclose for the purposes of payment but not for treatment, and so as a primary care provider, when I don't know that my patient is on buprenorphine, but I know that

they're getting OxyContin, if I'm going to the PDMP and I can see the ortho has prescribed them OxyContin, but not that they are also on buprenorphine and I'm trying to manage that patient and I'm keeping all of their information in a HIPAA-secure way, that gets very confusing and very difficult for treatment.

And I have concerns about going down this path of Part 2 that creates separate systems that don't talk to each other and would love to see us find ways that Part 2 and HIPAA can be more aligned rather than separated out.

CHAIR THOMPSON: So let me ask you a question about that, Kisha.

In our earlier conversation on Part 2, what we said was we might have concerns and recommendations to make in the future about what Part 2 does, who it covers, how it affects Medicaid providers and patients and those kinds of things. But there's so much confusion in the community, even about what's happening today and what the rules are today that in order to get clearer at least on that point, while we might consider some future recommendations, we should start to promote this clarity in the community about what today's world looks like and what people can and

cannot do because today people are potentially not doing things that they could be doing because they're seeing Part 2 as an impediment, maybe it's not.

So I'm just wondering. I want to just test this proposition, given what you said. These recommendations, which are about -- today, we have Part 2 and we have HIPAA, and we need to understand what Part 2 is, where it's different, et cetera. Do you see us -- with the idea that potentially in the future we could be saying more about how the two systems come together, do you think it's not wise to be promoting that additional communication today?

COMMISSIONER DAVIS: Yeah. I mean, there was that very last line in the chapter that says it's the Commission's view that steps to clarify existing rules, blah-blah-blah, now before more fundamental change is considered, I have concerns about that line because I think that it could just in doing that take us too far along -- off the path. And so maybe the recommendation is looking to see further into where HIPAA and Part 2 are aligned and not and where are the patient protections that are not there in HIPAA that are in Part 2 that need to be further elaborated.

CHAIR THOMPSON: So that would be an element of further refinement of the recommendation to say that one of the parts of the sub-regulatory guidance or the communication has to do with relating Part 2 to HIPAA?

COMMISSIONER DAVIS: Mm-hmm.

CHAIR THOMPSON: Okay. All right. Thank you.

Marsha, you're next.

VICE CHAIR GOLD: Yeah. I have two comments. The first is sort of more to clarify for the audience, and the second is to respond to Kisha's comment, which was a thoughtful one.

In terms of the audience, I think one thing that you don't see is the draft chapter, and the draft chapter, I think -- or maybe it was stuff you presented earlier -- shows that we had an expert -- you convened an expert panel, and the source of the confusion and some of that came from that panel. And that panel also revealed that there were differences of opinion on how far to share information because of the tradeoff on treatment efficiency and effectiveness and protection against poor use of information and stigmatization.

And so Penny's comment suggested that wasn't

maybe as clear even in the chapter as it could be. I wanted the audience to know it's in the chapter, and I would hope you can sort of review it and see if there's any way to make that clearer, because that's the basis upon which the recommendations lay.

The second comment -- or maybe it's just a query -- is there was difference of opinion on how you reconcile it. I think there's a lot of concern among providers that it really does a lot of bad things when you can't tell if someone is recovering from drug abuse and you give them a pain killer in surgery or you give them extra pain pills. And so sharing is really useful, but then there is a recognition that there's some side benefits.

I wonder if there's a way to focus more specifically on what you pointed out -- I guess it's on page 11 -- but not for treatment purposes. That's, I think where the sharing becomes -- the benefit to risk issue is most.

And I don't think we have the information here -- we haven't looked at it enough -- to say that it could be done. I don't know if we do feel like we have enough to say that's our main -- the area where we have our main

concern or perhaps to suggest that the Secretary ask some group like the Institute of Medicine to look at this and recommend how perhaps one could maintain some of the goals of the Part 2 regulation while dealing with the coordination of care requirements, which are extremely important to the patient's perspective, with a focus specifically on treatment providers and what they are able to know.

CHAIR THOMPSON: I have Chuck, Kit, Brian, and then Martha.

COMMISSIONER MILLIGAN: Thank you for this. I think we're making a really big contribution. I think the panel that you led earlier in the presentation you did a couple of months ago was also a huge contribution.

I want to start with where Kisha ended because the way the chapter ended to me left me feeling like we didn't say enough, exactly the same comment that Kisha made.

Leading into that, we talked about looking ahead, but we don't really talk about looking ahead to what. When we talk about these recommendations and kind of the clarification benefit of this, but we didn't, I think,

signal at all where this might lead us next. And I think the absence of that vision and what we're going to learn from this exercise and actually what happens next in our analytic agenda, I think we need to develop.

To me -- I just want to go back to the panel a couple of months ago on this -- I was most persuaded by the sharing of SUD information outside the health care system, where it affected employment, custody, bankruptcy, all of those kinds of venues. For me personally, I would have been ready today to vote on a recommendation about amending HIPAA to create stronger sanctions and stronger protections about releasing SUD information outside the health care system, but I'm comfortable with doing this incrementally and going where the recommendations today would take us.

But I think personally, my vision is this all needs to fold into HIPAA down the road, and Part 2 needs to become obsolete down the road. And the protections that are critical in Part 2 should find their way into HIPAA. That's to me where I would like to see it go. I'm comfortable doing this incrementally.

And I guess I want to wrap by saying I was very persuaded by the consumer advocates and the legal aid and

other presentations earlier about the harm individuals experience when it affects child custody, employment, bankruptcy, other avenues. But I think HIPAA can find a way to accommodate those protections without needing to have these privacy provisions.

CHAIR THOMPSON: Excellent.

Kit.

COMMISSIONER GORTON: So I want to align myself very closely with what Chuck said, and maybe the solution is to strengthen HIPAA. You could argue that people's health records of any kind shouldn't be able to be introduced into criminal proceedings because your health is your health, right? And it should be private. It shouldn't become a matter of public record. So I was prepared to go farther.

But I'm comfortable with the incremental step because I do think it's worthwhile to make sure that we have a solid, well-grounded understanding of what the situation is today, and I do think the Secretary has work in front of him today that he should be doing while we think about potential policy recommendations going forward. So I'm very comfortable with the recommendations.

I want to say that I'm a tough audience, and you guys way exceeded my expectations for being able to take this very complex topic and synthesize it down into 20 pages of pretty clear description and examples of how this thing is supposed to work, so thank you.

I've been close to this for a while, and I felt as I was going through the chapter that I now finally understood it better. So that's good work.

Just a couple of little things. To Sheldon's earlier question, the PDMPs were, in their formation, a tool for law enforcement, and so that's why the Part 2 programs were specifically excluded from the PDMPs. So you can see -- if Kisha writes buprenorphine, you can see Kisha's prescription, but if somebody in a methadone clinic is also doing medication-assisted treatment and using buprenorphine, you will not see either the methadone or the buprenorphine. So that creates gaps, and since people don't know what they don't know, there are real risks there.

So that's why there's that exclusion there, and I think people need to know that. If nothing else, people need to understand that if somebody is in treatment, you

aren't going to see it in the PDMP. Prescribers need to be aware of that.

Two minor things. One is I think we very nicely grounded the draft and the recommendations in terms of the Commission's responsibility towards Medicaid. This is a problem for CHIP too, and I think everywhere it says Medicaid, it should say CHIP because I think we have equal status to be commenting with respect to that.

And to the extent that many of the CHIP programs are in fact Medicaid extensions, the provider is being paid as well.

And then the last piece that I might like to see a little more on -- you touched on it; it's in there -- is just -- what we don't talk about specifically is what ONC hasn't done. You do mention that they did not incentivize meaningful use for substance use providers. I'm not sure if we know --

VICE CHAIR GOLD: The legislation didn't do that.

COMMISSIONER GORTON: Well, right.

CHAIR THOMPSON: Well, let's not put it on --

COMMISSIONER GORTON: Yeah. But it didn't happen, right?

But I think we could use a lot more guidance from ONC about the datasets, how they get shared, what has to get segregated, what has to get de-identified. People don't know, and what we heard in the testimony, what we read in the comments to the Notice of Proposed Rulemaking, what we heard at the expert panel is when people are not sure, they leave stuff out. So they just don't report it. They just don't share it. They don't submit encounter data. They use nonspecific codes, and so I really think we need -- I think we should call out for the Secretary that ONC needs to help with datasets. How do states, how do providers, how do health plans appropriately report data from Part 2 providers, so that it gets incorporated in the datasets? Because we know from a risk perspective in setting rates and in quality measures and everything else, we know that substance use is a huge -- I don't want to call it social determinant because it's a biological condition.

And so it's really important that this gets captured in risk adjustment and those such things, and I don't think we have had anywhere near enough guidance from CMS.

CHAIR THOMPSON: Good. So we'll do Brian, then Martha. Then we'll go out to the public for comment before we come back and wrap up -- and Bill. Okay.

COMMISSIONER BURWELL: So in the spirit of full disclosure, I just want to say I work for a company that lives and breathes and makes its living off health care data, and we take in millions and millions of records every day from insurers and providers, and so as a result of that, we live and breathe HIPAA every day. Everybody gets training. It's a big deal. We don't want to have the company put on HHS' Wall of Shame, which is any breach. I mean, that would be a huge negative to our business. So it's a big deal to us.

So my observation kind of relates to that. I mean, a huge amount of money and resources and time was built into HIPAA. We may not like all of it, but, I mean, it was a huge undertaking. And to me, that creates a foundation on which Part 2 can be built.

And I agree with Kisha. I mean, ideally, we should align these two things. They're about the protection of information that if potentially used inappropriately could be harmful to patients.

So why not build Part 2 on the foundation of HIPAA and talk about, okay, here's HIPAA that protects general health care information, Part 2 provides additional protections, and point out to providers and insurers and all the people in the health care system what additional protections we want to make available to people with a substance use disorder.

I would think that that would make it more clear because I can tell you now, it's total confusion, and I'm also worried that there is -- the compliance is really scattered, particularly around payment data and sharing of data, et cetera. So that's one, you know, writing the supplementary, Part 2, point out the relationship between these two laws.

The second is -- and it's somewhat frank here -- I think part of the problem with Part 2 is that it was led by SAMHSA, who is not a payer. So it has a kind of very limited view into SUD treatment and doesn't have the broader health care view.

We have the second recommendation saying the TA should be provided by SAMHSA, ONC, CMS. I would like the first recommendation to say that additional guidance should

also be coauthored by those three agencies. So I think if that's the case, it would have a broader view of those these protections should be implemented.

CHAIR THOMPSON: Martha and Bill.

COMMISSIONER CARTER: I think this has been a great conversation, and I think we need to do a lot more of it.

I came in thinking that I was in support of these recommendations, but now what I think is be careful what you ask for because I think that there's so much confusion that there are a lot of practices, especially multidisciplinary integrated practices that probably fall under Part 2, but aren't acting as if they do.

And so if we get clarification from HHS that all these practices are covered, then it sets a whole set of actions in motion.

I think our electronic health records are not consistently able to sequester this information in an integrated practice. So, again, it would set a whole set of actions in motion, and I don't think that's the direction we want to go.

I think that we should actually say that we

recommend that Part 2 be -- that we are allowed to share for treatment purposes, and that should be a stand that we take, and not just ask for guidance and then wait for the ax to fall and everybody is scrambling to say, "Oh my gosh, how do I comply now?"

CHAIR THOMPSON: So I want to take us back because we did kind of talk a little bit about this at our last meeting in terms of the direction to the staff to come back with these recommendations.

And it will be interesting to see -- I want to hear from the public -- what their reaction is to this. There's a couple of things to think about, though. So one was the idea that we know that the desire for additional guidance and information about what am I supposed to be doing, how do I comply with this is substantial among our providers. I agree there's always the danger that the answer is unpleasant.

But we also said to ourselves, before we as a Commission can decide what we would want to recommend, we're also in need of some of that clarification as to where those boundaries are today and are not today and what the implications and impacts are. That if we're saying

there's a situation in which there is a lot of confusion and questions about what applies where, then how can we make recommendations about changes to that?

So let's first clarify the situation, and let's understand it better, and then through that understanding, let's promote improvements.

I would also suggest there's a timing issue. So for some of these matters, if we're talking about some regulatory guidance, if we're talking about outreach, that can happen under one kind of timeline. If we're talking about legislative change and regulatory change, that happens under a different timeline.

So the other thing that Commissioners might want to think about is if we were to say, well, because we think the situation today may not be the optimal situation, let's focus on promoting the better policy objective, which I think is what I hear a little bit of -- let's promote the policy objective and then focus on the implementation of that better policy objective rather than focusing on today's world and the clarification and communication needed around that, which may even focus a light on some of the policy impacts and program impacts that are unpleasant

to us.

We need to recognize that if we were to do that, we're talking about allowing the current situation to exist for a longer period of time because it's just going to be -- and some of what's happening today is not a matter of -- which we think is not productive is not a matter of actual problems in the statute or the regulation but in the interpretation and understanding. I mean, there's some amount of the problem that is associated with that, so that may be something to think about. But I'll be interested to see what the public reaction is to that.

So, Bill, you get last word before we open it up.

COMMISSIONER SCANLON: Okay. I mean, this is incredibly sort of helpful to me. I thought you did a great job in terms of explaining it and was supportive of the recommendations. Maybe I have Penny's perspective of you need to know what you know before you jump, and so that's an important thing.

The reason I wanted to comment was because HIPAA has come up so much, and actually, it was kind of strange to hear it used in the past tense because I don't think we're done with HIPAA yet.

I was on the National Committee on Vital Health Statistics, which is the Secretary's HIPAA advisory body, and my sense of six years there was that conversation could go on forever.

And they dealt with some of the same issues that we're talking about here, this issue of privacy for sensitive health information, and so there's this question of -- and I've been off for a while. So I don't know what their current set of recommendations are, but whether there are recommendations that they made that would reinforce sort of what we're talking about in terms of issues that we've identified, because again, HIPAA sort of -- and maybe Part 2 too -- are these organic things that just keep evolving, and so we need to be thinking about how we can get a grip on them and sort of what their current status is.

Thanks.

CHAIR THOMPSON: Okay, great. Great conversation.

Let's go ahead and open it up for the public for that perspective.

PUBLIC COMMENT

* MR. GORDON: Good morning. Stuart Gordon from the National Association of State Mental Health Program Directors.

I was happy to hear Commissioner Davis suggest that HIPAA should be -- mention of HIPAA should be included in the direction you're giving HHS on the guidance. I think as good as I suspect Nevena's diagrams are in the chapter, I know -- and this is a dirty little secret, but sometimes I just read recommendations without reading what underlies the recommendations, and so I think it's very important that the recommendation include language about comparing 42 CFR Part 2 to HIPAA.

And with regard to Commissioner Burwell's recommendation, it's important to remember that HIPAA is a product of the Office of Civil Rights at HHS, and so if you are going to include agencies, specifically name agencies in Recommendation 1, you need to also include the Office of Civil Rights.

Needless to say, we would prefer that a recommendation include aligning the underlying statute for 42 CFR Part 2 with HIPAA, and we and 39 or so other entities are working the Hill right now to try to get that

done legislatively. But in the meantime, this is a good first step, and we thank you for it.

MR. GUIDA: I want to thank MACPAC. My name is Al Guida. I'm with Guide Consulting Services, and I represent Netsmart Technologies. We make electronic health records for mental health and addiction providers.

We want to thank you for taking this issue up. Your staff, Nevena, Erin, and Kate have been enormously welcoming to us, and so we thank you for your serious consideration here.

Just a couple of things very briefly. I note that the National Governors Association, as recently as last month, recommended that Part 2 be fully aligned with HIPAA, and there were a couple of reasons for that that came out during the discussion today.

The advent of medication-assisted treatment in the substance abuse field has changed the paradigm. With the introduction of buprenorphine and Vivitrol, which is an injectable product, we are medicalizing the addiction space, and so there are pressing patient safety issues that a number of the Commissioners outlined during the course of the discussion.

Secondly, with regard to the technical assistance recommendation, my client -- it goes beyond technical assistance. My client has estimated that it's going to cost providers about 3- to $4 billion to adopt the consent to share technology that SAMHSA has issued in order to comply with the rules and make them functional as they exist today

And then, finally -- and this was also raised during the initial presentation -- what the research shows is that there is an absence of behavioral health information, both on the addiction and the mental health side, in medical records today, and that's in large part because this provider set did not receive health information technology incentives.

There is legislation on Capitol Hill, H.R. 3331, and S. 1732, that would authorize a CMMI demo to permit providers to receive health IT incentives, and we would hope that that might be Recommendation No. 3.

Thank you.

MR. BARTON: Hello. My name is Corey Barton. I'm here representing the American Society of Addiction Medicine. So, on behalf of the Society, we'd just like to

thank you for taking up this issue. It's one of the issues that are very important to us, and as you may be aware -- and I'm sure you're all aware -- the addiction medicine field is one of the most regulated fields for many important reasons.

So we, first of all, thank you for taking up this recommendation. Our providers would love to know their responsibilities as far as how they handle 42 CFR Part 2. So any effort the Commission may make to address those recommendations, the addiction medicine field appreciates.

And as you talk about the subregulatory guidance, we appreciate any examples or recommendations you might make as far as what that may look like, so providers will know their responsibility in treating their patients.

CHAIR THOMPSON: Okay. Let me make a suggestion and see how that sits with the Commissioners in terms of being ready to vote on these recommendations later today.

With respect to the general chapter, I think that it's clear that we want to be more definitive about the idea of moving in the direction of assessing the extent to which HIPAA and Part 2 can work better together, whether that is an alignment process, whether that is an embedding

of certain aspects of Part 2 into HIPAA writ large, and maybe also suggesting that as a result of that, we're a little concerned about promoting an implementation of a policy that we would like to be changed, but that nonetheless, we understand that today we are dealing with a fair amount of obstacles and confusion that are actually permanently affecting people's treatment. And it is in that context and with that priority and focus that we make these recommendations.

And maybe, Martha, that addresses a little bit of the concern that you have about suggesting that we're not saying just in general do some kind of widespread compliance effort per se as much as focusing on those areas where we may have -- and have seen through some of the reports and conversations that we've had with Medicaid plans and providers, a concern about whether adequate treatment is taking place.

So, at some point, there's -- again, sort of going back to the HIPAA example, there's a long process by which you identify some of these areas of focus for subregulatory guidance or for technical assistance, and I think maybe we can think about ways in which to focus the

attention of the agency on those particular areas that seem most problematic for promoting effective treatment for people.

I think in Recommendation 1, we should be -- and in 2, so to the point of there are various agencies within HHS that may want to play a part, STAFFDIVs as well as OPDIVs, and so maybe we just need to mention that there's a number of agencies that need to be involved. And those agencies -- I think particularly those agencies dealing with treating providers -- can help focus and prioritize the efforts of where is the most confusion, what is going to be of the most help to people, what can we do now versus later, and I think that will be an element of the success of this effort that we're suggesting.

Marsha.

VICE CHAIR GOLD: Yeah. I think I generally agree with that.

I would, though -- maybe a friendly amendment. It seems to me that I don't want us to get so involved in the nomenclatures and the aligning HIPAA and the Part 2 that we forget that it's really about the patient and the provider, and I think what we're fundamentally concerned

about is that the way it currently works is both confusing to providers and while potentially protecting patients against some adverse events really -- outside the health care system -- really may undercut the ability of them to obtain appropriate safe care, and so that's really the fundamental goal of why we're doing it.

If you can do it some other way besides aligning, fine, but the goal is to make sure people can both be protected but get the right care and that providers know what they're supposed to do.

CHAIR THOMPSON: Any final words or instructions?

Okay. We've got Chuck and then Fred.

COMMISSIONER MILLIGAN: Two quick comments. I do think there's some value in Recommendation 1 of mentioning SAMHSA and CMS. I mean, we can go down whatever list is appropriate -- ONC, OCR, whatever. But I share Kit's concern that -- I think it was Kit who mentioned it -- that we not leave Recommendation 1 in its current form because it will then be SAMHSA, and I think that isn't -- I think SAMHSA needs to be doing this side-by-side CMS. So I do think it's worth calling that out.

I think the second comment is -- and, Marsha, I

like the way you framed it because I do think -- personally, I think that we're all motivated by patient's best interest here, and I think that my own personal view is that we've erred on the side of protecting patients from disclosure in a way that could create adverse medical events because of the lack of PCP knowing what's going on.

I do think it's worth articulating that our goal is patient outcomes and that we need to keep looking at whether sharing information within a treatment team is the better solution to patient outcomes.

COMMISSIONER CERISE: Yeah. I agree with Chuck on that and will echo Martha's comments.

I mean, I do think -- I came in thinking this is good to get some clarification, but I am concerned that you clarify around policy that we find is going to be really problematic, and if that's going to lead to sort of more clarity, that will lead into compliance, that you're going to have the risk of having some negative consequences where you do have multispecialty providers who are going to shy away from this once it becomes more clear of kind of what you're dealing with and would prefer to pursue a path of let's -- the discussion around aligning HIPAA with these

protections seems to me that is what the sentiment is.

So I realize and appreciate the need to be clear on sort of what you're trying to fix before you lead to fix it, but I do think there is some risk there that with the time you're talking about to get better -- to get the ultimate fix, that in the meantime, some guidance that's going to lead to compliance and enforcement is going to have a negative effect on the availability of services.

CHAIR THOMPSON: I wonder if there's something that we can say in the body about enforcement discretion. I mean, this is an element of common question for any government agency is it's issuing instructions with respect to something.

To the extent that the clarification that's being issued or the additional guidance that's being issued starts to break new ground in terms of the government saying something that it's never said before and maybe with the specificity that it has never said before, there's options to basically say we recognize that we have not said it this way before and said it exactly like this, and we think, therefore, there should be a period of time for providers to come into compliance with that.

So we may want to acknowledge that clarification and the way that we're describing may both break new ground, that providers will need time to understand in order to be compliant, and may identify actual problems. That should be part of a discussion about a policy direction, and again, it is not unheard of for an agency to say, "This is how we interpret the law currently. We recognize that it has these potential effects and potential issues. We are evaluating whether additional policy change should take place, or we are planning additional policy change in this area."

Martha.

COMMISSIONER CARTER: I think it's not just that the government is saying something different than what they were saying before, but that the landscape is changing very fast out in the field. And so, like I said, we have practices providing a substance use treatment that we didn't even have a couple years ago, so there's been a big boom in integrated care that really isn't even, I think, addressed adequately here. So I think we've got two issues going on.

CHAIR THOMPSON: That's an excellent point too,

which is that the landscape is very different.

I think if we can drive the language of the recommendation about our desire to promote better patient outcomes, then that provides a way in which we are focusing efforts.

EXECUTIVE DIRECTOR SCHWARTZ: I want to make sure we don't lose sight here, though, that in our effort to put the patient at the center, that we don't sort of lose sight of the fact that the patient has the opportunity to allow the disclosure, and then that should be part of a discussion between patients and providers, rather than just part of the registration that you have to do to enter care rather than an actual discussion.

VICE CHAIR GOLD: If I understand the material right, they have to do it each time. I mean, there's a lot of ways in which --

EXECUTIVE DIRECTOR SCHWARTZ: Yeah. But I --

VICE CHAIR GOLD: Even if a patient wants information to be shared, it could --

EXECUTIVE DIRECTOR SCHWARTZ: I have to update my address every time I go to the dentist. I think we have to be careful about saying how much we're doing this on behalf

of the patient without sort of thinking about how else the patient is included in the decision-making process.

CHAIR THOMPSON: Sure. And I think that that was a little bit of where we were the last time we talked about this, which is that there are hard tradeoffs here, and so there are lots of things to consider. And we were not ready at that juncture to kind of say this is how we think those balances ought to be struck and adjudicate all of those different puts and takes, and so I think that's right.

And the fact that we think we have a situation now where a lot of providers may not be understanding what they can do under -- I mean, a lot of the motivation again -- and this is what I'm getting to in terms of the tone of the recommendations -- a lot of the concern came from not so much people aren't complying with Part 2, which is one issue, but rather people think Part 2 is keeping them from doing things that actually Part 2 is not keeping them from doing.

And so I think we understand that when we talk about doing regulatory guidance and we talk about doing communication and outreach, we may end up touching on both

of those ends of the spectrum, but our motivation was a lot around that part about do we even understand what we can and cannot do, so that we can at least do all that we can do.

All right. So let's ask you to come back with a revision in light of that. I think we are asking for a couple of clauses and points to be made, and then the underlying justification, of course, is something that we can continue to work on -- and then see where the Commissioners are in voting on those recommendations.

And, as always, thank you to your both.

Okay. We're going to come back and take a look at a letter, a draft letter on Money Follows the Person before we move into lunch and executive session.

[Pause.]

MONEY FOLLOWS THE PERSON: REVIEW OF DRAFT COMMENT LETTER

* MS. VARDAMAN: Good morning, Commissioners. I'm here today to provide an overview of a draft comment letter from the Commission on the Secretary's report to the President and Congress on the Money Follows the Person Demonstration Program.

There's a copy of the draft comments located under Tab 4 in your meeting binders.

We drafted these comments in response to the discussion that Commissioners had on the findings of the report at the January public meeting.

I'll begin with a brief review of the Secretary's report and then outline the draft comments before moving on to next steps.

In review, the Secretary was required to send the final report to the President and Congress, including the findings of the national evaluation of the Money Follows the Person Demonstration and to provide conclusions on its conduct and effectiveness. This report was published this past December.

MACPAC's authorizing statute directs the Commission to review the Secretary's reports to Congress and to provide written comments.

On this slide, we've listed some of the key findings of the report to Congress, which we discussed in more detail at the January meeting.

Just in summary, as of 2015, the Money Follows the Person Demonstration had helped over 63,000

beneficiaries transition from institutions back to the community. Again, as a reminder, MFP continues. States have the ability to continue transitioning beneficiaries through the end of this calendar year, but some are ending on an earlier timeline, so that number continues to rise.

Next, evaluators estimated that between 2008 and 2013, the demonstration had resulted in $978 million in savings. This was an upper-bound estimate, as the report acknowledged that some portion of these transitions may have occurred in the absence of the program.

The report also highlighted positive outcomes among individuals who transition back to the community through the program and noted funds were also used to create programmatic changes to promote rebalancing, such as reductions in waiting lists for home- and community-based services waiver programs.

Next, I'll outline the three areas, which we have drafted comments for the Commission's review. First, regarding funding, the draft letter notes that the final report does not provide a full accounting of program spending. So, if approved, the letter would urge the Secretary to issue a supplemental report, which would

include state-by-state data on the amount of grant awards received, expenditures for beneficiary care, staffing, and other structural changes that were necessary for program development and implementation.

Next, the letter acknowledges the data limitations that were noted in the report to Congress. MACPAC has repeatedly expressed concern in the past about the effect of Medicaid data lags on program monitoring and evaluation. Given that at the time the evaluation was conducted, they could only produce saving estimates through 2013 and that transitions will continue through the end of this calendar year with services provided to individuals transitioning through the program through the end of 2019, the letter notes that it would be helpful to update the evaluation once later data is available. Thus, the draft letter requests that the Secretary provide additional program evaluation information for later years.

The third area of comment is regarding states' plans to sustain transitions after the end of the demonstration. The report does not discuss states' abilities to transitions following the end of the demonstration in the detail. The Secretary was not

required to compile or analyze the sustainability plans in the final report, but states were required to submit that information as part of their final supplemental budget request.

MACPAC staff were able to locate a handful of sustainability plans that have been posted on state websites; thus, the letter requests that HHS make all of those plans readily available for analysis.

In our review of the plans we were able to locate, we saw states had varying approaches regarding how they would sustain transition services. The letter also notes that HHS should report on services that states may not be able to sustain, given existing authority or other barriers. Making the sustainability plans readily available would also assist MACPAC and others in making that assessment.

This information could be useful to the Congress in understanding whether there are steps that need to be taken in order to allow states to continue transition services and strategies that were found to be successful during the demonstration.

In today's discussion, staff would appreciate

comments on the draft letter and whether it captures your concerns on the Secretary's report; for example, if there's some additional detail that you would like regarding the request for supplemental information on spending.

After today's meeting, we'll respond to your comments and in order to finalize a comment letter for submission to the Secretary and Congressional committees.

Thank you.

CHAIR THOMPSON: Let me open it up to the Commissioners and see if you have any comments or direction on the letter as drafted based on our last conversation.

Marsha.

VICE CHAIR GOLD: I generally think the letter is fine.

I have a suggestion for refining the page 3, second paragraph in the letter. It's dealing with the contents in 5.

It seems to me that we would do well to be a little more explicit on two things. One is, when we ask about an accounting of program spending, what's the question we're trying to answer? Because we've said that there were some limitations on what the report covered and

could cover, given timing, so are we trying to answer just updated spending? Are we looking at updated spending adjusted for administrative costs, and why is that important? So in policy context, that would be good.

And I sort of think that as a separate point than just sort of talking about a supplemental report, and the supplemental report, I think, deals with sort of learning as much as we can from the demonstration, and again, I think you tried to do this here in some of what you pulled out, but what questions do we think what we know can answer that we think should be the focus of the attention by people? And if there's things that are important that weren't the focus, should we mention those as well? So it's a little bit more analytical and directive.

CHAIR THOMPSON: Yeah. I had a little bit of that view as well, that if we could focus attention -- I remember Chuck talking about -- a question about how long people had been in a nursing home before they were transitioned and the relationship between length of stay to the success of their transition. I think if we have some other examples like that, where we would say these are the kinds of things -- Leanna had mentioned the importance of

some of the services pre-transition to success and transitioning, and so I think there's some things like that, that I think we want to call out to help sharpen the conversation, so that it's a little less general about we would just like to see more, and we would like to see some data, and we would like to get it to be up to date and so forth, because in fairness, there's a lot of stuff out here to grapple with.

And I think to the extent that we can provide some things that we think are most important for understanding what this demonstration did and what the future might be for continuing all or part of it or moving some of it into different kinds of authorities, I think that can be -- as a matter of fact, maybe we should be formulating the question that we think we're trying to answer for ourselves and that the Congress will be trying to answer in looking at these reports and using that as a guidepost to suggest what additional information could be provided.

Darin.

COMMISSIONER GORDON: Somewhat on the point that Marsha brought up, I wish we would give a little bit more

clarity on some of the issues with the state data reporting delays because I myself don't have a good grasp. So is there something that could be done differently with these programs? Is it that they didn't require the data to be submitted at a certain time period, and that created the delay, or is it inability of states to do it? I mean, I'm unclear what it is, and I think if we're going to say it's an issue, then I think we should be able to provide some kind of context to what might be contributing to that problem. And I just can't say I can put my finger on it.

I think about the lag you're talking about, and I was like we have the data, and it was current within about a 60-day period after the end of a quarter. So I'm missing that point.

MS. VARDAMAN: Sure. So, to clarify, there were a number of different datasets and things were collected from states that are participated, including transition reports that were on a quarterly basis.

Some of the concerns about data lags in regard to the evaluation were around general Medicaid claims data lags that limited the amount of time the evaluation covering in terms of producing the estimates of overall

Medicaid and Medicare savings, and so the Medicaid claims data was only available for a certain time period.

EXECUTIVE DIRECTOR SCHWARTZ: And doesn't it also relate to -- compared to whom?

MS. VARDAMAN: Right. So they --

EXECUTIVE DIRECTOR SCHWARTZ: Because if you have good data on those you are transitioning, if another state wasn't doing that and that consisted of the control, that state -- that's part of the issue.

MS. VARDAMAN: Right. So they were constructing a comparison group, and so they only had Medicaid claims data that were available through 2013. So having later data would help to update those savings estimates.

COMMISSIONER GORDON: Yeah. And that's my point because there's an inherent lag in the health care system. I mean, I'll tell you, we pressed that as far as we could without providers losing their mind because you can only take it to a certain point before it becomes too disruptive.

But that explained why you had to go back to 2013, and so I don't know if the issue is with the states -- CMS having that data and the format by the time you need

it because --

VICE CHAIR GOLD: Is this the T-MSIS issue, or is this a specific issue of --

COMMISSIONER GORDON: That's what I -- I guess that's what I'm saying, is I'm not clear, because when we say this -- and I've had this. This has come up multiple times. We just need to be clear what the data situation is because you could read this as they just don't have the data, and I don't know if that's consistently the issue.

I think sometimes the issue is by the time it goes through all the processes and gets into T-MSIS and all the QC checks and everything and then they make that data available and they believe that period is complete, and then that's out there for everyone to look at.

I just think we need to be clear if we're saying there's a problem here, that we help them focus a little bit about what that bottleneck is, so as to help these evaluations be more current.

CHAIR THOMPSON: Yeah. And it's possible that that's something that we should address outside of even the letter -- right? -- because the letter is commenting on what is present in the report, and in a way, we're saying

we're focused on what's absent from the report, but that's generally your comment about the report itself, is what's not there.

But I do think that issue is something that we -- I mean, I think we'll have more conversations about research and evaluation and how we can get better science inside of the program in the next meeting and the context of 1115s and GAO's report. I think that provides a launching pad for some of this discussion that we should have about how do you deal in a less than perfect data enforcement, but to maximize the value of the information that you can or should get and hold people's feet to the fire to provide it and what are for certain kinds of experiments to continue or for the ability to make decisions about permanent program changes.

EXECUTIVE DIRECTOR SCHWARTZ: I mean, I think also that this is something that going forward, T-MSIS when it's fully operational will help with the -- it's one thing if you're running the program and you want to know what's going on with your beneficiaries, but if the agency has to compare it to someone who is not doing it, it's not in their interest. So it has to be part of the routine data

collection, which should get better, but obviously, we're looking backwards here.

VICE CHAIR GOLD: Isn't there also -- there's just a -- what should an 1115 waiver program look like? I mean, if you have a program that's so broad-based that there's no comparison group, it's almost impossible to be able to rule out that it was secular change, and it comes up with Welfare-to-Work. It came up with Financial Alignment, where they almost wanted to go national with it, and thinking about what you can and cannot do before.

Now, I don't know in this case. I'm not as familiar with Money Follows the Person, whether it was a valuable -- or seemed to be at the beginning and they just ran into problems or it just was set up to not be able to generate information, in which case that's an awful lot of money.

COMMISSIONER GORDON: That's my point, is just being clear what that issue is, and I agree. I like your idea that we address it more broadly somewhere else, but at least here being as clear as we can be of what that issue was.

CHAIR THOMPSON: Yeah, what the hold-up was.

Brian, do you want to --

COMMISSIONER BURWELL: So the data issue is entirely related to T-MSIS and the lack of availability of T-MSIS data.

The MPR evaluation design report assumed when it was written at the beginning of evaluation that T-MSIS data would be available to generate data on the outcomes of people who have been transitioned, which would be a comparable database for all those states participating in the demonstration, but also provide a comparison group from states that did not.

That data did not become available; therefore, they went back to the last year in which comparable data was available based on the MAX files, and that's 2013.

COMMISSIONER GORDON: That kind of explanation, I mean, something that is being clear here, because eventually we're going to have to help them figure out what that issue is.

CHAIR THOMPSON: Yeah.

COMMISSIONER GORDON: And I just think being clear that because of there wasn't sufficient information in T-MSIS, we had to go back that year, because this reads

very differently.

COMMISSIONER BURWELL: Right.

VICE CHAIR GOLD: It's the transition period. Presumably, hopefully, if that's the case, if we think it's resolved, then there's still the general issue is it takes a long time, but maybe it won't be as bad in the future as that, which is less actionable than to point out the problem as to just explain it.

CHAIR THOMPSON: But for the purposes of this letter, what we're talking about trying to say is there were reporting delays, what were those reporting delays, are they now solved, such that you could now update this information, right? I mean, that's the concrete thing that we're trying to drive them to, which is we get it. You may not have had it at the time that you were pulling all of this together, but now you do, and so now you should update it because we think that updated information contains some important insights that people should have.

VICE CHAIR GOLD: Which can answer XYZ questions in the report.

COMMISSIONER BURWELL: I just want to say, in general, I'm very, totally supportive of this letter.

CHAIR THOMPSON: Good, good.

COMMISSIONER BURWELL: I think it's really well written, and I think it accurately reflects our discussions from the previous meeting. And I am very happy with it being sent as-is.

Going back to Marsha's comments and the accounting of the $3.7 billion, it's just that in the evaluation, there is mention of the money that was used for the enhanced FMAP for people who were transitioned. We got 75 percent instead of the regular. That was a very small proportion of the $3.7 billion. So we're just interested in all these other components of mounting the demonstration and implementing it that do play into sustainability issues. It's just not the direct services provided to transition people. It's all the infrastructure around it, so we want to know what those costs were.

And I think it's right to focus on the sustainability reports because that does -- I mean, the logic of the demonstration is you had this demonstration. We learned things that we would want to mainstream into the Medicaid program after the demonstration is over, and so the sustainability reports are interesting data points on

that from states saying, "Well, we are going to continue certain -- you know, we are going to continue transition services and try to get people out of institutions, and this is how we're going to finance them," and others saying, "No, we can't do this," or it's not worth the investment. So those are very interesting pieces of information to learn about the impact of the demonstration.

CHAIR THOMPSON: Okay. So I think we're very close Kristal, a couple of things. If we can sharpen some topics and some focus of conversation, explain a little bit about what we know about the data lag and whether or not that's been solved and how we can adjust for that going forward.

But thank you very much. I think I agree completely with Brian that you've really responded to the conversation that we had in the last public meeting in terms of pulling this together -- and very appreciative of that work.

Okay. Let's see if there's any last public comments before we break for lunch and executive session.

[No response.]

CHAIR THOMPSON: And seeing none, we are

adjourned for lunch.

* [Whereupon, at 11:55 a.m., the public meeting was recessed, to reconvene at 1:00 p.m., this same day.]

AFTERNOON SESSION

[1:12 p.m.]

CHAIR THOMPSON: All right. Sorry for the delay in getting started, folks. Thanks.

All right. So for the first session this afternoon, we're going to hear from Kristal on MLTSS for individuals with intellectual and developmental disabilities.

So why don't you go ahead and get us started.

TAILORING MANAGED LONG-TERM SERVICES AND SUPPORTS PROGRAMS FOR INDIVIDUALS WITH INTELLECTUAL AND DEVELOPMENTAL DISABILITIES

* MS. VARDAMAN: Good afternoon. I'm back to present to you the highlights of MACPAC contractor research on the extent to which states have tailored managed long-term services and supports programs to meet the needs of individuals with developmental and -- with intellectual and developmental disabilities.

I'll start off with some background and then provide an overview of the results of the contractor review and interviews that Health Management Associates conducted and then talk about some next steps.

In recent months, the Commission has discussed MLTSS on a number of occasions. In October, there was a panel discussing states' experiences with MLTSS, and in January, you heard from a panel of stakeholders.

As the Commission moves forward towards a foundational chapter on MLTSS, part of the discussion has been an acknowledgement of the differing needs of individuals who use long-term services and supports -- it's not a monolith -- and to try to incorporate some discussion of that into the chapter.

At the same time, last year we had contracted with Health Management Associates to conduct some research into which state programs do include services for individuals with intellectual and developmental disabilities, and that work was recently completed, just in time for us to incorporate some of that work into the June chapter.

I'd like to take a moment just to thank the team at HMA for their hard work in reviewing the MLTSS contracts and in conducting stakeholder interviews.

In terms of background, just to provide a quick overview, intellectual disability is characterized by a

significant limitation in both intellectual functioning and adaptive behavior, and developmental disabilities are severe chronic disabilities that can be either physical or cognitive.

I just wanted to highlight that the needs of individuals with IDD vary over the course of their life span and include services that are a bit unique in terms of what's traditionally provided in either Medicaid managed care broadly or even in managed LTSS, which is why we wanted to pay particular attention to this population as we look towards developing a chapter.

So while nearly half of states now have managed LTSS programs, only about eight cover most or all LTSS for individuals with IDD. So HMA's review focused on those states, which are listed here.

The state programs vary widely on many dimensions, as do all MLTSS programs. Particularly here, the managing entities, as in some states the department that handles services for developmental disabilities is the managing entity for the program for this population. They vary in terms of whether enrollment is mandatory or voluntary and also whether or not the MLTSS program

includes other LTSS populations.

So HMA provided some background research for us as well, looking at some of the reasons why fewer states have included individuals with IDD in the MLTSS programs. One reason is that there has been traditionally an underdeveloped relationship between managed care organizations and IDD service providers. IDD service providers have often been small and have been used to dealing primarily with a major payer, the state, and similar to what we heard in discussions about implementing MLTSS more broadly, there's a lot of need for engaging the provider community in making that transition.

The second is resistance from the stakeholder community. Individuals with IDD often use services for years and even decades, and there are some very strong and activated stakeholder networks that have had some resistance to managed care in cases where there was some fear of service reduction, in particular.

Next, difficulty in achieving cost savings. About three-quarters of the population of individuals with IDD are in the community, and therefore, some of these savings that are from possible rebalancing are limited by

the fact that the service is already largely rebalanced.

Next, there is a lack of data for capitation rate development. Some of the types of services are hard to capture into billable units in order to develop those capitated rates.

And finally, silos in administration of services for individuals with IDD, again, depending on the state, some administer HCBS waivers for individuals with IDD through the state developmental disability agency. Those silos between that agency and Medicaid agency can result in an added layer of complexity in implementing managed care for this population.

So in conducting its work, HMA reviewed the eight contracts, its model contracts between states and managed care organizations for the states we had up earlier. They found that IDD-specific provisions were more prevalent in programs that were designed specifically for that population compared to those that include all or other populations using LTSS.

The contracts also tend to reflect state-specific goals. So, for example, Tennessee's efforts to increase employment opportunities by providing more supported

employment services is reflected in its contract. New York is focused on Medicare and Medicaid integration, as reflected in its contract as well.

There's some additional findings from that contractor review results, and I'll talk a little bit later about how we are considering disseminating some of the results of this work.

And next, I'll just turn to the key interview themes. So HMA conducted a series of interviews with states, providers, beneficiary advocates and consumer groups, as well as managed care plans to understand some of the implementation challenges and successes that groups have had in implementing MLTSS for this population.

One of the key themes that arose was that in terms of implementation, many stakeholders suggested that incremental implementation, either by region, by eligibility category or both was a successful strategy because it allowed time for stakeholders to acclimate to change -- for example, training the providing community -- and also created opportunities for course corrections.

However, one of the challenges of incremental implementation that was noted was that a state must operate

dual programs for some period of time, and that has its own challenges compared to trying to do things in a more rapid fashion.

Another key theme was that stakeholder engagement is really critical to program and policy success, and there were a number of examples that various stakeholders gave us of what managed care organizations are doing to engage stakeholders, included having a member advocate on staff, hiring people with disabilities or family members, including advocacy and stakeholder organizations and service coordinator training and reviewing materials, also supporting local disability-related events and hosting regular stakeholder meetings for ongoing feedback.

Another key theme was that even in places where stakeholders felt there had been a large degree of transparency and responsiveness from the state and managed care organizations, they still continue to want more transparency, responsiveness, and more accountability.

Second, providers said in some interviews that timeliness requirements can conflict with person-centered planning, so that the desire to get a service plan in place, that it can take time to get to know someone's needs

and to develop that service plan, and that some of the timeliness requirements could be a conflict with that in some cases.

Next, there was a discussion about outcome-based payments, and those arrangements are emerging as states gain more experience in servicing this population in managed care.

And finally, there was a discussion of transitions as states re-procure the plans, that this can cause some disruption, particularly when it comes to residential or employment services. Again, these services and many LTSS services are received on a daily basis, so those transition points, both in implementing new programs and in re-procuring contracts are really a critical time to make sure things are gotten correct.

So today, I really wanted to just hit on some of the highlights and the key themes. HMA did give us a variety of material in terms of the review of some of the contract provisions and some additional comments from different stakeholders on what they felt was most important and successful implementation and ongoing administration of MLTSS for individuals with IDD.

The June chapter that will be foundational chapter on MLTSS will cover a lot of ground, and so we wanted to kind of hit on the highlights in this session in order to think about what could be incorporated to a chapter, but we'd also like to develop some supplemental materials to give more information on what HMA found in their review.

We'll also continue to monitor a state activity in this area. Again, while fewer states incorporate individuals with IDD compared to other LTSS populations today, we have heard that there is increasing state interest in implementing MLTSS for this population, so we'll continue to monitor that.

And also, there have been some implementation challenges in certain states that may prompt changes, and so we'll continue to monitor that and think about what else we can put out in the future regarding those issues.

So I'm interested in hearing if there's any particular findings that you would like us to highlight in the chapter in June, if there's other interest in this area for the future.

Thank you.

CHAIR THOMPSON: Okay. I know we'll have people wanting to jump right into this.

I'm going to ask a question and ask Leanna to kick us off, and then I see at least Marsha and Chuck to begin.

I'd just like to step back for a second, Kristal, because we've talked before about how different the populations are that we're talking about in terms of the populations using MLTSS and how important it is to understand those different populations and their needs as you formulate successful strategies.

On the other hand, it does seem like, thematically at least, there's a fair amount of consistency in, yup, transitions and readiness, and that can be bumpy. And you got to think about timelines, and you've got to think about phasing in and, yup, stakeholder engagement. You've got to get everybody ready. You've got to get clear on what you're trying to achieve, communicate people, gain people's support, cooperation. Yep, difficult because what we're paying for isn't always well understood or established. The outcomes and measurements aren't always there.

So I just want to challenge us to really think about what really is different about this particular population, and maybe that framework can be completely consistent, but the particular manifestations or things that you're paying attention to in those categories are varying because I see the message that it's different, but I don't see a lot of evidence about exactly, then, how is it different when you're considering how to make this successful.

So let me just turn to Leanna and see what additional observations that you would like to make at this juncture.

COMMISSIONER GEORGE: Well, I think the chapter is really good. I love page 3 with the details kind of describing about what it's like with being a parent of an infant compared to a young adult, as the person moves up the ages throughout the intellectual developmental disability.

One thing I think is really important that in North Carolina we really stress is we have a really strong stakeholder engagement process and program. In fact, we have a state-level CFAC that advises on considering our

family advisory councils, MCO-level advisory councils.

One of our biggest fears is right now we have several MCOs that talk about bringing us all together, so we have fewer MCOs in the state, is how is that stakeholder engagement going to work and look like.

My county, we have our own because we're in a very rural situation where I live at, but when we have some of these MCOs with 20, 30 counties, how do you get fair representation throughout rural and more urban counties and things like that. It's a great concern for a lot of families.

Right now, we're also -- I think we're moving into more of an integrated system of care with regular health care as well as MLTSS for these populations -- or LTSS for this population, and I think that also raises a lot of concerns as we're bringing in -- the MCOs are expanding to be responsible not just for the people already on the waiver programs, but even like my son who's on the waiver program, he's already under one of the MCOs. It's just really getting complicated as far as being a parent to keep up with, okay, what -- does this change his services that he needs, is this what he's eligible for. So there's

always a lot of questions for parents as well.

But I think, in all, the chapter is really well written and some really good stuff.

CHAIR THOMPSON: Thank you so much.

All right. Marsha and then Chuck.

VICE CHAIR GOLD: Yeah. I was pleased to see this chapter because I've always had a sense that there is this subpopulation among the disabled in Medicaid that I know very little about and probably because I focused on managed care and they're not in it as much.

So I think I agree with everyone. It's well written.

I think there are some things that would help us better put this in context. I'm interested in these programs and how broad-based they are. I think Arizona probably has everyone. I don't know if Michigan does. I don't know if they're voluntary or mandatory.

Just numbers. If you knew the underlying population with intellectual and developmentally disabled people, what can we understand about geographically which -- how many enrollees out of the total and the population are in them and then how many are enrolled?

I think like New York is probably quite small because it's only in the city, and I don't know how many are included.

Just to give us a scale of how big the IDD population is vis-a-vis the other SSI and then how big in managed care, that would be a help.

And similarly, it would be a help to know whether they're on separate contract, separate waivers, or where they overlap.

I think -- and I may be wrong on this, but I think what you'll find is it's not like the protections differ or the implementation differs, but the provider network and benefits that the patients use are going to be different because of who these people are, and sort of maybe if we can make them more human by talking about what the key service mix is or what people need and how that's different and the same, then it is for other kinds of people with disabilities, that would be a help, especially as we start thinking of what's similar and different about all the people with disabilities and different kinds of things and where the monies come from now for this population.

I think probably a lot of these are grant-funded organizations that maybe don't even bill fee-for-service, or I don't know, but what they are, are they mainly places where people can live or go to school or get trained, or are they medical services? I mean, what does the profile of those services need, and does that mean there's different contract-type issues and network issues than there are with some other populations?

CHAIR THOMPSON: I've got Chuck, Brian, Bill, Kit, Sheldon.

COMMISSIONER MILLIGAN: Nice job, Kristal.

I have two comments. The first is I think the history in the chapter doesn't get into near enough detail about a lot of the litigation that led to the rebalancing.

The first time I became a state Medicaid director in the mid-'90s, there were probably at the time, 30 states that were under consent decrees. Part of the history of how accelerated the rebalancing was for IDD services compared to people with physical disabilities, disabilities of seniors, was that a lot of these individuals were in state-run KF-MRs, the term at the time, instead of in private nursing facilities, and so there was a lot of state

action and litigation about the failure of states in running those public facilities to do an adequate job of delivering care.

And it led to a lot of deinstitutionalization and a lot of court involvement and consent decrees, and I think that whole history needs to be developed a little bit because it also continues to this day in terms of the strength of the advocacy communities. So I think that's my first comment.

My second comment is, if you can just go to your very last slide, in your next-to-last sub-bullet, you talk about several states have indicated they may incorporate this population to MLTSS.

I think we need to be very precise. Are we talking population, or are we talking services? Because in many, many states, people with IDD are in managed care for their medical care and often for their behavioral health services. What they're not in managed care is for their 1915(c) services, and so we need to not talk about it as a population issue, I think. We need to talk about it as a service carve-out versus a service carve-in to managed care and be very, very precise because people commingle those

terms, and it leads to a lot of confusion.

CHAIR THOMPSON: Good.

Brian.

COMMISSIONER BURWELL: So I for one am very glad we're getting into this area. I think it is a new, relatively new area.

Most states have carved out the IDD population from their MLTSS initiatives for a variety of reasons and generally very good reasons. It's almost like the beginning of MLTSS in which states were reluctant to move the populations into MLTSS without a supply of organizations who knew anything about it and could serve this population.

The same is true of this population. Before you contract with people to manage this population, you want to make sure that they have the expertise and capability to do that.

I do think that we should -- this is a population that has kind of floated under the radar. I do think it's fundamentally different from other MLTSS populations, and we should treat -- I mean, I would like to see another -- a stand-alone chapter maybe as a follow-on to our MLTSS

chapter about IDD programs.

We would be doing it at a relatively -- at the earliest phases of this. I do think that all states are going to go -- or most states will go into this direction eventually, but it would be a chapter at more of the early stages. And I do think we have some examples where states have not done it right and have done it too quickly, have contracted with organizations that don't know what they're doing, have contracted with organizations that have cut -- tried to make more money by cutting services, and it has led to negative outcomes.

We cite a couple of these in the chapter, and I think we should investigate those instances in more depth and see what happens.

A big difference between this population and other MLTSS populations is cost. I mean, the cost, many people require 24-hour care. So a typical HCBS waiver recipient may live in a group home with three 8-hour shifts and go to a day program, and what was the average in here? $64,000 a year. That is a fundamentally different contract in terms of managing the population than our MLTSS, which it's like $8,000 a year. Most people live at home. They

get intermittent services, maybe three or four hours a day.

I guess my main argument is that this population warrants its own separate research and investigation.

CHAIR THOMPSON: I found it interesting when you were bringing up the point, Kristal, here about what you can expect in the cost experience of this population and what you can expect to gain by moving to -- and we can ask Stacey to account for all actuaries here when we sort of have this conversation.

This is sort of to my earlier point. I would like us to draw out these similarities and differences in a much more pinpointed way because I think it does not quite come across in the way that, Brian, I think you're describing it. And maybe we settle that by some of this additional work in terms of what you're suggesting, Kristal, here, which is that we've got some key things that get incorporated into the total picture, where we can sort of draw some comparisons and contrast, but then there's some additional research that we want to publish specific to the population.

Brian, I would just say your point about it's not always gone well, that's a tough thing to grapple with.

And I see that we didn't -- or at least the contractor did not have success in really getting states to come to the table to talk about some of those failures, but that is absolutely -- or I won't say even failures. I'll just say challenges or problems.

I think it is really important that we try to understand when things have gone wrong, why they went wrong, why people thought they wouldn't initially go wrong, what they would do differently now in retrospect. I think that that's taking the positive lessons from other states is very important, but so is taking the less positive lessons from other states.

Bill.

COMMISSIONER SCANLON: Yeah. I mean, this follows on what Brian said.

To me, a very distinctive part of serving these people is the fact that you may be responsible for 100 percent of their life and care. We talk about sort of LTSS in terms of rebalancing, and we say we're moving people from nursing facilities to home with HCBS services, and it's not a one-for-one sort of tradeoff.

When they're going home and the equation can

work, when there's family supports to compensate for the fact that in the nursing facility, they were getting 24/7 -- or supposed to be getting 24/7 sort of care.

And when we're talking about at least a segment of these individuals in this population, there isn't an option to go home with family support. They're going to need sort of 100 percent care. I mean, they could have outlived their parents, and they may be facing sort of literally decades of need for assistance. And siblings are not about to stand up and say we will take this on and so I think ultimately a responsibility that needs to be addressed.

Now, having said that, there's this question of how does Medicaid, a health program, deal with a whole range of issues. When we deal with nursing facilities -- and we used to deal with KF-MRs --we were handling housing. We were handling sort of food. There was no kind of question there.

But now when a person goes into the community or to a small sort of home, how are all these different needs sort of going to be addressed and fully satisfied? That's the obligation of the state.

Second question then becomes, if I now turn to a managed care plan to take this on, what's going to be the extent of their responsibility? It is going to be very different than the extent of their responsibility with someone with -- let's say a senior with a physical disability, and is that going to work, particularly going to work when we're talking about small numbers that you're asking a plan to deal with, to set up arrangements that are going to be able to handle just a few people?

I've run into this in other contexts, that plans, they may do a great job in terms of putting together a capacity, but the cost of doing that becomes prohibitive when you only have a few customers, to so speak, or users, so to speak.

So this is a very distinct sort of group of people, and we need to recognize the breadth of their needs to make sure that those needs are addressed as we talk about sort of the Medicaid role in that.

CHAIR THOMPSON: Kit, then Sheldon, then Toby.

COMMISSIONER GORTON: So I agree with what everybody has said about this is important work. I'm glad we're doing it. I don't think we're going to get it done

this year, next year, or the year after that. So a foundational chapter makes sense to me.

We do have to chunk it up logically, and I thought that the draft chapter did a nice job.

But for me, this is sort of my home turf. I came to the chapter knowing the answer to the question that Penny posed at the beginning, and so I think you've got a lot of it in here. It's just a question of emphasizing it, and we've talked about some of the things -- and I'm happy offline to help massage this, if you want, or if you're tired of me, you don't have to talk to me.

But first, there's the life cycle, and I think you did a good job on pages -- was it 2 and 3? -- of laying out how people need different stuff. What might be useful is contrasting that with other populations that use MLTSS, right?

Frail seniors start at a place, and they fade, sometimes not evenly, but the whole idea is safe aging in place. That's very different from what you're doing with an 18-year-old or a 22-year-old with a developmental disability who is now transitioning out of his school program into life and who wants to get married and who

wants to know about girls and wants the dignity of risk that Dennis Heaphy talked about, and how do you provide him with all of those things at the same time as making sure that he's safe and well cared for and that sort of thing?

Another facet of this is if you have a senior in your family who is frail, people's relationship to that, their emotions to that, these are people who often were strong once as opposed to folks with intellectual disabilities who -- the pediatric community is familiar with the fact that when a family has a child with a disability born, they go through this whole grieving process that the perfect child they were expecting isn't the perfect child.

We have all these cultural things about is it appropriate to terminate pregnancies of people with disabilities. Should we be screening for disabilities in pregnancy? I don't think we want to go down that rabbit hole. The emotions attached to people with disabilities are different.

I would point out that many, many people with disabilities -- when I was medical director of a state institution for people with developmental disabilities, the

average age of the population was 67, and the average length of -- I started to say incarceration -- institutionalization was something north of 50 years.

So rebalancing that, those people also have parents who are in their 80s. So they remember what the bad old days were like, and so you've got all that other stuff factored in.

The services that they use are different services. The habilitative services, we try and shoehorn it into a medical model, but in fact, it's designed to help people acquire skills and be more independent. And it's a whole different thing than does Ms. Jones need five episodes of PT a week for how long until she plateaus.

These folks often are plateaued. So the mindset is different from managed care, and I just think if we can sort of do a compare-and-contrast and pull those pieces out, it will help. If you spend a lot of time with people with disabilities, it becomes sort of second nature, but I think we need to help more. And if I can assist with that, I would be happy to.

The one other point that I want to make, since we're in the context of Medicaid here, particularly when we

talk about managed Medicaid, you're talking about -- and, Stacey, I'm getting out of my depth here. The classic insurance model involves a lot of people who don't need much by way of services in any given period of time and then a few people who do need services. The problem with this population of people is they all need a lot of services all the time, and there's a legitimate question to be asked as to whether an insurance model is the right model -- and I agree with Brian. This is the direction it's going, but my experience on the insurance side is people quietly saying, "Well, should we really be the people who are doing this? Because it's not an insurance model." These are people with known risks.

It would be like selling home replacement insurance in New Orleans after Katrina. The people who are wiped out are wiped out.

So I think that's worth thinking about in the context of the funding of the program and how it gets put together, and rate setting and risk, there are efficiencies to be gained. There are people who have been told for 20 years that they need a service that they probably don't need. What's a compassionate way to wean that off? How do

you create equity? How do you say, "Well, Johnny down the street doesn't get that?" Those are important challenges, and person-centered planning is very important but can be very subjective.

So I think we need to, as part of the future work, think about whether our models of payment are right or not. In an aging population, you have a bunch of people who will not need nursing home care and then some who do for some period of time and some who do for longer periods of time. This population just doesn't behave in that insurance model.

CHAIR THOMPSON: I think that's very well said, and that's a little bit of where I was getting at in terms of saying that I think that even if you understand the differences in the populations and the services, then it becomes a question of but what makes MLTSS successful or not successful. Do we have something both from the standpoint of the cost experience and our expectation of what the cost experience looks like, which is exactly to that point, and to the point of how do you create a contract and how do you establish success in the contract, and what are the interim steps as a state that you're

taking in order to make that successful, and is there a difference in those aspects of this as we turn from the question of who this is and what do they need to -- how do we meet that need?

Sheldon and then Toby.

COMMISSIONER RETCHIN: Well, I feel it's a little difficult for me to add. Kit just brought up like five, and I hope you were taking notes because they were incredible insights. I think it was Kit. I don't want to belittle everything else you've ever done, but that was your greatest moment.

[Laughter.]

COMMISSIONER RETCHIN: And I will say that for me, I think you had all the elements in the chapter, Kristal. Some of them needed to be -- I mean, the chapter, in the background. But some of them needed, I think, maybe a little bit of expansion.

And for me, contrasting the IDD population with an aging population would probably bring almost all of it out.

I call attention to the chapter -- or the paragraph you've got on cost savings. Cost savings is

difficult to achieve. So, in there, there are some elements that for me, if you had contrasted or could contrast with the aging population, it would really probably make some salient points.

And as an example, as I think about it, a family that has, let's say, an infant on a vent, their lives are just transformed. The first floor of their house is a hospital. It literally is the closest has -- where all the inventory is with chucks, and for that infant, they need -- or for that individual, they need 24/7 care.

And your bold type there, I think really comes home to me. Where are you going to save money for that family or that individual case? They need it 24/7. It's not as if you're going to avoid hospitalizations, whereas for an aging population, avoiding hospitalizations or ER visits, that's kind of bread and butter. But for this population, they're going to need a hospitalization or an ER visit for a rare decannulation or those kinds of things, so it is so different.

And then, lastly, one thing that -- I don't know. Maybe somebody mentioned it, but it's the workforce. Boy, I got to tell you, you've got a workforce that's just

hanging by a thread, getting minimum wage, very little training, no benefits, independent contractors, and they're there 24/7. And then there's some problems where actually they're not getting paid, because they may have to eat. So there are some real issues that I think make this a very difficult population to manage in the true sense, where you can give better coordinated care and actually save money.

CHAIR THOMPSON: Okay. I'm going to go to Toby.

We're really over time, so I'm going to have to probably cut off a great conversation here so we can move on to other subjects.

COMMISSIONER DOUGLAS: Well, first, I'm really glad Sheldon is back for both his health, but really just because we missed your humor.

COMMISSIONER RETCHIN: I could have phoned them in.

[Laughter.]

COMMISSIONER DOUGLAS: I know when we look at this, we look through the Medicaid lens of MLTSS, but I was surprised there wasn't anything earlier around the Medicare, the interaction with Medicare, and most, if not all of these individuals, are on Medicare. And I just

wondered if that came out around just the intersection between acute and home- and community-based care for this population and how that, not having that true continuum. Was there any discussions?

MS. VARDAMAN: In New York, where it is a part of the Financial Alignment Initiative, there was some discussion, and in the supplemental materials, we can certainly try to highlight the extent to which how they've approached it in terms of coordinating Medicare and Medicaid benefits.

Outside of that, I don't know if that was really the focus of some of the questions that we asked.

COMMISSIONER DOUGLAS: Well, I just wonder that somewhere where -- whether it's in this chapter, but as we look to explore and back to even just looking at the costs, I mean, we are showing the Medicaid side. But it would be interesting to look holistically. Again, we do, and maybe it's in the data book, the duals data book, but pulling out the overall cost of this population across the two systems and the issues that raises in the intersection and if opportunity is there.

CHAIR THOMPSON: All right. Marsha is going to

say something.

VICE CHAIR GOLD: Just quickly. One thing is you're looking at this, and maybe the data don't exist, so you can't do much.

A lot of the conversation assumes that while this group is different from others, they're homogeneous internally, and I wonder if there were any data, I mean, how -- are the causes and what they need very different? Are some of them really expensive, but others are less expensive and able to do much?

I know some of these are people who come from families that may have a reasonable amount of money, but not to take care of a child like this.

So more we can find out just a little bit about what the population looks like and certainly from a care or risk perspective, that variation in needs is important.

CHAIR THOMPSON: Great. Terrific conversation.

Kristal, so I think we'll see some of this in the foundational MLTSS chapter in June, but then more to come, and I think it sounds like we have a lot of different topics and a lot of appetite to explore them in this area. So thank you very much for your work.

Okay. We are going to go ahead and keep moving, since we are behind time, and talk about Medicare base and supplemental payments to hospitals.

ASSESSING THE ROLE OF MEDICAID BASE AND SUPPLEMENTAL PAYMENTS TO HOSPITALS

* MR. NELB: Hard to follow that good conversation, but diving back to a topic we've been talking about a lot, I'm going to continue our discussion of hospital payment policy by focusing on the role of base and supplemental payments to hospitals.

So I'll just give some background about various types of base and supplemental payments, and then I'll discuss some illustrative examples about how states can use these different types of payments interchangeably.

Finally, we'll conclude with some policy questions to help guide your conversation today, including about what the most appropriate relationship should be between base and supplemental payments, and questions about whether there are particular federal policy approaches that can begin to add more transparency and accountability to these payments.

So, first, just a quick refresher on our larger

hospital payment work plan. As you will recall at our last public meeting, I presented a long-term work plan that aims to broadly consider all types of Medicaid payments to hospitals.

Based on MACPAC's provider payment framework, the work plan proposes to collect information about payment methods, payment amounts, and outcomes related to payments in order to help inform Commissioner discussion about whether payments are consistent with the statutory goals of efficiency, economy, quality, and access.

So during today's presentation, I'll begin by presenting some information about the first part of our work plan, payment methods, specifically focusing on the question of what supplemental payments are ultimately paying for.

In later meetings, once we have a better understanding of these payment methods, we'll hopefully be able to better answer some of the other questions in the work plan, including questions about whether payments are adequate and whether or not they're achieving their intended goals.

Okay. So now some background on base and

supplemental payments specifically. Base payments, as you know, are payments for particular Medicaid services for Medicaid enrollees, while supplemental payments are additional payments made to providers, typically in a lump sum, that are not tied to a particular service.

In our prior work, we have documented that Medicaid-based payments are relatively low compared to costs and other payers, and we found that many states make large supplemental payments to help offset some of this Medicaid shortfall.

However, we have also found that supplemental payments are also used to address other objectives, such as providing access to care for uninsured patients and also promoting overall hospital financial viability.

Different stakeholders have different views about supplemental payments. On one hand, federal policymakers have sought to limit the use of supplemental payments, in part due to concerns about transparency and accountability for these payments. On the other hand, states value the flexibility of being able to pay providers using multiple payment streams, and they prefer to target supplemental payments to providers rather than broad-based increases in

base payment rates.

And from the hospital perspective, in part because base payments are so low, hospitals have expressed concerns that access may suffer if supplemental payments are reduced.

This figure shows the distribution of base and supplemental payments in fee-for-service Medicaid in 2016. You can see that about half of payments were base payments, and about half were supplemental payments, and that there's a variety of different types of supplemental payments, which I'll discuss in greater detail later.

Unfortunately, we don't have complete data on managed care payments to hospitals, but we do know that managed care accounted for about half of Medicaid benefit spending in 2016.

Okay. So, with that overview, let's take a closer look at base and supplemental payments, starting with base payments, which again can be made in both fee-for-service and managed care delivery systems.

So, in fee-for-service, base payments must comply with a variety of federal requirements, including federal access requirements that payments are sufficient to enlist

enough providers, so that services are available to Medicaid patients, at least to the extent that they are available to the general population.

CMS reviews state fee-for-service base rates as part of the state plan review process, and since 2016, states have been required to submit access monitoring plans every three years and whenever the state proposes a reduction in provider payments.

Despite these access requirements, we have found that fee-for-service base rates on average are below costs and are below Medicare rates for comparable services.

So, for example, in our review of DSH audits, we found that base payments covered 82 percent of costs for DSH hospitals, and as part of our inpatient hospital payment index, we found that payment rates were about 78 percent of Medicare in 2011 for the services that we studied.

Our inpatient hospital payment index work also found wide variation in payment rates across states as well as variation within states for different types of services and for different hospitals.

So moving to managed care, managed care has

different access requirements than fee-for-service. Managed care capitation rates are required to be actuarially sound, meaning that they cover reasonable, appropriate, and attainable costs in providing covered services to Medicare enrollees.

However, managed care plans have flexibility to design their payment methods to hospitals within that capitation rate as long as they meet network adequacy requirements and other standards.

One important exception to this is that states can now require plans to direct payments to particular providers for rate increases or quality improvement activities. The option for states to require these so-called directed payments was added in the 2016 Managed Care Rule, so we don't know too much about how the option is currently being used. But we do know that some states are looking to this option as a way to continue some supplemental payments, such as DSRIP in managed care without a waiver.

The relationship between managed care and fee-for-service payments to hospitals is unclear. We have found some examples where managed care payments to

hospitals mirror fee-for-service, but we have also found other states where managed care payments are higher or lower than fee-for-service payment rates, suggesting as usual in Medicaid that it's hard to generalize across all states.

Now let's take a look at supplemental payments. There are five major types of Medicaid supplemental payments to hospitals listed here. Some of these payments are intended to pay for services provided to Medicaid enrollees, but some of these payments are intended to support other goals.

For the discussion today, I have attempted to categorize the various goals here based on the federal rules. So, for example, DSH payments are allowed to pay for the cost of care provided to Medicaid patients as well as the uninsured, while UPL payments are determined based on services provided to Medicaid enrollees alone.

In your materials, I've provided more detailed information about each of these types of payments, but in the interest of time, I just want to focus on the two largest types of supplemental payments to hospitals -- DSH and UPL.

So although both DSH and UPL payments pay for Medicaid shortfall, the rules for determining the maximum amount of payments under each policy differ.

DSH payments to an individual hospital cannot exceed the hospital's uncompensated care costs for Medicaid and uninsured patients. In contrast, UPL payments are established in the aggregate for a class of hospitals.

UPL payments cannot exceed a reasonable estimate of what Medicare would have paid, but states have two different ways that they can determine this. First, they can use a cost-based method, which is similar to DSH, or they can use a payment-based method, which is based on actual Medicare payment rates.

DSH payments, as we've discussed, include costs for both Medicaid and uninsured payments, while UPL payments are only calculated on services provided to Medicaid enrollees.

One other quirk to be aware of is that DSH actually pays for Medicare shortfall provided to patients who are dually eligible for Medicaid and Medicare, while dual eligibles are not included when calculating UPL since Medicare is the primary payer of hospital services for

these patients.

At the end of the day, the differences and the limits for these two programs mean that some hospitals can receive more money from DSH than UPL and vice versa. In 2013, about one-fifth of DSH hospitals were receiving DSH payments that covered all of their uncompensated care costs, the maximum allowable under DSH rules. However, some of these hospitals could have received more payments through UPL, since UPL limits are established in the aggregate.

Although some states have maxed out their UPL limits, states reported the ability to make $6.5 billion more in UPL payments in 2014, according to information they submitted to CMS.

To help illustrate how states can use some of these different types of payments interchangeably, I wanted to highlight some examples from a few states.

So this figure shows Medicaid payments relative to costs for DSH hospitals in five states. First, you can see a range of overall payment rates, from 86 percent of costs in State A to 123 percent of costs in State E.

This figure also shows that states can use a

variety of mechanisms to pay hospitals the same amount. For example, in States B, C, and D, the hospitals receive roughly 100 percent of their costs. However, in State B, most of the payments are through base payments, while States C and D make larger supplemental payments.

Similarly, between State C and D, State C makes larger DSH payments, while State D makes larger UPL payments to the hospitals.

Finally, State E is an example of a state that pays hospitals more than their cost for serving Medicaid patients. However, I want to point out that in this state, the total payments are less than the cost of serving both Medicaid and uninsured patients; thus, it's likely that some of the DSH payments in the state are being used to pay for the uninsured rather than paying for Medicaid shortfall.

The different types of Medicaid payments to hospitals are often financed in different ways, and this can have implications on the net amount of payments that providers receive.

This figure shows the source of non-federal funding for different types of Medicaid payments in 2012,

and you can see the DSH and non-DSH supplemental payments are much more likely to be financed by providers than from state general funds.

In our work on DSH, we've estimated that these provider contributions effectively reduce the net amount of funding that DSH hospitals receive by about 11 percent.

Okay. Now that we've reviewed some of these different types of payments and how they relate, and I want to turn it over to you for a discussion about where we go from here.

To help jumpstart your discussion, we've outlined a number of policy questions for today, and I've divided them into two slides.

The first set of questions aims to get at what that relationship should be between base and supplemental payments. Specifically, we ask: What are the implications of allowing states to use supplemental payments to offset low base rates? To what extent are different types of supplemental payments used interchangeably? To what extent do supplemental payments pay for services provided to Medicaid enrollees versus achieving other goals, such as paying for the uninsured? Should policies affecting base

and supplemental payments differ in fee-for-service and managed care delivery systems?

This second set of policy questions asks whether there are particular federal policy approaches that could help improve the transparency and accountability of Medicaid payments to hospitals.

To get the conversation going, your memo outlines four examples of policies the Commission could consider. First, in order to clear up the confusion about what actually pays for Medicaid shortfall, the DSH definition of uncompensated care could be changed to eliminate Medicaid shortfall, so that DSH payments are only focused on paying for care to the uninsured. And other payment mechanisms could be used to pay for shortfall.

Second, to perhaps avoid the need to use supplemental payments to offset low base payment rates, there could be policies to strengthen oversight of base payment rates and perhaps establishing minimum payment levels of hospitals.

Third, as I discussed, there are different rules, determining the maximum amount that could be paid under DSH and UPL, and these policies could perhaps be aligned,

perhaps applying facility-specific standards rather than an aggregate standard.

And finally, rather than paying for supplemental payments in a lump sum, states could be required to include explicit performance metrics for supplemental payments tied to quality or access goals.

Just some examples to get the conversation going. As you consider particular approaches, you may want to think about how these approaches compare in terms of transparency, accountability, sustainability, flexibility, adequacy, or other factors not listed on this slide.

As I said at the start, this is the first step in a long-term work plan on hospital payment. Your feedback on the issues raised today will help inform our future work, including some forthcoming analyses of UPL and some interviews we're planning with states.

But I really look forward to your feedback to help guide our work ahead. Thanks.

CHAIR THOMPSON: Okay, great. Very useful. Much appreciated.

We have been asking to have this conversation, which is the theory of everything, for some period of time,

and so we asked for it.

Just a couple of questions about your view, Rob, about the analysis that we can do. To some extent, it feels to me like when we get into some of these questions that we're asking about, they become very policy- and normative-driven, like what do we think is just the right way to do business, as opposed to something that is really evidentiary based, where we would say, well, let's go out and do some data or modeling because the data or modeling will help drive us in a different direction.

Just in terms of your thinking about some of these different questions, are any of these particular questions in your mind interrogated best with actual research and data versus with different ideas where we might be thinking about policy objectives?

MR. NELB: Sure. So I can take a stab.

We are thinking of doing a closer look at the UPL payments. In particular, we have some new data from state demonstrations that basically talk a little more about how they've established their UPL limits, and I think that analysis will give us some understanding about sort of the difference between DSH and UPL and just to have a baseline

for talking about sort of how many dollars are at stake and how the money changes.

There then is this normative question, as you highlight, of are these payments intended to pay for a shortfall versus paying for something else, and that is probably more up to the Commission.

We did that roundtable last fall and sort of got some views of different stakeholders, and we are planning to do interviews with state officials and other stakeholders this summer to see kind of where they think which payments are paying for shortfall versus other goals. But that piece is probably more normative.

CHAIR THOMPSON: Yeah. Anne can jump on in.

EXECUTIVE DIRECTOR SCHWARTZ: Yeah, I just wanted to jump in.

I think a real problem here that we have is the lack of facility-level data on all these payments.

We have the DSH audit data, which gives us a lot of information on some of the hospitals, but on not all of the aspects that we want. That's something that the Commission has recommended in the past.

And we have talked about we can do these state-

level analyses, but there is a lot of stuff going on underneath that. So that's just an inherent limitation that we have.

CHAIR THOMPSON: There's some questions like should base payments be the majority of your payments, intended to fully reimburse a provider for the services that are being delivered to specific beneficiaries, and then are their other purposes that the program may have that it may want to support a fund. It's not a question that gets answered by knowing details about facility-level --

EXECUTIVE DIRECTOR SCHWARTZ: The only thing is that if you wanted to say like what would that mean for individual institutions and individual states, like what is the pain involved in moving to that, that's the thing that I think is --

CHAIR THOMPSON: Yeah. Okay, okay.

EXECUTIVE DIRECTOR SCHWARTZ: And that is obviously what is really important to people.

CHAIR THOMPSON: Okay.

All right. I know everybody is going to want to jump in. So we have Stacey, Bill, Brian, Sheldon, Fred,

Kisha, Chuck. Okay.

Stacey, kick us off.

COMMISSIONER LAMPKIN: Okay. Just I wanted to say about the normative question real quick, while we may be limited in some data analytics that we can do, it doesn't seem to me like it's impossible to get evidence to support a normative perspective with respect to like what kinds of barriers does the current structure put in the way of delivery system reform. What kind of incentives does it produce, and are those the incentives that we want to encourage? And so I think that the interview structure on some of the other less-quantitative analysis may give us some evidence for those kinds of things. I just wanted to say that.

And then a couple of just brief comments about where I think this is going, and my own opinion at this point in my learning and thinking about this is I think you've put together some very helpful background information. I learned a lot and thought it was really useful.

My own perspective is that I tend to weigh the transparency and accountability values very, very highly, I

think. It's really critical as taxpayers that we know what we're paying and what we're getting for what we pay, and we don't have that in the system that we have today.

I understand the positives about state flexibility and sustainable financing solutions. I do understand all that, but we have to balance that in a structure that encourages rational reimbursement, that produces the right incentives, that lets us know what we're buying with our money. So we need to figure out that balance, and so with that and starting with the framework of weighting the transparency and accountability, I think that shortfall is a great place for us to start.

If we want to understand what we're paying for Medicaid services delivered to Medicaid recipients, what is the most rational thing to do with shortfall? Is it to have it in DSH, for example, or is it to try to bundle it together -- my bias is primarily in base rates -- so that we understand what we're getting?

We can design a reimbursement -- or states can design reimbursement structures that produce the right incentives. Understanding the financing challenges that could be introduced by that kind of shift in some states,

understanding that especially in states with managed care programs, that may introduce some other challenges. But that seems foundational for us to be able to get to questions about adequacy, equity, transparency.

So I think shortfall is a great place to start, and if we can start working around shortfall and understanding the implications of gathering our Medicaid payments for Medicaid services in a rational way, what does that do to some of these other funding streams, and what are the implications? It seems like a useful place to start.

CHAIR THOMPSON: So does that include in your mind, Stacey, understanding whether we really have an accurate measure of shortfall in addition to how we account for it and where it gets --

COMMISSIONER LAMPKIN: Well, it certainly could, and that would go to our question about adequacy. And that also in my mind goes to our question about incentives because is it a cost-based analysis or to what extent is it a cost-based analysis is a question that we need to take up.

VICE CHAIR GOLD: Stacey, to help me, is what

you're talking about page 13 for every state by name, where that leave managed care out, and so it may not? On graph page, 13 -- on the slides, page 7. It's graph 13.

CHAIR THOMPSON: For the purposes of the audience, is that Medicaid payments to DSH hospital?

VICE CHAIR GOLD: Right. As a percentage of Medicaid cost. The shortfall, are you thinking about it's the black line? What data would tell us the Medicaid shortfall?

COMMISSIONER LAMPKIN: Well, looking at cost reports, I believe is the foundation of calculating it today.

CHAIR THOMPSON: Right.

COMMISSIONER LAMPKIN: And I think we should investigate that a little bit.

CHAIR THOMPSON: That's my question about --

COMMISSIONER LAMPKIN: Right.

CHAIR THOMPSON: -- whether or not we think we even know what he shortfall is.

COMMISSIONER LAMPKIN: Right. And I think we should investigate that and understand the implications of that particular calculation.

I don't personally know whether it's the right or best way to do it or not. I do think designing reimbursement in a cost-based manner is probably not the incentive structure that you want, but it may be reasonable for measuring shortfall. I don't know.

I don't know. Marsha, did that answer your --

VICE CHAIR GOLD: Well, it's okay. It's complicated.

CHAIR THOMPSON: All right. Brian.

COMMISSIONER BURWELL: [Speaking off microphone.]

MR. NELB: [Speaking off microphone.]

[Laughter.]

COMMISSIONER BURWELL: I thought this was outstanding. I mean, in some way, this is not my area. This was Chapter 1 of the theory of everything that I -- and I really think this could be turned into a stand-alone report or brief or something. I really think the policy really -- I don't think people understand, have the clue, basic clue about this stuff.

And the pie chart on Slide 5, over half the payments that hospitals get are unrelated to anything they actually do, and I was just blown away. I mean, like --

VICE CHAIR GOLD: Well, put managed care in there, and it might be -- I think -- that blew me away too, but I think one has to sort of talk about managed care, and that that includes those payments, most of which I assume are payments, directly base payment-type things. It probably makes it about a third or something.

COMMISSIONER BURWELL: I'm not sure about that rule.

VICE CHAIR GOLD: Oh, I don't know what the right number is, but it overstates it a little.

COMMISSIONER BURWELL: That's basically all I want to say. I really think that this would be a great stand-alone product of some kind, and get it out there sooner rather than later.

I mean, this sounds like something that we will be developing over the next couple of years further, but --

CHAIR THOMPSON: Sorry. I lost my list. I wrote it down someplace.

Okay. Bill.

[Laughter.]

CHAIR THOMPSON: Save me.

COMMISSIONER SCANLON: Okay.

CHAIR THOMPSON: Save me, Bill.

COMMISSIONER SCANLON: All right. I guess I find this to be a very difficult area because the question that's in my mind is are states structuring payments so that they are assuring access and being an efficient purchaser at the same time, and I particularly -- I mean, I'm very concerned about the fact that we only have data at a very high aggregate level, and we can't do it at the hospital level because to me it's the question of do the payments add up at the hospital level to the right amount.

And having said that -- let's say we had those data -- then I also have concerns about sort of concepts, and I'll start with sort of shortfall.

If shortfall is reported costs versus Medicaid payment, to me reported cost consists of two things -- necessary and unnecessary costs. All right. And so the question is how much should a state be responsible sort of for unnecessary cost.

And you can even ask the question should the state be fully responsible for every hospital's necessary cost because those include -- and I'll apologize for being the economist here -- both fixed and marginal costs.

On the fixed-cost side, maybe we should be factoring in other kinds of subsidies that hospitals are getting from the state. They're giving -- they're all, for the most part, given property tax exemptions. How much are those worth?

In states with strong certificate of need, how much does the monopoly positions that -- or monopoly power that a hospital get? How much is that worth? Should we be able to negotiate and exchange for those kinds of considerations, a discount where only a portion of fixed cost is being paid? And Medicaid shouldn't feel guilty about that.

Now, that's going to vary across hospitals, and this is where coming down sort of to the hospital level is very, very important. If I'm a hospital that's incredibly dependent upon Medicaid, those rates need to be adequate to keep that door open. If I'm a hospital that occasionally has Medicaid patients, it makes much, much less difference.

So I feel like we've got to think about how we break this down, and I know from a data perspective, we may not be able to break it down. But then we need to be cautious about our language in terms of how we describe

things, so we don't sort of create a basis for saying we're underpaying X group when we don't have the evidence to say we're truly sort of underpaying X groups.

CHAIR THOMPSON: Well, indeed, I think the other point to bring in here is the idea that the program, at least at the federal level, does not set requirements around adequacy of rates, except insofar as they affect access. So there's no federal sense of somehow we've got to be responsible for your financial condition, except insofar as those rates do or do not create the necessary network of providers and access to providers that are necessary for the program to deliver the services to its beneficiaries.

COMMISSIONER SCANLON: And even looking at --

CHAIR THOMPSON: So I agree that that then plays out very differently in terms of what market you're in --

COMMISSIONER SCANLON: Right.

CHAIR THOMPSON: -- and what the relative position of different entities is in that market.

COMMISSIONER SCANLON: Right. I agree.

And I guess in feeling good or bad about the access reports, one of the things that I wanted to

immediately factor in was what about EMTALA. I mean, the question is -- I mean, with that on the books, how much do the Medicaid rates matter in terms of the access measures we're getting? I think that would be something to also take into account.

CHAIR THOMPSON: I found my list. So Sheldon, Fred, Kisha, Chuck, and now I see Toby adding to it. So, Sheldon.

COMMISSIONER RETCHIN: So Rob's -- what should I say on the record? That was really terrific, Rob. You're amazing.

[Laughter.]

COMMISSIONER RETCHIN: So, for me, where we're at today is way, way, way too hospital-centric, and I am, though, I guess -- I think Bill just said it, that you have a whole taxonomy of hospitals. So you and I communicated, amazed by some of the statistics, that 3 percent of acute care hospitals in the United States account for 25 percent of Medicaid days. Further, 8 percent account for half of all Medicaid days. So you're dealing with a group of hospitals that I think for me, the figures in essence lead me a bit astray.

So if I look at those two figures, the first one doesn't net out provide taxes, and it looks like -- I mean, I come to the conclusion that hospitals and states are in cahoots, and they're stealing the federal government blind. Now, maybe that's true, but -- because I also, by the way, noted for the first time -- you said, I think in there, that provider taxes, although it's against the law, that in some way or another, that the provider taxes, they expect to get the money back after the tax, which means that it's not actually a tax. It's an investment.

So, for me, as I look at this, the hospital centricity really resonates strong, so that I think looking or getting away from the Medicaid shortfall is a real problem for that 8 percent and 3 percent. It's really going in the wrong direction.

The big safety-net systems that take care of the lion's share of Medicaid patients have other costs that are not reflected in cost reports, and the big one out there is the physician group.

So if I look at the goal of this as we -- because this is obviously the beginning of a marathon -- the goal for me is to reform the system. The incentives today are

to hospitalize patients for DSH, and what we should be doing is putting in a different type of payment structure that incentives hospitals to keep patients out.

To do that requires incentives, somehow or another, maybe in a VBP framework, like the global payment system in California, where the hospital safety-net systems are encouraged to vertically integrate with a physician population to take care of beneficiaries in the best way.

Today, it's very, very hospital-centric, and I would venture to say it's anti-provider.

One more thing. As we look at it, the -- and there's a percentage of cost or percentage of Medicare. Those numbers in the base payments are, let's say, 78 or 80 percent. You put supplemental payments in there; you probably get up to 95 percent or something like that. I don't know.

If you look at the physician reimbursement, it is significantly below Medicare. So it doesn't make sense to me out there that we don't have some sort of access problems. Just because 70 percent of physicians participate in Medicaid doesn't mean that 70 percent really take care of the Medicaid population. I think that's much

thinner, and the safety-net systems out there that really are taking care of the Medicaid population are hard at work at this.

And maybe, Fred, you're going to follow now and tell us how places like Parkland do that. I imagine you -- well, I know you transfer truckfuls of money. I mean, that's true, so I'll yield.

[Laughter.]

COMMISSIONER CERISE: We don't do it by truck.

COMMISSIONER RETCHIN: It's a continuous express, like a subway.

CHAIR THOMPSON: Go ahead, Fred. I think it's over to you.

COMMISSIONER CERISE: Okay, yes.

VICE CHAIR GOLD: With that intro.

COMMISSIONER CERISE: Well, first, I tell you, Bill, I like how you laid it, laid it out, and, Sheldon, as the hospital guy, I wouldn't probably say this plainly as you. But there really is a -- the incentives are messed up here, and if you did look at the base, look at the base and try to do something that didn't leave you so far from costs -- and I'm not saying cost should be your target because

that shouldn't be the target on your cost report, and there are all these other things about community benefit and tax-exempt status that should get factored in. I mean, these requirements on hospitals to do that, and then they do report stuff that the community doesn't really want them to do. They'd rather them see uninsured patients.

But, nonetheless, if you got closer to something reasonable there, then you could perhaps get some of the gamesmanship out of the program.

To address some of Rob's points about the various supplementals, they are fungible. They squish around, and the reason in many places that they're such a big portion of the reimbursement is because the states know that they can rely on the providers or local governments or some other entity other than the state to provide the local -- the matching share, the state share. And so for that, the states surrender then really the policy priorities of the program, and so you lose the ability to build in the expectations of the program because now half of your payments are coming from some other source. And you're letting it happen because you don't have to put up the state share.

So I think if you worked on the shortfall a bit, but don't think you have to -- nor should it be driven by what your number on the cost report it, but you've got something that was more reasonable, if the reg is, the expectation is your base rate ensures access, then why are you putting in another half?

I've heard the arguments from states that you have to do all these supplements to ensure access. Well, if the base rate is supposed to ensure access, the base rate is supposed to ensure access.

CHAIR THOMPSON: Well, I wouldn't say that. I would say the payment methodology is supposed to ensure access. So that's how that gets evaluated.

COMMISSIONER CERISE: Yeah. Okay.

CHAIR THOMPSON: So my payment methodology may be I'll pay you X amount for service for beneficiary, and then at the end of the year, I'll give you a portion of a larger fund, depending on the size of it that's available at the time, et cetera, et cetera.

So all of that constitutes your payment methodology, and that's what's being scrutinized for adequacy.

COMMISSIONER CERISE: I think if you did, say, though -- if you got closer on base and said this is reasonable for the population, then you could use your supplementals to target the policy goals that you want, to Sheldon's point. You look at quality and access, and in this program, access is a huge issue, and you could really target supplementals to say are you getting access to services outside of the emergency department, continuum of care, all the other wrap-around things that you need to take care of a population. They're not going to happen by paying a bunch of hospitals, a portion of their costs for people that come to their emergency room.

CHAIR THOMPSON: All right. Kisha, Chuck, Toby, Marsha, and then we'll see where we are, Rob, in terms of giving you some ideas for direction, though I think that what we will likely do in terms of both time and need for all of us to think about this and digest some of this information further, pick this back up at our next meeting as well. So no one should feel like this is going to be the point in time that we're going to solidify the strategy and the direction here, but we might settle on some kernels or some nuggets that we might want to live with for a

little bit.

Kisha.

COMMISSIONER DAVIS: Thanks, Rob. This was really good. Thanks for giving us the opportunity to take a bite out of this really, really big apple.

A question that I had, when we get back to the base rates and the variability, how does the administrative burden change when you just pay a higher base rate versus supplementing with DSH and UPL and what that looks like?

I think to Stacey's point of better understanding the shortfall and how that falls out, I think is really helpful.

And I also wanted to thank Sheldon. It didn't come to me, but this issue of value-based payment and do we just need to be changing how we're paying people -- because it's -- while the hospital is then making up the cost with all of these other, the providers aren't. And so that's not trickling back down to the providers, and there's an access issue there.

Lots of providers say they take Medicaid, and they don't when you call to schedule a patient.

So, to those points, that's all.

CHAIR THOMPSON: Chuck.

COMMISSIONER MILLIGAN: I'm disappointed that nobody has had their finest moment so far in this discussion about DSH, but, Rob, really great work.

I'm less inclined to kind of go to a normative place yet. So I just think personally, sort of putting some transparency around this is a really important value-add and continuing to dig deeper.

I think honestly some of the transparency and kind of the theory of everything that would, I think, be the next part I would be interested in is the financing source that leads to the payment, because I think -- and we've been talking about it, and I want to align myself to what Fred said. In my experience, a lot of the base rate payments come from state general funds match, and then a lot of the supplemental payments come from non-state general fund sources.

So it might be local government. It might be provider taxes. It might be intergovernmental transfers of different kinds, and I think in a lot of states, the ability to substitute supplemental -- increase base rates and reduce supplemental payments is not politically viable

at the state level to try to get county government, city governments, others to try to raise the state general fund portion to make up for that difference.

And so I think I was having this image of like Jenga, where you start pulling it out saying this is inappropriate. In some states, the financing isn't going to be replaced by state general fund raising base rates. It's going to just disappear because whatever Congress may or may not do or our recommendation may or may not say down the road, local government isn't going to care. Then they're not going to necessarily be willing to let the states raise taxes, and state governments are going to be hard-pressed to raise general fund to make up for some of that difference.

So I think personally, exposing and making more transparent not just the payments, but the financing underneath the payments -- this is my version of the theory of everything is -- because I do think we talk about it fungibly, but in terms of the revenue production part of it, to make the payments, politically it isn't fungible.

So I think I want to probably just make that comment. Otherwise a lot of what I was going to say has

been raised by other folks.

CHAIR THOMPSON: Toby and Marsha and Sheldon.

COMMISSIONER DOUGLAS: Chuck pretty much said exactly what I was going to say.

This whole discussion, without -- the non-federal share in all these states, as Chuck said, if you mandate or look at an idea around increasing the base, then these voluntary payments -- we have to remember that in the case of -- as well as providers, they're voluntary, will go away, and you're either doing as Chuck said, that it will lead to reduction, or -- and increase state burden, the view that the states are now having to pay more to meet the new requirements.

So we have to either separate the two or at the same time, analyze ways to turn the non-federal share, in essence, into a new -- whether we're changing the FMAP or doing something, but it's hard to deal with the policy goals on the payment, value-based payment, without taking into account how states or why states are coming up with the non-federal share in the way they are.

CHAIR THOMPSON: Can I just challenge that point from the following standpoint? Not challenge it from the

standpoint of do I think what you're saying is real or not. I think it is, but that forcing those conversations and decisions is part of what a legitimate state share was intended to create, which was that states would make decisions with their own money. They would make hard choices. They would make decisions about what it was worth. They would be accountable to their constituents around those issues.

And to some extent, what we're talking about is what's evolved over time as a cushion that's developed that is kind of invisible to a lot of those stakeholders now, and so the question that I would ask is that I recognize that we've built the Jenga -- what is it called? Is it the Jenga Tower? Whatever that is. So that exists today, and there's always this concern about pulling it out, things implode, and consequently why you went up with long transitions when you find out that certain practices have been -- states have been involved in certain practices for long periods of time. There are then always these long transitions out of them because of exactly that concern.

But appreciating whatever transition we'd be talking about, if you're going towards an end result, which

is we want to have adequately financed and paid-for services for Medicaid beneficiaries -- primarily, that is the focus of the Medicaid program, and we want states to actually put up their state share and federal government to match it -- is it really true that we're seeing those conversations and decisions and a state is ultimately going to lead to a diminution or an inappropriate reduction as opposed to a real grappling with the reality of we've got to pay certain money to get certain services and to have certain results, and those are not infinite resources.

COMMISSIONER DOUGLAS: There's no question it can be, but as you've said, we built up states' expectations or this is the rules of the game, whether we want to call it inappropriate or not.

CHAIR THOMPSON: Yeah.

COMMISSIONER DOUGLAS: It's the rules --

CHAIR THOMPSON: Yeah. That's a fact.

COMMISSIONER DOUGLAS: It's a fact.

And so to change those rules on one side of how the payments -- without how they're actually coming up with a non-federal share, that is -- by states, the view would be you're pulling the rug out from under. Even with the

transition, I think resetting on both sides of saying, okay, you have this amount of funding. We've kind of said that's your funding, and now we're changing the rule, so we're not expecting a new state share. That could be -- I'm just throwing one example, but I think if we try to set values on how payments should be made with the reality of how states are matching dollars, I think you're going to have a problem. That's my view.

I don't know, Chuck.

COMMISSIONER MILLIGAN: And, Penny, a couple of thoughts. What we have now isn't rational. It isn't rational, and going to what Brian said earlier about, Rob, your great work here, I think it's a huge contribution.

I mean, I was shocked personally to see the pie chart and see 51 percent is supplemental. So I think there is a huge contribution to be made in just putting light to all of this.

But to your specific question, it has been built up. So we can't say the goal was to have states and states share. We're five decades down the road on this deal, and so I think shedding light on the financing source -- you know, the per capita cap is going to come back around.

Block grants are going to come back around. These issues will become very pressing, and we need to be prepared to make intelligent recommendations at that time about carve-in, carve-out, state variation.

So to me, keeping that focus -- but I don't think we can in a hypothetical have it both ways, which is let's assume we're starting from scratch and also, by the way, let's assume we're not starting from scratch. And so I think we have to have that conversation around the source of funds if we're going to be making recommendations or moving in a normative direction around payment of funds. I don't think we can separate the two.

And I'm sorry. I just want to say one other thing. At a state level, there's so much variation between local control and state control and the governance. It's the federalism conversation pushed down.

In many states -- New York comes to mind. Many states come to mind where the administration of Medicaid is done at a county level. Wisconsin, Ohio -- many states do it at a county -- California has certain components where the counties are really the drivers of a Medicaid service and Medicaid decision-making and Medicaid state share

through these intergovernmental transfer vehicles, and so if we start talking about financing, it's going to get into that kind of governance level, which is state control, local control, and if the base funds go up and supplemental funds go down, counties could get really nervous about the loss of their contribution is going to mean the loss of their control. So it unpacks all of that at the state level.

CHAIR THOMPSON: I'm going to turn to Marsha and then Sheldon, and then I think we'll have to bring this to a close.

Rob, to the point about how many years this has been going on, do we have historical data about base and supplementals over the years? I think it could be helpful to see if we have seen substantial change over time in those buckets.

COMMISSIONER LAMPKIN: And the changes in the financing of the non-federal share to.

CHAIR THOMPSON: Yeah, yeah.

COMMISSIONER LAMPKIN: I think you have showed us some historical data about that.

CHAIR THOMPSON: Yeah.

MR. NELB: Yeah. So we can definitely look at that. In short, there's been a growth in particularly UPL and these waiver supplemental payments in recent years.

CHAIR THOMPSON: Right.

MR. NELB: They're financed in different ways.

CHAIR THOMPSON: Right.

So I do think that that's helpful too to kind of see what's more recent, what's longstanding in terms of understanding at what level of the Jenga tree we might be inclined to pull something out.

All right. So Marsha, Sheldon.

VICE CHAIR GOLD: Yeah. Hi. I want to align myself with what everyone said, especially the transparency and the analysis. I think this will be good information.

One thing, I think, to me, when I looked at these, the most market figures were the one on page 3. It was Figure 5, which is that national pie chart everyone is talking about, and then those unnamed states on page 13, which I assume we'll try and get all states, maybe even named.

And I guess what I'm concerned about -- and maybe Stacey will have some ideas here because I really think

that we need to do something more to account for managed care, because my assumption is that the supplemental payments are just supplemental payments, and they're program-wide. Most of them don't occur through the managed care program, but they affect everyone.

The revenue flow to the hospital is the fee-for-service payments, the managed care payments, and the supplemental payments. I don't know if there's something that can be done with the way capitation rates are set or fee-for-service cost experience, just to do some estimates, and the reason it's important is, one, I do think it's a little -- even though it's market and I think it will still stay market, it's a little misleading to just say half of the payments are in supplemental, when there's a flow from managed care into that.

And it's particularly misleading if you're going to look state by state because some states have a much higher penetration of managed care than others, and you're losing a lot of money on the base payment rates when you -- through the capitation rates.

So, Stacey, I don't know if you have any ideas. I know it won't be ideal because all we get is managed care

payments, but I don't think we can afford to not deal with it.

COMMISSIONER LAMPKIN: No. I do agree with you. I think that we'd have a more complete picture if we could proxy the managed care payments to inpatient. So there might be ways to organize this to make it a little bit fairer look in the absence of having that.

For example, if UPL payments are made only on fee-for-service utilization, it might be useful to look at the proportion of the total spend on fee-for-service and UPL, what proportion of that is UPL, and take some of this other stuff out of the mix. So there are things that probably can be done to help.

VICE CHAIR GOLD: I leave that to --

MR. NELB: If I could just interject, we're looking at it and we'll keep looking at how to do that.

One, we are looking at like how national health expenditure data, CMS actuaries, account for payments to hospitals. One general approach, all we have is the payments with the capitation rate and trying to assume what percent of the capitation rate goes to hospitals.

But one challenge we get into pretty quickly,

given on the fee-for-service, half the payments are base payments, half are supplementals, is to what extent are the supplementals built into the managed care rates or not.

We've looked into some different states. Some states build them in; some don't. So we'd have to come up with some assumptions there in order to apply that.

VICE CHAIR GOLD: [Speaking off microphone.]

Small number of people who are experts on this finance thing together and talk it through. If it was Medicaid, I tell you, you could just go to the way capitation rates are constructed, and you'd have a reasonable sense of at least what Medicare thinks it's paying, not necessarily what the plan is spending.

EXECUTIVE DIRECTOR SCHWARTZ: If it was Medicare, we wouldn't be having this conversation.

VICE CHAIR GOLD: Well, yeah. Right.

[Laughter.]

VICE CHAIR GOLD: But it may be that the state -- from what we know about states' hospital payment policy and with what some actuaries know about how payments are made, at least maybe the biggest states, you can figure out some things.

COMMISSIONER CERISE: It won't change the argument, though. I mean, I can tell you, even in a big state, it's half, is supplementals.

VICE CHAIR GOLD: Even with the managed care payments?

COMMISSIONER CERISE: Yeah. But I do think building in some more -- better data from the managed care side is going to be important, and to Anne's point, institutional-level data ultimately is going to tell a story too.

CHAIR THOMPSON: All right. Sheldon, do you want to take us out?

COMMISSIONER RETCHIN: Yeah, I'll take us out.

I do want to say that, Rob, this was your finest moment.

[Laughter.]

VICE CHAIR GOLD: You said it twice today.

COMMISSIONER RETCHIN: No, I didn't. I never use that language. Chuck left it open for me.

Just getting back, so we have two different issues going on here. Everybody is recognizing. Just to join Toby and Chuck that there is a federalist issue here

in terms of source of payment. I know everybody that -- I will say I do not believe that the supplemental revenues that are coming into the states for this purpose is unrelated to what we do. The days of using those to build bridges are long since gone, and now -- shedding light and getting transparency on that is fine. I don't think we should change radically the ecology of payment in terms of the supplement.

Just think of it this way. We have 12 million new people who are beneficiaries today as a result of expansion of Medicaid. If that FMAP went from 90 percent down to a state's normal FMAP, those people are gone. There will be a change in the benefits or eligibility or something. Same thing would happen here.

So I think just looking at it is fine. Let's look at it. I'd rather spend our time on the incentives. That's where I think we need to restructure the way the payment incents. In particular, as Bill brought it up, there are a major number of the hospitals who would have admitted these patients because of EMTALA anyway. They don't need the supplemental revenues. But those that are heavy health safety-net systems, to encourage them to

change the way they practice, I think that's where we ought to spend our time.

CHAIR THOMPSON: So I think we have some different points of view around these things and some ideas about where we could take it. It sounds like at the very least, there's some interest in some additional data.

We're going to have the UPL conversation at the next public meeting. I think we should try to digest what we've all heard today, both from Rob and from each other, and pick this conversation back up.

I think, Rob, if you have some of the additional things that people have said, it would be interesting to take a look at.

I certainly agree -- and I think there's a consensus here -- that publishing this information and making it widely available is certainly something that is a contribution that we can make, and so whether it's building on the framework that you have here, building on what we're going to see from the UPL analysis, putting that together with some of the previous stuff that you've shown us on historical information or other things, I think that kind of a brief would be very useful to the Congress, to

stakeholders, to others in our community, and would be a great contribution at least.

All right. Let's go ahead and move on to the next subject, and we are a little behind time. That's okay. We do have some recommendations to vote on that we want to be sure to have an opportunity to do, and we have some public comment that we want to be able to get, so, Erin, no pressure.

CHAIR THOMPSON: Not looking for you to get us back on schedule, so don't think that is the task. But I think we would like to go ahead and kick off your session now.

SUBSTANCE USE DISORDER TREATMENT CONTINUUM OF CARE AND THE IMD EXCLUSION

* MS. McMULLEN: So before I get started, I just wanted to take a minute to --

CHAIR THOMPSON: Can you just go a little closer to the mic?

MS. McMULLEN: Yeah.

CHAIR THOMPSON: Thank you.

MS. McMULLEN: Here we go.

Before I get started, I just wanted to take a

quick minute and thank Nisha Kurani and Nevena Minor, who helped me with this analysis. There's no way I could have reviewed all 51 state plans by myself, so thank you.

The Commission has expressed an interest in identifying gaps in the substance use disorder continuum of care, including residential treatment and how the IMG exclusion impacts coverage.

Staff developed a work plan that was presented to you back in October on using the American Society of Addiction Medicine, known as ASAM, criteria as a guide to identify those gaps in coverage.

The Commission also heard from a panel back in January regarding the role of residential substance use treatment and IMD exclusion.

So today's presentation will focus on seven elements that are outlined at the bottom half of this slide. The information will help the Commission evaluate gaps in the continuum of care and particularly in residential settings and whether the IMD exclusion should be changed.

So, as I said, we did use ASAM to identify gaps in coverage for the reasons that are listed here on this

slide.

Commissioners may recall that back in January, Dr. Olsen presented on the ASAM criteria in greater detail, so I'm not going to summarize all the different levels of care.

She also provided examples of characteristics you would see of an individual who was in need of those residential treatment services.

And there's a few things Commissioners should keep in mind when we talk about using ASAM to classify benefits.

So, first, some states do not use ASAM within their Medicaid programs. So the degree to which they use different terms to describe their benefits can vary a great deal.

So this meant when we were reviewing documents to determine whether certain services were covered, there was not always a clear cross-walk to ASAM. So what we went ahead and did in those situations is we reached out to states directly to determine whether certain services were provided.

This analysis also doesn't talk about medication-

assisted treatment coverage at all or recovery support services, which we're planning on addressing.

The Commission also cautioned against talking about coverage without -- talking about access to SUD. So, on Slide 4, we displayed some results of a MACPAC analysis of SAMHSA's 2016 National Survey of Substance Abuse Treatment Services Data. That dark green bar represents a percentage of providers that offer each level of care, while the lighter bar represents the percentage of providers that offer each level of care and for accepting Medicaid.

So, as you can see, outpatient services are provided by most substance use treatment providers; however, only half of providers accept Medicaid for outpatient treatment.

And then for those higher levels of care, such as partial hospitalization or short-term residential treatment, you can see that only a small percentage of all substance use providers accept Medicaid for those services.

So, on Slide 5, I'm going to begin our discussion of our analysis of coverage of substance use services. In order to document coverage, as I said earlier, we reviewed

publicly available documents. So what you see reported here is inclusive of services that are covered under the state plan but also under approved Section 1115 waivers.

So this chart demonstrates that only 11 states offer all nine discrete services that are defined by ASAM, and roughly half of all states provide between four and seven services.

So the majority of states pay for those three services that are listed out under the first bullet, but gaps did persist in two different levels of care, one being the ASAM Level 2 services, which includes intensive outpatient and partial hospitalization, and then we also saw a gap in coverage for the ASAM Level 3 residential services. So I'll talk about those two in greater detail on the next two slides.

So ASAM defines ASAM Level 3 residential services as having four discrete levels of care, and all of those services are delivered in facilities that are staffed 24 hours a day. So only 18 states provide all of those services, and 12 states don't provide any. In part, that probably has some attribution to the IMD exclusion. The remainder of states, about 40 percent fall somewhere in

between covering anywhere from one to three services.

And there's a few things you should keep in mind when you look at this information. This analysis doesn't account for additional states that might be utilizing the in-lieu of provision in the Managed Care Rule to provide access to IMD levels of care, and I'll discuss that more further along in the presentation, but then also just a reminder not to kind of view these services in a silo, they are part of that broader continuum.

And then in some states, the gaps in services are further pronounced by additional coverage limitations and those ASAM Level 2 services. So there's only 29 states that cover intensive outpatient and partial hospitalization services, and since this level of care is not impacted by the IMD exclusion, it's clear that there's other factors that are influencing state coverage policy.

So when gaps exist at this level and then also at the residential level, states aren't able to offer that seamless continuum that was discussed at our January panel meeting.

So now that I've talked about the different findings from our analysis of state plans and 1115 waivers,

I wanted to transition our discussion to talk about how states are paying for substance use treatment. Generally, that coverage is in the state plan or in 1115 waivers or a combination of the two. However, states have two authorities if they want to pay for those services in IMD settings.

The first one is that in-lieu of provision under the managed care regulations. States can draw down FFP for capitation payments that are made on behalf of enrollees who are a patient in an IMD for less than 15 days in any given month, as long as that care is delivered as an in-lieu of service.

In response to a Kaiser Family Foundation survey, 26 states did say they planned on using the in-lieu of provision to pay for substance use treatment and IMDs, but most states that were surveyed did voice some concern that the 15-day provision was too restrictive.

That concern was echoed by informal interviews MACPAC staff have had with select states. In order to accommodate those individuals who need a stay that's longer than 15 days, states are being forced to reevaluate how they pay for those residential substance use treatment

services.

Some states might seek a Section 1115 waiver to be able to pay for stays that are longer than 15 days, or other Medicaid programs are partnering with their single-state substance use authority to use non-Medicaid funding to pay for those stays that last longer than 15 days.

And then the second pathway to pay for substance use IMD services is through 1115 waivers. States were originally given this authority back in July of 2015. CMS issued guidance saying that if states could demonstrate their residential substance use providers were meeting ASAM criteria, then they could utilize this authority.

Back in November, CMS issues some changes to that guidance. Mainly those changes applied to those provider requirements. Instead of having residential providers meet that level of ASAM criteria up front, states have about two years to get providers up to that level.

There's also some changes in the evaluation and reporting requirements in the 2017 guidance.

So, to date, we've seen 17 states request this authority, and 9 are approved and 8 are pending. For both those approved and pending waivers, the design components,

for demonstrations vary, especially since some states are seeking additional substance use treatment modalities within their waiver.

So West Virginia and Kentucky are actually expanding methadone treatment under their waiver in addition to providing the residential services, and then West Virginia and Massachusetts, just for example, are also providing recovery supports.

There's also some day limits that have been placed on IMD stays through the waiver. Some states don't mention day limits at all. Other states, in their terms and conditions, it says they can only pay for 30-day stays or two 30-day stays or, in some instances, 90-day stays.

So in an ideal environment, the day limits for residential services would reflect what's medically necessary, but state Medicaid officials have various constraints that influence their ability to offer a service, including budget shortfalls.

And then the limitations on residential services is also influenced by a lack of information regarding what a typical length of stay should look like. We heard a little bit about that back in January.

And then we also through our research have -- it's been noted that ASAM also thinks additional research is needed to predict what those typical lengths of stay are.

So I'm going to spend a couple minutes summarizing early results from preliminary waiver evaluations. While there are several states that have been given the authority to pay for these services, only California and Virginia have some preliminary results that have been published. This is because mainly most states are just getting to a place where their demonstrations have been approved or still trying to kind of stand up those demonstrations.

California's waiver was approved in August of 2015, and through the waiver, they do plan on offering a continuum of services based on the ASAM criteria, but the waiver is being implemented in phases, and when the preliminary evaluation was being done, only three counties had started to sign contracts with the state to deliver these services.

So the early evaluation findings are pretty limited, and they were only based on stakeholder interview

surveys and then some non-claims-based data, and there's four bullets listed at the bottom half of this slide. Those are some of the highlights from the evaluation.

Of note, stakeholders did report concern in expanding residential treatment. In part, the up-front cost of setting up a residential treatment program, while awaiting licensure was cited, as well as Medicaid certification processes.

Care transitions were also cited as an issue. Based on some data from their outcomes measurement system, very few people moved from residential settings into a lower level of care within a reasonable time frame.

Since the expansion to residential services was cited as an issue in California, I just wanted to take a minute to discuss access to this level of care. When you heard from Virginia back in January, they advised most residential service providers already existed before they stood up this new benefit. They just weren't contracting with the Medicaid program.

The degree to which those providers actually exist in other states varies, and as you can see on the map, the number of beds per 100,000 adults ranges from 16

in Idaho to 780 in Rhode Island. So there's varying degrees of which these services are already available, and this information was taken from a GAO report that was issued back in August on IMD spending at the state level.

I'm not going to spend a lot of time talking about the results from Virginia, since you just heard about them, just to quickly highlight they did see that increase in substance use service utilization and spending, a decline in those emergency department visits, but that was given with the caveat that this was only five months of data. And total ED visits for all Medicaid members decrease over the same time frame, so they were still parsing through what that meant within their program.

So from a staff perspective, there's a few observations that can be made regarding this information. The Commission may want to discuss some of this in greater detail, including how feasible it is for some states to offer the full continuum and whether they're at the place to utilize an 1115 waiver to pay for treatment and IMDs.

A few factors are listed on this slide that influence a state's ability to offer the full continuum. First, Medicaid programs that already pay for the majority

of services described by ASAM may be a better position to take advantage of this waiver opportunity.

These states are more likely to already pay for some level of residential care that's defined by ASAM under their state plan. As a result, they might have these providers that are already contracting with Medicaid or enrolled with managed care programs. That can reduce some of those administrative burdens that we heard about in California.

Even when there isn't Medicaid coverage for a specific service, states that already pay for certain levels of care through non-Medicaid funding may be well positioned to take advantage of an 1115 waiver. For example, both Massachusetts and Maryland both were providing certain levels of residential care through other state agencies. So they were already working with these providers in some capacity.

And then states that already utilize ASAM criteria may be well poised to expand services under the waiver since they are more capable of meeting those CMS provider requirements.

Although most states do provide the SAMHSA-funded

providers to use ASAM when determining a patient's treatment needs, based on what we heard back in January, it appears that there is additional work that's needed to get providers up to speed and familiarize them with ASAM more. And CMS did acknowledge this by issuing new guidance by allowing that phased-in providing requirement over two years.

So, finally, states are at various stages of implementing a continuum of care. Those gaps are most pronounced at the residential and partial hospitalization levels of care.

ASAM does advise that when that funding is limited just at certain levels, it discourages that seamless continuum that is really a goal that states should try to offer.

Therefore, in states with gaps that span across these service levels, you might see individuals leaving a hospital setting, and they have to step down to maybe traditional outpatient services that might not be supportive enough for their recovery. Maybe they have higher withdraw potential. Those residential services just might not be there.

CMS guidance over the past few years has promoted the full continuum, but states' abilities to take advantage of that varies.

And then, finally, we have incomplete information on outcomes and results of states that are providing that, that full continuum of care, since those 1115 evaluations are largely unavailable at this time.

So thank you. This concludes my presentation, and I look forward to your feedback on this topic.

CHAIR THOMPSON: Okay. Thank you very much. I appreciate your responsiveness to the continued interest of the Commission in this subject and continue to explore different corners of it.

Let me ask Kit to start us off.

COMMISSIONER GORTON: So I agree this is important work, and we need to plug away at trying to figure it out.

I think in contrast to the last conversation where we were looking at 50 years of accreted policy, it's important -- and for those who were not here for the January panel discussion, it's important to understand that the ASAM guidelines and criteria are an academic proposal,

a hypothesis for how the optimal delivery system should work. And when we asked them whether the full array had been put in place in any geography in the country for any period of time that could be evaluated, the silence was resounding. So this is a grand experiment.

Now, we need to offer people who need these services something, and so this is as good a way to do it as any, but we just need to be cautious as we think about this. As these things roll out, we may find that the continuum as it exists as a blueprint today may need to be radically changed. The continuum may not be right. It may not go far enough in one direction or in the other, and we certainly have no idea in terms of the density of how many of which kind of things that we need.

So Erin has pointed out the way things sort of sloped down. We don't know whether that's good, bad, or indifferent, and so this exercise, this national experiment is going to help us figure that out.

But this is a long-term project, and we're going to learn an awful lot. So it's important that people not draw conclusions that just because this is how it exists today, it's good, bad, or otherwise.

I mean, arguably, there should be some intermediate level of care available for people between inpatient and outpatient. That just makes sense, given the way we know people's brains work. But whether the four Level 3 standards, levels of care are the right four, nobody knows. So I want to make that point.

The second point, there's a big caveat with what Erin has just shared with us, which is the -- we're talking about adults. All of these services, to the extent they're medically necessary, are covered under EPSDT for children, and states and health plans have been for a long time doing side agreements and other things in order to get intensive outpatient and partial and other things, not uncommon for states to send kids to other states if they don't have a child or adolescent program in their own state. So that goes on.

It's only the most needy and visible of kids who get those services, and so there's an unevenness there, but important to understand that children have a different level of access than adults may have.

Then the third thing is as -- and we talked about this some with the panel -- a state may have the services.

They may cover it. They may have a certain number of providers, but if in the state of New York, the bulk of those providers are in the five boroughs of the City of New York, if in Texas, those providers are all in Houston and Dallas and Austin, but they're not anywhere else in God's country, then even though a state might have certain numbers, the geographic dispersion of it may not be okay because particularly as you get to the lower ends of the continuum, lower levels of intensity, those need to be community-based services in people's home communities. And if they have to travel hours in order to get to those services, then even the fact that they're available in the state and they're accessible in the state do not make them accessible to those individuals and their families.

So I do think that as we watch this going forward, we're going to have to get a lot more granular in terms of looking at access and in terms of time and distance, and a question that I don't think anybody has addressed yet is, is there a role for telepsychiatry, tele-behavioral health in addressing some of those gaps? Can you do intensive outpatient remotely? I don't know. It would feel like you can't do partial remotely, but maybe

you can. People haven't thought about that.

So, anyway, just a whole bunch of cautions to us that this is very, very much a work in progress.

CHAIR THOMPSON: Brian.

COMMISSIONER BURWELL: At our last meeting, I think the Commission made a fairly strong statement that we wanted to have another chapter on SUD in the June report, but I personally am kind of rethinking that at this point in terms of do we have enough new information to present in a separate chapter.

To me, this work is a very good step forward about to what extent are states implementing the ASAM criteria, so only part of the question. But what we really want to talk about is what has the state response been to developing a comprehensive delivery system for people with opioid addiction.

The ASAM criteria thing is just part of it. I agree with Kit. Just the fact that a state covers these services doesn't mean they're accessible to everybody in the state, and I've seen a number of presentations by states that shows where their providers are versus where their overdoses are. I mean, it's like they have a huge

rate of overdoses in the rural areas, and there are no providers there.

The third thing is around a number of states trying to expand access to medication-assisted treatment. I don't think we can have this conversation without bringing in MAT into the conversation.

So I kind of feel like we need to develop our data more fully before we can really talk about access, comprehensive access to services.

CHAIR THOMPSON: I think that when we have been talking about this over time, it's been about recognizing that we will continue to develop our thinking on this, and that if we don't have a June chapter, we can always do something in the fall instead of that. We can have a June chapter with additional information following that in the fall.

Obviously, we need to continue to test whether or not we think we have a sufficient basis to talk about things, but the ASAM criteria is really our reference point for how to organize a discussion about the delivery system.

But I agree that's the question, which is do we have an adequate delivery system, so part of that is do we

have all the levels and settings covered that need to be covered in order to provide care based on people's needs.

And then the other is, is there a sufficient number of those providers in the right places, also picking up Kit's point and one that Martha has made before about the necessity of people to maintain employment and maintain daily life in addition to being able to see some of our -- receive these kinds of treatments?

So I think we need to begin to put it together. We talked about specifically wanting a discussion about where we stood with the IMD exclusion and how states were pursuing that. So I think we have a little bit of information here about that, but we're early stages with both states seeking those waivers, receiving them, and actually implementing them. By necessity, we'll have less to say on that score.

I was actually interested in the states that are not pursuing IMD. So on the one hand, we have 17 states that are seeking or have received, so that leaves the majority of states without any kind of pathway to an 1115 waiver for IMDs, and so I'm wondering what makes the difference between the states that are seeking the IMD

exclusion and the states that are not seeking the IMD exclusion and whether or not we have any particular insights to share on that score, Erin.

MS. McMULLEN: Yeah. So in our conversations with a few states, some of them felt like they were better poised when that guidance came out in 2015 to seek that waiver because they already offered a robust continuum of care. They were already covering certain residential services through Medicaid or the single state substance use authority was paying for those discrete levels of care using grant funds.

So those states were kind of already a little ahead of the game. They were used to working with those providers, and it was easier for them to come up with the rates, do the waiver application, enroll the providers, and really go ahead and expand that service.

I think that states that aren't going after this don't have as robust of coverage, and I think that kind of puts them behind the eight-ball when they want to see this type of waiver. And if you kind of layer on top of that, that there's not a -- they're not using any sort of -- you know, whether it's ASAM or it's something else, if they're

not using any sort of criteria, I think that's another -- just another hurdle that they kind of have to jump over before they can start providing those services.

COMMISSIONER BURWELL: Was it also true that -- I mean, states had a number of residential beds funded under non-Medicaid sources of funding and thought that while there was an opportunity to get federal match on a good number of those beds, the conditions under which they had to go -- the hoops they had to go through in order to do that were not worth the additional financing that would come through an 1115.

MS. McMULLEN: I think it probably depends on the state.

COMMISSIONER BURWELL: But that was part of the thinking of some of the states.

MS. McMULLEN: Yeah. There's definitely other states that are paying for these services using grant funds or non-Medicaid funds that haven't sought a waiver.

CHAIR THOMPSON: I've got Martha and then Marsha.

COMMISSIONER CARTER: Some random thoughts, I think. To Kit's point, I know of several treatment modalities that aren't really reflected in the ASAM levels

because, as I said earlier, people are innovating on the fly constantly. Residential peer-supported recovery would be one. Non-hospital care for drug-addicted infants is another.

So I think the ASAM -- you've got to pin it on something, but we also have to recognize that the landscape is just changing constantly. So I'm not sure what to do with that, but I just want to bring that up.

We don't want to just evaluate based on these criteria because there's stuff that just doesn't fit. So what do you do with that?

Anyhow, the other point is I think that there's so much focus on the opioid epidemic that we missed some of the other levels of addiction or types of addiction, and I was just talking with a hospital administrator of a small private hospital that was having trouble getting paid for patients with meth addiction. So there isn't as clear criteria. There is an MAT for meth addiction, but we're seeing a resurgence. So where does that fit into all of this?

And I think it really comes down to are the needs of the people being met, not whether the state is

fulfilling all the levels of the criteria.

CHAIR THOMPSON: Marsha.

VICE CHAIR GOLD: Yeah. My comment is a little on that line, but maybe following up where Brian is going.

I'm sort of a little confused with whether we've almost created a tautology. We're looking at what Medicaid pays for versus what the patient needs or can get, and if you remember, the whole point of the IMD exclusion, I think, was that states were doing this, and the federal government didn't want to substitute Medicaid money for what the states are doing.

So I'm not saying that's always right, and I know financing for substance abuse is a big issue and a limitation, but if we're evaluating by whether Medicaid is just paying for it, I don't know how it relates to that original rationale for the IMD exclusion. And if -- and it's a big "if" -- if the Medicaid beneficiary could still get the service and the service was being paid for, because the state did another way and it was coordinated with what Medicaid did, I don't know that that would be a bad thing to happen.

I know there's a lot of ifs there, but it's sort

of -- in putting together a few of the comments that other people are saying, it's sort of like more we can go back and sort of use this framework, but then put the patient in there and the access criteria as to whether people are actually getting to use the services they need and the services are getting paid for some reasonable way may help us, because otherwise you just have to say -- you're almost by definition saying the IMD exclusion is a barrier to care, and it may be. But we need to know if that is or isn't.

CHAIR THOMPSON: Any other comments on this?

Chuck, I'm glad you're back. There was a question, as you were gone, about whether or not -- and this might be something you have a view on -- whether or not what we have here, with this commentary and some adjustments perhaps to better focus and acknowledge on the ASAM criteria as a reference point just to kind of organize some of the material and so forth, whether it's sufficient for June chapter and just whether you had any thoughts on that point.

COMMISSIONER MILLIGAN: Thanks. And I'm sorry I missed a lot of it, Erin. I had to take care of a work

call.

Personally, I think it warrants being part of the June report. I do think that given the activity at CMS with some of the 1115 waiver parameters around IMD exclusion and some of the changes that were made by CMS in November and some of the activity at the state level, I think it's timely, and I think we should make a contribution.

CHAIR THOMPSON: I think a number of the points that have been made here in addition to what we've discussed previously and in conversation with panels that you've arranged for us to hear from really focus on how much is changing, how much is unknown about what's effective treatment, where it takes place, how to build the provider capacity.

That challenges all of us in terms of how we're thinking about these things. It creates to my mind some particular challenges, given some of our continuing conversation about how well positioned we are to collect data and evaluate is and use that to make proper adjustments as well as potentially in where to help guide states to make investments and potentially in the

possibility for challenges associated with the integrity of the program and the benefit when it is fuzzy in terms of who gets what, where.

So I think we just need to -- I think we just got to continue swinging at this issue, continue to build the evidence base and the information that we're making available to people.

I really do think we should aim for a June chapter, but I also think we should continue to iterate on that in the fall, in the winter, next spring.

COMMISSIONER BURWELL: If we go ahead with the June chapter, I do think that we need to at least acknowledge or mention, say something about states expanding access to medication-assisted treatment and how that relates to the ASAM criteria, and my understanding is that there's just an overlay on all levels of care because I just don't think that we should do a chapter without mentioning that.

MS. McMULLEN: So back in October when we first presented this work plan, we did not choose to look at medication-assisted treatment when we did this because SAMHSA is undertaking an update of something they issued a

few years ago that laid out coverage of medication-assisted treatment at the state level within the Medicaid program. So we're kind of awaiting the publication of that, which if it does come out in time could be incorporated into a June chapter. But we could definitely just acknowledge the fact that there's some other medication-assisted treatment work out there that we can reference on how many states are covering buprenorphine or methadone or those types of things.

And then another thing I heard was about the recovery supports, the peer support, those things that don't fall in with the clinical levels of care. That's kind of the next phase of our planned work. We're planning on looking at that with the help of a contractor over the summer, so that can be something that we mention in the chapter, that we're kind of looking ahead to continue doing.

CHAIR THOMPSON: Okay. Let me pause and ask for any public comments on any of our discussions earlier today or this afternoon in particular and in advance of taking votes on recommendations that are coming up, as we discussed this morning.

PUBLIC COMMENT

* MR. BARTON: Hi. I'm Corey. Again, I'm from ASAM.

I just wanted to state that we're pleased that MACPAC is looking at the ASAM criteria to identify gaps because it's really important.

So we recognize that conducting a standardized assessment using the ASAM criteria to identify what patients need and, in many cases, what the assessment identifies may be in some cases unavailable to patients.

The inabilities of properly matched patients to a level of care they need results in worse outcomes.

The other gap associated with the ASAM criteria is ensuring the program to which the patient is sent is delivering the services that the ASAM criteria recommends for that level, ensuring that a third-party verification is critical to making this possible.

ASAM is beginning work on a certification program to help close this gap. ASAM would love to work with MACPAC to be a resource as it looks at these gaps based on the ASAM criteria.

Thank you.

CHAIR THOMPSON: Thank you very much.

MR. DZIENGELSKI: I'm Scott Dziengelski from the National Association of Psychiatric Health Systems.

[Laughter.]

MR. DZIENGELSKI: I'll just lean down.

CHAIR THOMPSON: Do what you can.

MR. DZIENGELSKI: One thing on the origins of the IMD and how it relates to substance abuse treatment, I think one of the issues at the advent of the IMD exclusion was the idea that substance abuse came from a personal flaw as opposed to a disease, and I think that the understanding of that has very much shifted to the facts in the science that this is a disease of the brain and therefore is a medical condition and should be treated as such.

I think there was a lot more ambiguity about that in the development of the IMD, which has been very much cleared up on the science side now, so just something to sort of keep in mind when you're talking about -- maybe a lot of things have changed in terms of the efficacy of that policy.

CHAIR THOMPSON: Thank you.

Okay. SO I know we're running behind time, but I

want to be sure all the Commissioners are actually present and in their seats when we take recommendations, and not everybody has necessarily had a chance to step out into the hallway, if they need to.

So I'm going to ask for just a very quick break, as much as possible, five minutes, to come back, get back on target, and take up our recommendations.

* [Recess.]

CHAIR THOMPSON: Okay. All right. We are back, and now we are going to take back up recommendations as have been adjusted by the commentary this morning for the Commissioners to vote on with respect to the Medicaid drug rebate program.

So, Chris, can you show us what you've done.

IMPROVING OPERATIONS OF THE MEDICAID DRUG REBATE PROGRAM: VOTE ON RECOMMENDATIONS TO BE INCLUDED IN JUNE REPORT

* MR. PARK: Sure. Okay. So reflecting comments from this morning's session, we have withdrawn Recommendation 3, which related to sharing the line extension rebates with the states. We still have the first two recommendations remaining.

Draft Recommendation 1, the language has not changed from what we had presented earlier this morning. It reads: "To ensure that manufacturer rebates are based on the price of the drug available to wholesalers and pharmacies, Congress should remove the statutory requirement in Section 1927(k)(1)(c) that manufacturers blend the average manufacturer price of a brand drug and its authorized generic." Again, this has not changed from this morning.

Draft Recommendation 2 has changed based on the commentary from the Commission, and it has now been revised to read: "Congress should give the Secretary of Health and Human Services the authority to level intermediate financial sanctions to compel drug manufacturers to submit accurate drug classification data and strengthen enforcement actions. These authorities can include clear authority to reclassify an inappropriately classified drug and to level civil monetary penalties for the submission of inaccurate drug classification data."

CHAIR THOMPSON: Thank you, Chris.

Can we put up 1 and 2 at the same time, or no?

MR. PARK: Yes.

CHAIR THOMPSON: Okay. All right. Thank you.

So I think based on the conversation this morning, while we had some questions about Recommendation 1, we didn't really have any suggestions to give you on the changes in the wording of that recommendation, right?

MR. PARK: That's correct.

CHAIR THOMPSON: And on Recommendation 2, I think you've captured the conversation, which was, first of all, that we were interested in financial penalties or financial actions, related actions, rather than actions that might impede beneficiary access to drugs, and that we also wanted to both think about the ways in which CMS -- or where the HHS presumably through CMS would take actions to reclassify as well as to assess some penalties for inappropriate submission.

So I think that you've captured all of the commentary that we had this morning.

So let me just invite any Commissioners who want to have any -- make any points or comments on any of this before we get ready to take a vote.

[No response.]

CHAIR THOMPSON: Okay. All right. So seeing

none, first of all, I just want to be clear. Before we open up for the vote, we did have a meeting of the Conflict of Interest Committee with respect to recommendations that might be made by the Commission relating to prescription drugs, and we met by conference call on January 19th and determined that no Commissioner had a reportable interest that would be particularly, directly, predictably, and significantly affected by the outcome of the recommendation vote.

All right. And with that, I'll turn it over to Anne.

EXECUTIVE DIRECTOR SCHWARTZ: Okay. So this is the vote on Recommendation 1 for the chapter improving operations with the Medicaid drug rebate program.

Brian Burwell?

COMMISSIONER BURWELL: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Martha Carter?

COMMISSIONER CARTER: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Fred Cerise?

COMMISSIONER CERISE: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Gustavo Cruz?

COMMISSIONER CRUZ: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Kisha Davis?

COMMISSIONER DAVIS: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Toby Douglas?

COMMISSIONER DOUGLAS: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Leanna George?

COMMISSIONER GEORGE: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Marsha Gold?

VICE CHAIR GOLD: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Darin Gordon had to leave, so I will mark him as not present.

Kit Gorton?

COMMISSIONER GORTON: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Stacey Lampkin?

COMMISSIONER LAMPKIN: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Chuck Milligan?

COMMISSIONER MILLIGAN: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Sheldon Retchin?

COMMISSIONER RETCHIN: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Bill Scanlon?

COMMISSIONER SCANLON: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Peter Szilagyi?

COMMISSIONER SZILAGYI: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: And Alan has not been with us today, so I'll mark him as not present.

And Penny Thompson?

CHAIR THOMPSON: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Okay. So that's 15 voting yes and 2 not present.

Okay. So then I'll call the roll again for the second recommendation, as on the screen there.

Brian Burwell?

COMMISSIONER BURWELL: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Martha Carter?

COMMISSIONER CARTER: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Fred Cerise?

COMMISSIONER CERISE: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Gustavo Cruz?

COMMISSIONER CRUZ: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Kisha Davis?

COMMISSIONER DAVIS: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Toby Douglas?

COMMISSIONER DOUGLAS: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Leanna George?

COMMISSIONER GEORGE: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Marsha Gold?

VICE CHAIR GOLD: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Darin Gordon is being marked as not present.

Kit Gorton?

COMMISSIONER GORTON: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Stacey Lampkin?

COMMISSIONER LAMPKIN: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Chuck Milligan?

COMMISSIONER MILLIGAN: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Sheldon Retchin?

COMMISSIONER RETCHIN: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Bill Scanlon?

COMMISSIONER SCANLON: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Peter Szilagyi?

COMMISSIONER SZILAGYI: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: And Alan Weill marked as not present.

And Penny Thompson?

CHAIR THOMPSON: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Okay. Again, 15 yes and 2 not present.

CHAIR THOMPSON: Great. All right. Thank you, Chris. Thank you, Rick.

We'll now turn to our second batch of recommendations with Erin and Nevena relating to substance use disorder confidentiality regulations and care integration.

And, again, we had a robust discussion this morning that suggested that there could be some changes in the recommendation, that asked for some changes in the recommendations before voting.

So, Nevena, are you going to kick us off on those changes?

SUBSTANCE USE DISORDER CONFIDENTIALITY REGULATIONS AND CARE INTEGRATION IN MEDICAID PRIVACY: VOTE ON RECOMMENDATIONS TO BE INCLUDED IN JUNE REPORT

* MS. MINOR: Sure.

So based on your comments an updated draft recommendation is that: “The Secretary of Health and Human Services should direct relevant agencies to issue joint subregulatory guidance that addresses Medicaid and CHIP provider and plan needs for clarification of 42 CFR Part 2

provision."

So based on your discussion this morning, we took out the specific mentions of some of the agencies because we didn't want it to be an exclusive list. We wanted to make sure that it is inclusive of all the different agencies within HHS that are touched by this that should participate in this.

You all mentioned the Office for Civil Rights. So this is something that we could elaborate on as, for example, in the rationale.

We also added the mention of CHIP as well since it's not just a Medicaid program. It also applies to CHIP as well and is within the purview of this Commission.

And then in terms of -- we took out the language that specifically called out some of the key concepts, and we're moving that into the rationale, again, trying to be more expansive related to what the guidance may or may not cover and really highlighting that this is about trying to issue guidance that helps clarify some of the issues for the providers and plans in the service of promoting information sharing within the current confines, and that this isn't just a compliance exercise, but this is about

being responsive to the needs of providers and plans who are trying to deliver coordinated care to their patients with SUDs.

And then the second recommendation now reads: "The Secretary should direct a coordinated effort by relevant agencies to provide education and technical assistance on 42 CFR Part 2. Such efforts should target state Medicaid and CHIP programs, health plans, primary care and specialty providers, patients and their families, and other relevant stakeholders." And in there, we again added mention of CHIP, took out the -- calling out specific agencies. Again, this will be discussed in the rationale where we talk about SAMHSA, CMS, ONC, OCR, as well as anybody else that is relevant to communicating with Medicaid and CHIP stakeholders.

And we also took out mention to promote compliance because it should not just be strictly about having more compliance processes in place. It is really about trying to promote information sharing within the current confines until whether or not things down the road -- whether or not there's other additional regulatory or statutory changes.

CHAIR THOMPSON: Can we go ahead and put both of them up there, then, at the same time?

So I like how in both now, these recommendations, we're kind of putting the Medicaid provider and plan front and center as it's meeting their needs, addressing their questions, helping them do their work. I think it's very useful to put the conversation about the methods, the means, the who, the how, all of that underneath these recommendations, just to try to keep that clean because the Secretary may want to pull in a number of different STAFFDIVs as well as OPDIVs to this conversation. There's a number of different things that I think we can promote as avenues by which the regulatory guidance is developed, who gets consulted in the process of that development, what are the ways in which some of the information can get disseminated, who the partners are in those efforts, those kinds of things. I think how to prioritize the issues that people are most interested in hearing about. I think all of that can be information that we provide underneath these recommendations and doesn't have to be part and parcel of the recommendation itself. So I like what you've done there.

Okay. Comments? Questions? Points, opinions relating to the draft language here?

Kisha.

COMMISSIONER DAVIS: I'm in favor of the recommendations, but I do just want to continue to go back to the point of trying to create alignment between HIPAA and Part 2, and that we as a Commission continue to look at that issue, and that it comes back to us in the future.

CHAIR THOMPSON: Yes. And that will be an adjustment that we will make in the chapter itself to sort of point in the direction of the Commission's interest in that subject and desire to continue those conversations.

Chuck.

COMMISSIONER MILLIGAN: I agree with Kisha, and I want to acknowledge that I also, just for purposes of the chapter, Nevena and Erin, I think the public comments that we took after we last had a conversation, I think were very useful. So I just want to encourage you to capture the public comments around, for example, what the NGA is going, what potential legislation has been introduced as part of the context. So I would encourage you to do that as part of the narrative around this discussion.

Penny, when you say STAFFDIVs and OPDIVs, that may need definition for people who are not former CMS-ers.

CHAIR THOMPSON: Yes.

[Laughter.]

CHAIR THOMPSON: Lots of people.

Okay. Any --

EXECUTIVE DIRECTOR SCHWARTZ: She's not going to do it.

CHAIR THOMPSON: Oh, you mean now.

[Laughter.]

CHAIR THOMPSON: Sorry. I thought you meant -- no. Operating divisions or staff divisions, so like if Assistant Secretary for Planning and Evaluation, that's a staff division versus CMS, which is an operating division, so yeah.

So just to say there are people with direct line responsibility who would be convened naturally, but also other people who have staff-level responsibilities who might also want to come into that conversation. We would not want to dictate how the Secretary organizes his team to respond to this.

COMMISSIONER MILLIGAN: My personal acronym

definition is now complete for my lifetime. Thank you, Penny.

[Laughter.]

CHAIR THOMPSON: Okay. Any other comments?

[No response.]

CHAIR THOMPSON: All right. So we will be ready to take votes on this recommendation, and the Conflict of Interest Committee met with respect to recommendations that the Commission might consider on the Part 2 regulations and convened virtually via email on January 29th and determined that no Commissioner had a reportable interest that would be particularly, directly, predictably, and significantly affected by the outcome of the recommendation vote.

All right. Anne.

EXECUTIVE DIRECTOR SCHWARTZ: Okay. So the first one will be on Recommendation 1 on issuing joint subregulatory guidance.

Brian Burwell?

COMMISSIONER BURWELL: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: You're always going to be first, Brian, so --

COMMISSIONER BURWELL: It's the only place I'm

first.

[Laughter.]

EXECUTIVE DIRECTOR SCHWARTZ: Martha Carter?

COMMISSIONER CARTER: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Fred Cerise?

COMMISSIONER CERISE: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Gustavo Cruz?

COMMISSIONER CRUZ: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Kisha Davis?

COMMISSIONER DAVIS: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Toby Douglas?

COMMISSIONER DOUGLAS: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Leanna George?

COMMISSIONER GEORGE: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Marsha Gold?

VICE CHAIR GOLD: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Darin Gordon, I will mark as not present.

Kit Gorton?

COMMISSIONER GORTON: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Stacey Lampkin?

COMMISSIONER LAMPKIN: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Chuck Milligan?

COMMISSIONER MILLIGAN: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Sheldon Retchin?

COMMISSIONER RETCHIN: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Bill Scanlon?

COMMISSIONER SCANLON: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Peter Szilagyi?

COMMISSIONER SZILAGYI: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Alan Weil, I'm marking as not present.

And Penny Thompson?

CHAIR THOMPSON: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Okay. Fifteen, yes; and two, not present.

And then on the second recommendation, on the coordinated effort for education and technical assistance.

Brian Burwell?

COMMISSIONER BURWELL: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Martha Carter?

COMMISSIONER CARTER: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Fred Cerise?

COMMISSIONER CERISE: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Gustavo Cruz?

COMMISSIONER CRUZ: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Kisha Davis?

COMMISSIONER DAVIS: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Toby Douglas?

COMMISSIONER DOUGLAS: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Leanna George?

COMMISSIONER GEORGE: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Marsha Gold?

VICE CHAIR GOLD: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: I'm marking Darin Gordon as not present.

Kit Gorton?

COMMISSIONER GORTON: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Stacey Lampkin?

COMMISSIONER LAMPKIN: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Chuck Milligan?

COMMISSIONER MILLIGAN: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Sheldon Retchin?

COMMISSIONER RETCHIN: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Bill Scanlon?

COMMISSIONER SCANLON: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Peter Szilagyi?

COMMISSIONER SZILAGYI: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Alan Weil, I'm marking as not present.

Penny Thompson?

CHAIR THOMPSON: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Okay. And again, 15 voting yes, and 2 not present.

CHAIR THOMPSON: Okay. Thank you both. Much appreciated.

Last opportunity for public comment on today's proceedings?

PUBLIC COMMENT

* [No response.]

CHAIR THOMPSON: Okay. I'm going to ask the Commissioners to stay put to handle a couple of logistics, things that we need to talk about, and otherwise adjourn for our public meeting. Thank you.

* [Whereupon, at 3:55 p.m., the meeting was adjourned.]