PUBLIC MEETING

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

Thursday, December 14, 2017
9:06 a.m.

COMMISSIONERS PRESENT:

PENNY THOMPSON, MPA, Chair
MARSHA GOLD, ScD, Vice Chair
BRIAN BURWELL
MARTHA CARTER, DHSc, MBA, APRN, CNM
FRED CERISE, MD, MPH
KISHA DAVIS, MD, MPH
TOBY DOUGLAS, MPP, MPH
LEANNA GEORGE
DARIN GORDON
CHRISTOPHER GORTON, MD, MHSA
STACEY LAMPKIN, FSA, MAAA, MPA
CHARLES MILLIGAN, JD, MPH
SHELDON RETCHIN, MD, MSPH
WILLIAM SCANLON, PhD
PETER SZILAGYI, MD, MPH
ALAN WEIL, JD, MPP

ANNE L. SCHWARTZ, PhD, Executive Director

AGENDA PAGE

P R O C E E D I N G S

[9:06 a.m.]

CHAIR THOMPSON: Okay. Why don't we go ahead and get started. And first up is Joanne Jee. We have an update on CHIP.

UPDATE ON CHIP

* MS. JEE: Okay. So this is a very brief update on CHIP, just to let you all know, Commissioners, sort of where things are, what the state of play is today.

Since the last time you all met in October, there have been a couple of things that have occurred, small things that have occurred -- don't get your hopes up -- and the first thing, of course, is the continuing resolution. I guess I should say at the outset CHIP funding has not been renewed yet. But there was the continuing resolution that funds the federal government through December 22nd. It was thought at the time that there might be some language renewing CHIP funding associated with the CR, but there was not.

Instead, the CR made a change to the way in which the CHIP redistribution funds are provided to states in that they identify the group of states that they're calling

-- what are they calling them? -- "priority states" or "emergency shortfall states," and those are states that are going to run out of their funds in the first quarter of the fiscal year. And, basically, it directs the Secretary to provide those states redistribution funds in the amount of their shortfall rather than the current law rule which requires the Secretary to provide redistribution funds in a pro-rated fashion because the amount of total redistribution funds is not enough to cover the total national shortfall. So it is a small change to how the redistribution funds are made. CMS I think has yet to act on, you know, implementing that, so I don't have any real details yet on how that will work. So that was what was in the CR.

Before the CR, sort of going backwards, on November 9th CMS did issue an informational bulletin, and in that informational bulletin, CMS laid out some guidance and some information to states on the specific steps they would need to take with respect to both separate CHIP and Medicaid expansion CHIP programs in the event that CHIP funding is not renewed. So it sort of puts it all into one place a lot of the things that we've been talking about, as

well as things that you've seen probably in the press.

The guidance also explained how states could access the redistribution funds as well, and there's a copy of that guidance in your meeting materials.

And, lastly, and importantly, states are beginning to act. We talked a lot about states' planning in previous meetings. You may have heard that some states are starting to send out notification letters to their families. Colorado is an example. Virginia is another example. I understand that those letters basically just let families know that their CHIP coverage might end and the CHIP program in their state might end if the federal government -- sorry, if the federal CHIP funding is not renewed, but that there is no change sort of in this immediate moment. They are very clear on that point.

Other states are planning on and getting ready to send termination notices to families, so that is another step that states are starting to take. They haven't sent them yet, but I understand that they're planning on that.

Other states are still looking for ways to fund their program and to sort of make up for the lack of federal funding. D.C. is an example, Arizona is an example

of states that are looking to do that, and there are a couple different ways, I think, that states are looking for that.

Kansas I understand plans to transition its program from a separate CHIP to a Medicaid expansion CHIP, which, of course, means that they can continue to draw a federal match just at the Medicaid rate.

Oh, and I should mention that House appropriators released a draft of the next CR, which would fund the federal government through January 19th of 2018, and that draft CR includes the House-passed CHIP funding renewal bill with the five-year renewal of CHIP and sort of the ramp-down of the match and keeping the MOE, the current law MOE. So, you know, that has yet to play out, and the draft was just released kind of late last night. So that's what we know.

CHAIR THOMPSON: Joanne, can I ask a question about the CR and this emergency shortfall designation? Obviously, we're still working with the same pot of money, so we're solving the problem for the states that are at most urgent need of additional help, but we're also potentially then, depending on how much money we are giving

them that we wouldn't have given them under the prior formula, accelerating other states' exhaustion of funds. Is that correct?

MS. JEE: That's how we understand the language. But like I said, you know, we haven't had yet a chance to connect with CMS for sort of the details on how that will work. But it does seem that it does accelerate the spending, and we're not really sure sort of what happens for the states that are later, that are more in sort of like that spring-ish time frame for exhausting funds.

CHAIR THOMPSON: Right. Okay. I'm just acknowledging that, given the fact that one of the things that we've been concerned about is how states plan and whether states have time and if they've been sort of looking ahead on the basis that they would exhaust their funds at a certain future date, and now potentially that date has moved up on them. They're going to have to make some of those adjustments if the permanent funding doesn't come through.

Kit?

COMMISSIONER GORTON: So another question about the new draft CR, which is not about CHIP per se, but is

there anything in the new draft about the National Health Service Corps or Federally Qualified Health Centers? Or is that funding still not authorized yet?

MS. JEE: So I have to admit that I didn't read it word for word, but I do believe --

EXECUTIVE DIRECTOR SCHWARTZ: Yeah, I think the House bill that Rules passed last night had community health centers, National Health Service Corps, delay of the DSH cuts, and, you know, several other things along that line. So we'll see what the next step is.

COMMISSIONER GORTON: Thank you.

CHAIR THOMPSON: Any other questions from the Commissioners on the status of CHIP? Of course, we continue to hope for permanent reauthorization or the five-year reauthorization.

Okay. Thank you, Joanne.

Next we're going to have a session on State Strategies for Managing Prescription Drug Spending, and we have a group of three panelists that we are very excited to hear from, and they will be introduced to us by Rick Van Buren.

STATE STRATEGIES FOR MANAGING PRESCRIPTION DRUG

SPENDING

* MR. VAN BUREN: Good morning. So we will now have a panel to discuss, as Penny said, state strategies for managing prescription drug spending. The panel builds on the discussion of Medicaid drug spending from the September Commission meeting. It's the first of two drug presentations at today's meeting.

During the September session, staff presented on a range of potential policy options that could reduce Medicaid spending on prescription drugs. At the end of the session, Commissioners expressed interest in both learning more about the leverage states currently have within the existing structure of the program and further developing our analysis of some of the more technical changes to the rebate program for consideration.

This panel will provide information on the first of those issues and will focus on tools states currently use to manage utilization and spending, including preferred drug lists and supplemental rebate agreements.

Our first panelist will be Dr. Renee Williams. Renee is the director of clinical pharmacy services for the Tennessee Medicaid program, TennCare. Dr. Williams earned

her degree as a Doctor of Pharmacy from St Louis College and maintains a license to practice pharmacy in Missouri and Tennessee. She has over 10 years' experience managing prescription drug formularies for commercial and government payers.

Our next panelist will be Doug Brown, who is the vice president of account management, pharmacy pricing, and value-based solutions for the Medicaid Division at Magellan Rx. He has strategic and operational responsibility for both of Magellan Rx's multistate purchasing pools. He earned a Master of Business Administration from Virginia Commonwealth University and has a Bachelor of Science degree in pharmacy from the University of Rhode Island. He is also a registered pharmacist.

And, finally, we'll hear from Dr. John Coster, who is the director of the Division of Pharmacy at the Center for Medicaid and CHIP Services, which is a component of CMS. He is responsible for policy and operational issues related to the Medicaid Pharmacy and Prescription Drug Rebate Program. He holds Master's and doctoral degrees in health policy from the University of Maryland Graduate School and a Bachelor's degree in pharmacy from St

John's University. Prior to CMS, he served in various government affairs position with safety net hospitals and pharmacy professional associations.

And, with that, I will turn it over to Dr. Williams.

* DR. WILLIAMS: Thank you, Rick. I just want to say I do appreciate the opportunity to come and represent my state and our program, which I am very proud of, and how we manage our formulary, and then also real quickly I want to acknowledge our former Medicaid director, Darin Gordon. Good to see you. And, with that, I'll go ahead and begin.

Today we will take a look at how our state uses the tools to manage our formulary and how we leverage our plan design in order to improve the value that we receive from our pharmacy benefits management benefit, and then also the impact of formulary management on the various stakeholders throughout the state.

Here you'll see it's just a quick snapshot of TennCare and the plan and the number of members that we serve in our state. Right now our eligibility is topping out at about 1.4 million members, and that is about 20 percent of our state's population. And we actually do

cover and pay for 53 percent of the state's births.

Again, just a quick overview of how we spend those funds and how we manage our budget. Our annual budget hinges in at around $11 billion a year, and of that, approximately 75 percent of that is related to clinical services.

I say all that to bring you a high-level review of our plan design, and we currently have three managed care organizations, including AmeriGroup, Blue Cross Blue Shield, and United Health Services. But our pharmacy benefit for outpatient therapy is 100 percent carved out and is managed closely by the state in partnership with our Pharmacy Advisory Committee and our pharmacy benefits manager.

Just real quickly, a high-level overview of our net spend for the pharmacy budget, and we net out at about $400 million a year, and that's after rebates and incentives on the pharmacy spend. In addition to that, of the percent of utilizers within the state, we did mention that we have 1.4 million members, but about 26 percent of members use the pharmacy benefit on average per month.

Another thing to point out within the utilization

of those services is the relationship between pharmacy reimbursement costs -- and that's without the rebate taken into account -- and the net cost to the state. And if you'll look at the slide here, the blue line represents that pharmacy reimbursement cost. It's nothing unexpected that cost continues to rise year after year, but essentially we use our tools to keep the green line that you see below, our net spend relatively stable.

And the question becomes: How do we do that? I mentioned our plan design and our close relationship with our pharmacy benefits manager, but one of the things that is simple and makes sense to us but is sometimes overlooked is the fact that we use our PBM and leverage their capability quite well. They manage our PDLs, our formulary and preferred drug. They manage our clinical criteria. They manage our point-of-sale edits at the pharmacy level. And they also manage our rebate program. And so it has been a very nice concert of events that helps us to maintain that cost that you saw there, that net cost and flat line.

Our preferred drug list is divided into, of course, class of drug but also preferred and non-preferred

status, and it was essentially created to promote clinically appropriate utilization of pharmaceuticals in a cost-effective manner. And we do that for many reasons, but one of which -- and many of you may know this already. Tennessee was one of the first states to actually adopt managed care, and it was a pretty choppy time, and we've taken that opportunity to refine the program. And as a result of that, one of the things that occurred was the carve out of the pharmacy benefit, and then narrowing it down to three managed care organizations to manage the medical costs of the program.

At the height of that adoption in the '90s, we had, I think, more than -- or around 12 managed care organizations. Each had their own formulary. We had instances of patients receiving up to 25 medications. Many were duplicate therapies, you know, using both a brand and generic, switching from a managed care health plan to a health plan and then getting more prescription drugs. And so we could not sustain the benefit that way, and that led to the carve out of the pharmacy benefit and the close management that still remains in place today.

Our Pharmacy Advisory Committee consisted of

government-appointed membership of physicians, doctors, pharmacists, and nurse practitioners, and including a patient advocate, so that we're hearing from not only those providers but the patients as well and hearing their side of what they would need from us to maintain access.

One of the things I'm most proud of -- and I like to attribute this to my time at TennCare, but the fact of the matter is that there's a lot of work and resources and individuals that help to maintain our preferred drug list compliance. And as you can see here, it's maintained at over 95 percent for the course of the outpatient preferred drug formulary. And I've worked in the commercial plans and on the commercial side, and 95 percent is kind of the pinnacle, and here we are maintaining it at 96, 97 percent.

The way we do that, again, is just the careful outlining of our clinical criteria and consideration. We do take that to our Pharmacy Advisory Committee, and we provide them with the tools necessary to make that decision. And that's evidence-based medicine. We also partner with a group out of the Ohio Science and Health -- Oregon -- sorry. Thanks, Darin -- the Oregon Health and Science University, and it's called the Drug Effectiveness

Review Project. And we, along with 12 other states, actually support this group and have them compliance meta-analysis for our formulary and plan, and use that support in making decisions about formulary placement and clinical criteria.

We also utilize quantity limits and step therapy, and the step therapy is usually based on standardized or national guidelines, and the quantity limits are simply for the most part based on the FDA-recommended daily dose.

Another method we use for the plan as a whole is medical necessity criteria that's unique to Tennessee, and it's five-pronged. Essentially, the recommended therapy must be requested by a licensed physician or health care provider within their scope of practice. It must be required in order to treat the condition. And it must be safe and effective and cannot be experimental or investigational. And, finally, but important not to be left out, is that it must be the least costly alternative for the treatment or therapy requested.

So as I talked to Rick and Chris about the focus of this particular panel and discussion, the question came up around the pharmacy benefit and federal regulations, and

we recognize and we track as a state what other states are doing. And that's the one thing in Medicaid. We do share our approach and methods as much as we can, but there are nuances between all of the states that sometimes make it difficult for us to apply new and interesting ideas in our environment. And so with those limitations, though we recognize that as much as we have managed our plan and we feel that we've managed it well, there's always room for improvement, and there's always room to provide better access or better outcomes for patients. And one of the ways we do that internally now and that we're doing is to innovate more closely, and we're now working with a primary care transformation grant in order to provide outcomes, improve outcomes and pay for services based on outcomes rather than volume. So that's something that TennCare feels very strongly about, but at the same time, I did want to acknowledge that there are other states considering ways that we could maximize outcomes for patients, and doing so in a way that is cost-effective and without interrupting access. And, again, you know, as we look at -- the states of Arizona and Massachusetts are seeking ways to manage the formulary in a way that is more closely related to

commercial plans out there in the market.

So what does the future hold for TennCare? We are also exploring the value-based purchasing, not from just a level of value-based purchasing at a prescription drug level -- because I know that is actually being explored with some programs. If anyone has heard of SMART-D, that's the nonprofit group that's looking to explore how we could pay for outcomes-based medication. But I think really and truly if we look at the innovation design and center within TennCare, we're already doing that from the perspective of that primary care transformation, episodes of care, trying to, again, pay for outcomes rather than volume.

And then the other item here that I just mentioned was the closed formulary model. That is how commercial plans operate, and it certainly increases the objectivity or the ability to introduce competition in the marketplace and trying to gain the most cost-effective care for patients and members.

Another option that we've explored as a part of the DERP consortium, because we have all of this data and we do have patients receiving lots of these medications,

the idea is that we would explore potentially sharing some of the claims data in a way that we could really do our own cost-effective models. And so it's very early in the design and talk, but we're all very excited about it from the DERP perspective and think that that might be a good direction to -- and that there's value in exploring how we could use that data to better support our mechanisms of pharmacy benefits management.

And then, finally, I would be remiss if I didn't' mention again and hone in on the resources that we use currently and leverage. Again, having that one-stop shopping with our pharmacy benefits manager and using our contract with our pharmacy benefits manager to leverage resource to drug information and clinicians, to help us manage the program all under one hat, and then also belonging to our partnering up with the DERP program and using that as leverage, and then participating in some of the national CMS initiatives and quality improvement initiatives as well to try to shape care. And, you know, just really again wanting to shine a hot light on our resource and managing and using that resource to its fullest capability.

And, with that, I will close because Rick is giving me the "time's up" sign. So thank you, and I'll pass the mic.

MR. VAN BUREN: Thank you. Thank you, Dr. Williams.

Now we'll hear from Doug Brown with Magellan Rx.

[Pause.]

* MR. BROWN: Okay. Good morning, everyone. I want to thank Chris and Rick for inviting me to present today, and I'm pleased to be on the committee with both John and Renee, who I've had the pleasure of working with and have known for a number of years.

So let's jump in. For those of you that are not familiar with Magellan, we are one company with two unique platforms -- Magellan Healthcare and Magellan Rx Management. I sit on the government side of the Magellan Rx Management business, with a focus on Medicaid pricing.

Today, what I'd like to cover is -- provide some high-level details around Medicaid pricing and then talk about multistate pools as it relates to supplemental rebates and preferred drug lists. Then I'd like to speak about some of the tools that we see being used in Medicaid

to manage utilization and cost and how that compares to what some of the commercial plans have, and then finally, I'd like to wrap up with outcomes-based contracting and a quick discussion around some of the points in where we are with that in the market.

This map is the map of kind of the footprint that Magellan has, where we negotiate supplemental rebate contracts and manage the preferred drug list for 25 states and the District of Columbia.

And the stats that we are going to go over next are from the Magellan Medicaid Trend Report published this summer. It's 2006 statistics. On average, we see that federal rebates are 53 percent of drug spend. Supplemental rebates add another 3 to 6 percent on top of that 53 percent, taking us to about 56 or 59 cents, meaning that 59 cents of every dollar comes back to the state in manufacturer rebates on their drug spend.

Net spend, net of federal and supplemental rebates, on traditional drugs was down by 5 percent over the year-over-year period, 2015 and 2016, and conversely to that, specialty, the net spend of specialty, was up 20 percent in that same time period.

The other thing that's unique to the Medicaid program and I want to point out for the group is that some brands' net of federal rebate are lower cost in their corresponding genetics, and states have taken advantage of this. The Magellan state saved $330 million by preferring lest costly brands over generics in 2016.

This slide looks at traditional drugs and the traditional drug trend over a 2-year period. Traditional drug trends, as you can see, is flat. The tools to manage traditional drug spending, they're mature at this point, and they've been used in the space since the first PDL was put in place in Florida in 2000. The tools here -- preferred drug list, clinical criteria, prior authorization, MAC programs for maximal-level cost on generic pricing, and rebate contracting. And clearly, they worked to hold down cost.

As we look at the specialty drug trend, that trend is going in a much different direction. At the gross level, the top line of 22.8 percent over the period, and net spend is up 20 percent over the period.

PDL management here is less effective. Medicaid has fewer tools to manage specialty drugs, and there is a

need to develop new tools in this space. And I think that leads us to outcomes-based contracting, which may be at least one tool toward that end.

I want to now focus on preferred drug list contracting and talk about multistate pools and why states move to those pools. Pools tend to be best fits for small to midsize states so that they can achieve buying power of larger states in this pooled arrangements.

There are currently three multistate pools nationally across 29 states plus the District of Columbia.

The National Medicaid Pooling Initiative, or NMPI, is a Magellan program, 10 states and the District of Columbia. The optimal PDL solution, or the TOPS program, is also administered by Magellan. It's seven states in that program. And the Sovereign States Drug Consortium, SSDC, is administered by Change Health Care, and there are 12 states in that program.

The smallest pool from the number -- live standpoint in this group is 4.5 million lives, 4.3 million lives in that smallest pool. The other ones are larger than that, between 5- and 6 million lives.

From an operational standpoint, these programs

and PDL program and contracting revolves around competitive products, planning market baskets of competitive drugs, asking manufacturers to bid with those competitive drugs in those defined therapeutic categories, and manufacturers there bid to be exclusive in that market basket, one of one, one of two, or just included in that market basket with preferred status.

Member states and P&T committees. States retain independent control of their preferred drug list. There is no national formulary with these pools. There's pricing, and then states determine what's best them and pick their own formulary.

Financial modeling is done showing all the pricing. The pricing is transparent to Medicaid directors and pharmacy directors.

States through their P&T committees select the drugs that are clinically and financially in the best interest of the populations that they serve.

Supplemental rebates are just one part of an overall strategy to manage drug cost. It's important to note that maximizing rebates does not generate the most cost savings for a state. Managing to the lowest net cost

does manage that.

In the next slide, I want to talk about the tools that Medicaid has versus what other payers have from controlling utilization. In Medicaid -- and I've mentioned these already -- Medicaid uses a preferred drug list. On the clinical levers, there's prior authorizations, clinical criteria utilization management, and then the financial levers, supplemental rebates in contracting, and then maximal allowable cost programs.

Other payers use these same tools, and they use tools that currently don't fit in the Medicaid space, like copay differentials and tiered formularies to drive consumer behavior. They also use drugs excluded from plant coverage, and then they optimize the channel, meaning they have preferred retail networks, specialty networks, and they use mail order.

It's important to understand the difference as we look now toward outcomes-based contracting. It is important to understand the difference between how supplemental rebates will work and how outcomes-based contracting will work.

Supplemental rebate contracting is an effective

tool in lowering unit cost for traditional and some specialty drugs, where there's a therapeutic alternative available, which creates competition, and where there can be subject to prior authorization, most often through a point of sale or other transactional system.

Outcomes-based contracting can be an effective tool for lowering unit cost for traditional and specialty drugs that generally do not have therapeutic alternatives and where cost per claim is high.

Understand outcomes can be expensive to measure. States must ensure that the value received from an outcomes-based contract is worth the cost to measure it.

As we look now at the slide here, we're looking at where we are today in the market. To my knowledge -- and I'm going to defer to John here in just a second -- there are no outcomes based contracts in the Medicaid fee-for-service space yet. Magellan is working collaboratively with SMART-D to bring an outcomes-based contract and open-source contract to market.

A template agreement is pending CMS approval. Manufacturer negotiations are ongoing at this time using that template agreement.

The hurdles for outcomes-based contract include the CMS approval process, best price implications, and off-label contracting.

Opportunities include the addition to -- on existing high-cost drugs, on new-to-market drugs. It can be measured against their FDA approval criteria when they lack evidence in the market, so I think there's an opportunity there.

Finally, states may use a combination of those supplemental rebates and outcomes-based contracting to achieve optimal overall cost savings for the Medicaid program.

That concludes my comments.

MR. VAN BUREN: Great. Thank you.

And now, finally, we'll hear from Dr. John Coster with CMCS.

* DR. COSTER: Thank you very much.

Good morning. I'm John Coster, Director of the Division of Pharmacy for the Center for Medicaid and CHIP Services.

What I'd like to do is first describe for you a little bit of what we do in the division that helps states

manage their pharmacy benefits. We work with manufacturers. We work with states, and ultimately, the goal is to make sure that patients have access to their medications.

So what are the things that we do in the Division of Pharmacy? First and foremost, we administer the Medicaid Drug Rebate Program. That's one of our major responsibilities. The rebate program brings in annually about $38 billion a year to the states and the federal government in terms of reduced spending on prescription drugs. It's one of the primary ways that states help to manage their prescription drug costs.

So every quarter, what we do is we receive data from manufacturers that they send us. We turn around and we calculate various metrics that we then send to the states, such as unit rebate amounts and AMPs, and they use those to calculate the rebates that they go and subsequently bill manufacturers for on a quarterly basis. So that's one of the most important things that we do in our division.

Second, we are in the process of implementing a new Covered Outpatient Drug Regulation. The regulation was

issued in February of 2016. It was a compilation of implementation for various laws that have been enacted over the years regarding the drug program -- Deficit Reduction Act and the Affordable Care Act. It also implemented a new payment mechanism for retail pharmacies under the fee-for-service program, so we've had a deluge of SPAs. The plan amendments come in over the last year where states have proposed to change their pharmacy reimbursement to conform to the new AAC-based methodology in that final rule.

Our division also works with states Medicaid drug coverage and SPA reimbursement policies. We don't in general review specific state PDLs or state formularies, but we do, as I said, review state plan amendments for changes in reimbursement.

We also administer two important files that all states use for reimbursement and payment for drugs. One is the NADAC, the National Average Drug Acquisition Cost file. This is a relatively new benchmark in reimbursement for drugs. Traditional files that have been used by payers -- AWP, average wholesale price, and WAC-based reimbursement -- most of the states have been moving towards a more acquisition cost-based reimbursement for prescription drugs

as a result of the new covered outpatient drug rule.

The NADAC file is published monthly by CMS. It represents essentially the average prices being paid by retail pharmacies for prescription drugs, and the states use this to reimburse retail pharmacies, which is the primary mechanism through which Medicaid patients obtain their drugs. So we think it's a more accurate, more transparent pricing benchmark than the traditional benchmarks that have been used, which are not based on actual transaction prices or purchase prices by retail pharmacies.

We also publish the Federal Upper Limits file. This is a little bit older file, but what it essentially is, the maximum amount of match that we'll give to a state for a particular multiple-source drug or particular generic drug.

We also work with states on their DUR programs. Each state is required to have a Drug Utilization Review program. The original law creating the rebate program back in 1990 also required that states establish a Drug Utilization Review program to assure that drugs being used by Medicaid patients are used appropriately and not likely

to result in adverse medical consequences.

Each state has operated a program. They report to us every year on how their program works, and we turn around and we take that information, and we put it in a comparison report so that states can see what other states are doing. It's a really, really comprehensive report about all the various mechanisms that states are using to manage their pharmacy benefit, all the way from their generic utilization rates to what they're doing in terms of controlling opioid prescribing. So we just published the 2016 report. In a few years, we'll also include information on MCO DUR programs.

We also work across agency to make sure drug policies are, to the extent possible, consistent. For example, we work with Medicare Part D. We work with HRSA on 340B policies since 340B is another primary source of access for prescription medicines for Medicaid patients, and we'll also work with SAMHSA.

And finally, we work with states and our Division of Managed Care Plans on their Medicaid MCO drug coverage policies. MCOs, as you know, is the primary mechanism of delivery for health care services to Medicaid patients.

The recent Medicaid managed care rule contains several provisions relating to how the pharmacy benefit should be administered under managed care plans.

Some of the next slides, I'll skip over quickly. You're probably very familiar with a lot of the -- how the rebate program works in general. Prescription drugs are an optional benefit under Medicaid, but all states elect to cover drugs. Medicaid doesn't buy drugs. It pays for drugs, and those drugs are primarily dispensed through chain and independent pharmacies. Rebates are also collected on drugs administered by physicians.

We review state payment parameters for drugs dispensed under fee-for-service, but we don't really get involved in reviewing payment policies under managed care plans, and as we all know, the rebate program helps to offset federal and state cost of prescription drugs dispensed to Medicaid patients.

Medicaid receives rebates from manufacturers. Those rebates are paid on a quarterly basis based on average manufacturer's price, the benchmark that was created back in 1990, or the best price. And, of course, best price is also in the original law, designed to make

sure Medicaid as the program for the poor gets the best price manufacturers are offering to any payer.

There's also an inflation rebate. Part of the significant rebate that states are getting back now from manufacturers is attributable to the inflation penalty, which was established for brand drugs in the original law and was just created for generic drugs by Congress a few years ago and went into effect this year for the first time for generic drugs.

There are about 650 manufacturers that participate in the program, and that spans all states and the District. The territories, we hope to come in over the next several years. In fact, the earliest they can come in is April 2020.

MCOs. Outpatient drugs that are covered under the fee-for-service program should be covered by the state's MCO. The MCO preferred drug list may differ, but the state can also require that they align. And there are some states that align their PDLs in MCOs and fee-for-service so they can maximize the supplemental rebates that they get, but in essence, in MCOs, the amount, duration, and scope of coverage must be the same as is the fee-for-

service. And the medical necessity criteria cannot be any more strict, and if an MCO does not cover a particular drug for some reason, the state has to make that available through the fee-for-service program.

And I'm getting the hook. Let me just mention the pharmacy service, the pharmacy sections of the Medicaid managed care rule. Just a couple things to point out. This was the first time that the agency was able to provide any type of oversight of the MCO contract specifically as it relates to pharmacy. These are the provisions you'll see. I'll point out a couple. For example, there's a requirement that state contracts with MCO have a mechanism to prevent duplicate discounts in 340B and -- or also a requirement that the MCO DUR utilization, drug utilization programs confirm with the requirements in Section 1927, and in a few years, we'll be able to report on how those programs work as well.

Value-based purchasing. The administration is interested in value-based purchasing. There's been several releases, one last year from the agency that talked about value-based purchasing arrangements and their impact on Medicaid, and also CMMI, Center for Medicare and Medicaid

Innovation, is also looking for new payment models to test that might look at value-based contracting and the impact it would have on cost and outcomes for patients, and in the question-and-answers, I can respond to some of the other comments with respect to where we are on some of these other contracting issues.

So thank you for the opportunity.

CHAIR THOMPSON: Thank you all very much. That was very useful. And, of course, this is a topic that we have a lot of great interest in.

Let me just kick things off and ask a couple of questions. I wonder, Renee, if you could just talk a little bit more about your operation of the PDL. What does it really mean to be preferred versus non-preferred in terms of beneficiary or member experience and their access to those therapies?

DR. WILLIAMS: Sure. I'll try to keep it short and sweet. One of the ways we determine access and status on the preferred drug list, as preferred and non-preferred, is to use the evidence-based research to determine whether or not specific drugs in a class, all other things being equal, you know, if they're effective and they're safe and

that's equivalent across the board in the class, whether or not then cost would be a determination as to whether or not that would move to preferred or non-preferred. And though a drug may be on the preferred drug list or categorized as preferred, they still would be subject to in some cases prior authorization and clinical criteria, step therapy, and potentially even quantity limits.

From the members' perspective, again, we're seeking to establish first safety and effectiveness, and so there's really no interruption in their access to those therapies. The provider, again, would request a prior auto if one is required. And if there are exceptions to that particular treatment of condition such as a contraindication or other concerns about adverse effects, then they would be given an exception to receive another therapy within the same class. And so members essentially still maintain a high level of access, but the goal is to provide access to a safe and effective drug therapy.

CHAIR THOMPSON: Is it possible that through the prior authorization process, on the basis of cost alone, that a beneficiary may not have access to a therapy?

DR. WILLIAMS: No. Actually, the primary focus

then is access for need and medical necessity. And so we have a robust appeals program, and if for some reason that exception was not supported or brought to the attention of the call center or providers or under a peer-to-peer review, they're given additional opportunities to show that medical necessity is required. And a patient or a provider can request an appeal or prior authorization, and so in that process, the first-level appeal would go to -- and that's after the prior authorization -- would go to a clinical pharmacist to review at that level to determine whether or not there were gray areas or something that perhaps the provider missed on the first round of prior auth.

If it is still upheld at that point, it then goes on to a medical necessity review panel. It's a third-party panel within TennCare, and that's a group of physicians that would then determine medical necessity based on that criteria. And they're looking for those exceptions to the black-and-white rule that we've laid out, or guidelines. And then at that point, still if the patient is unable or the provider is unable to support, you know, need and use within the confines of guardrails, it then goes before an

administrative law judge for review to consider.

CHAIR THOMPSON: And so I wanted to follow up on that with Doug about then the leverage -- part of the interest in this session was the extent to which states have available levers to use to manage prescription drug spending overall and that benefit. So in terms of negotiating, as you do, with manufacturers around their place on a PDL, how much leverage does that really provide? And what is the basis of those negotiations?

MR. BROWN: PDL placement is primary to manufacturers' concern here. They want their drugs preferred. They want open access for the drugs. And they're willing to pay in most cases, as long as it's competitive, a discount to the state to have open access. Prior authorization is a hurdle, a barrier to that product. States provide the pathway, as Renee just said, to get to the product, but it's a process, and manufacturers want to bypass that process so that physicians will write for it.

One of the slides that Renee showed is a 95, 96 percent compliance to the preferred drug list. That's very powerful for manufacturers when the discussions come up and say this product needs to be priced here in order to be on

the preferred side of the ledger. And that's a very powerful tool in that, in the Medicaid space.

CHAIR THOMPSON: Sheldon and then Darin.

COMMISSIONER RETCHIN: I think I want to go back to the slide that was sort of an eye-popping slide maybe from you, Doug, the 20 percent increase on specialty drugs and through specialty contracting. First, let me just ask, I couldn't see it. Was it 20 percent increase per unit prescription or 20 percent increase in spending?

MR. BROWN: It was the average of all cost, gross, for all specialty classes over the period was up 20 percent.

COMMISSIONER RETCHIN: Per unit prescription?

MR. BROWN: For prescription, yes.

COMMISSIONER RETCHIN: Okay.

MR. BROWN: Per prescription.

COMMISSIONER RETCHIN: So perhaps that is -- I mean, there are many reasons for that. I guess the novel explosion of biologics, we would all recognize that.

MR. BROWN: Yes.

COMMISSIONER RETCHIN: I was intrigued by your reference to outcome-based contracting, and I wonder if --

I would assume that would have to be something that would be explicitly measured rather than subjectively reported for -- I wonder if you could just sort of take us through -- and would the manufacturer have the risk in that?

MR. BROWN: A manufacturer will have risk in an outcomes-based contract.

COMMISSIONER RETCHIN: Can you describe a vignette or some -- like name a disease or a drug and how that would work?

MR. BROWN: So the way it's envisioned -- and, again, we're still at the infancy of this because we don't have one that's currently active in the space. But, in general terms, you'll have a contract that I can foresee in the market that a manufacturer will -- you'll engage with the manufacturer on a product that is, let's say, non-competitive, doesn't have a competitive product in the market, which is driving some of the cost here. And the measurement will then be this drug is supposed to work the way it's advertised, and if it doesn't in my population, I want a rebate on that, or I want free drug or some other mechanism or some other payment back to the state for failures that don't meet up to whatever standard you set.

By way of example, making it up, if the drug is supposed to cure 50 percent of the people and at the end of the measurement period you've only cured 40 percent of the people, then the 10 percent that miss will have some penalty that the manufacturer will pay back to the state. And if it performs as it's supposed to, then the state has paid for a drug that works as it's set up to do.

COMMISSIONER RETCHIN: I think it's an interesting concept. Many of the drugs, the orphan drugs, and specialty contracts, specialty pharmacies, have a very subjective response. I guess you could turn in the measurement. The recent introduction and the FDA approval of Spinraza -- is that it, Peter? -- for spinal muscular atrophy has a price tag of, as you may know, three-quarters of a million dollars per year. And I could see where you could do that, just be -- anyway, just a comment.

CHAIR THOMPSON: Darin.

COMMISSIONER GORDON: First of all, I want to thank Renee and the rest of the panel, but particularly Renee because she and the team made me look really good. It's because of people like her, so I appreciate that.

Two things, two questions for you, and then John

and Doug can sort out this next question. But, one, I'd like to hear a little bit about how things are going with the SmartD project, just get a sense fry on that. But, also, are there other tools that would be helpful in managing the pharmacy spend? I know every year we always would come and ask what else can you guys do to help us meet our budget targets. So I'd want you to think about that.

And then either John or Doug, when it gets to the value-based purchasing, Doug, on your side you mentioned some different hurdles. I'd like to get a sense from either of you, are those perceived or real? Renee, if you could go first.

DR. WILLIAMS: Sure. Thank you. So with regard to SMART-D, as a state, one of the states that were asked to come forward, one of the things we asked if we could do was to observe before jumping in and getting involved in the contract for this outcomes-based measurement, and part of the reason why we've come from the standpoint of being a more reserved observer is because of one of the things that Sheldon mentioned about the difficulty in determining what it means for it to be a solid outcome that's measurable.

As you know, with some of these newer drugs in these smaller spaces, they're using surrogate markers to determine whether or not a drug is effective and get it to the market very quickly. And based on that experience in this value-based purchasing exploration, it's very -- I imagine it's going to be very difficult to come to terms with the contract that a state can get behind and feel comfortable with, and that it may be the level of detail and the time involved with trying to make that determinant would be very difficult, as Doug mentioned in his presentation, and that we would have to really assess whether or not the juice is worth the squeeze, so to speak.

So from the perspective of SMART-D and the experience, although it's very novel and we're interested in leaning in, our state as a whole hasn't moved forward with the contracting piece of it. But we do still internally explore those options, even with manufacturers that are outside the SMART-D program.

And then with respect to what we are thinking about as the solution to what we see as a mounting problem of the increase of specialty drugs in this arena and this fast tracking by the FDA with surrogate markers, from our

perspective it would be a wonderful thing to, again, emphasize utilizing the resources that we have, maximizing those, and then going down the line of pooling data to create our own cost-benefit analysis. And I think it is worth exploring very heavily the idea of affording some of the flexibility maybe awarded to Medicare Part D or some other commercial plans, and being able to tier or use the actual PDL as a greater leverage mechanism before allowing a drug on to the class.

I know in my previous life working for a large pharmacy benefits manager outside of Medicaid, they very much have a team of individuals, a P&T committee that would go back through the data and start very much fresh from the condition and dig deep into the mechanism of deterioration and progression of the disease state in the current therapies afforded to the patients in the population, and then do cost-benefit analysis in support of the additional clinical data that they gathered before they made a decision as to whether or not all agents in that particular class needed to be on the formulary and available or if they could single it down to one or two agents that could cover the majority of patients and then allow a medical

necessity review outside of that to determine access and coverage.

MR. BROWN: Regarding the hurdles in outcomes-based contracting, the CMS process of doing a state plan amendment can take up to six months. There's certainly energy on both CMS' side in the administration and the folks that want to push these through to elevate this so that hopefully that time frame is a little bit shorter.

I think one of the concerns is do we approve a template contract like we have for kind of the transactional world of supplemental rebates where you're simply filling in the price the manufacturer is willing to pay. In the outcomes-based contract, it's much more detailed and you have to identify all the different elements that you're going to measure, the time frame you're going to measure, the parties that are going to measure that, how those parties are going to interact with the data. Potentially, there's PHI issues that have to be solved in that, and then putting that together, and does CMS have to review each one of those contracts because they're different in what they're measuring and how they're getting from Point A to Point B? Or is it the template

that we have and then you've got an addendum that kind of fills out the rest of that?

I can tell you that we would like to see a template that allows for some flexibility to fill out the balance of that to work independently with each manufacturer to arrive at the endpoint of an outcomes-based contract without having to go back to CMS multiple times.

The other hurdles, I mentioned Medicaid best price, you know, manufacturers are certainly sensitive to that. I think we need to be careful that anything that we do there doesn't impact best price with an unintended consequence for a manufacturer, and then off-label contracting, because we're looking at outcomes, patient outcomes. Oftentimes, that's not in the approvable FDA label from a manufacturer, and they're very skittish about -- and rightly so -- of contracting on an outcome that's not part of their label. And I think some manufacturers are closer to saying, "I think we can go there because our data supports that outcome, anyway," and others are much more reserved in that and kind of waiting for others to go first. So those are some of the hurdles that I see today.

John?

DR. COSTER: So as I said in my comments, I think the administration is generally very favorable towards these contracts. What we've done in the past in supplemental rebate agreements is a state that wants to enter into a supplemental rebate agreement generally submits to us their template, and we generally approve the template, but we don't approve every contract entered into under that template. You know, that would overwork our already overworked attorneys. So, you know, with respect to value-based contracting, we don't have in front of us now a state plan amendment to enter into an agreement from a state for value-based contracting.

We have worked with the DERP group and we've worked with Magellan, but we don't have an official submission before us yet from a state on a value-based contracting template. Once we get that, I think our general position will be that, you know, because it's a substantially different approach than traditional value-based contracting -- I'm sorry, supplemental rebate contracting, that we need to look at it, you know, we need to review it, because I think just being good stewards of the taxpayers' money we want to see what states are

committing to with respect to these contracts. So all I can say is at this point we haven't received one yet officially from a state.

I agree with some of the other comments made. We've met with manufacturers, multiple manufacturers, about value-based contracting over the last several years. Some of them see best price as an issue; some of them don't. You know, they've come up with very creative ways to work around best price while still giving Medicaid, you know, a good deal. There's also the fact that supplemental rebates are exempt from best price. So if a manufacturer in a state could structure a value-based or outcomes-based contracting such as it's in the form of a supplemental rebate, it would not affect best price, so that, you know, that state wouldn't have to give that price to every other state.

On the commercial side, if they enter into commercial contracts, that could affect a Medicaid best price. So best price, you know, is definitely something that has been identified as an issue, metrics, you know, who's going to measure the outcomes. So, again, I think once we receive a submission from a state, we will review

the base template and try to move that forward.

CHAIR THOMPSON: Okay. I have Kit, Chuck, Toby, and Stacey.

COMMISSIONER GORTON: Thanks. I have two questions, one for Renee and one for John.

First, for Renee, going back to specialty drug, can you talk about -- I assume your specialty drug trend was elevated like the national data that Doug presented, and so can you talk about the specific case of -- and, Darin, happy to have you weigh in as well -- the specific case of the emergence of the hepatitis C drugs over the 2014-2017 period and what actions, to the extent that you can disclose what you did, Tennessee took to try and moderate that trend and how effective or ineffective those actions were?

And then for John, following up on your comment about this new file, the NADAC files, could you talk a little bit about whether you think those data are sufficiently robust, mature, and reliable, stable, that they could be used as an alternative basis for calculating rebates in replacement for AWP?

DR. WILLIAMS: Sure. So with respect to

hepatitis C and this new advance and treatment, I'd have to say that our approach was, you know, a conservative one, but we certainly opened up access and used the guidelines as a starting place. But before the guidelines were even changed or presented, we were working internally to take the actual studies that had been done to bring this product to market. And one of the ways states again have resources and tools are those clinical studies, and we take a look to see what type of member or what type of patient was included and those that are excluded, because, quite frankly, if it has not been studied in a certain population, then perhaps those particular patients it would be irresponsible to provide access in that population that may have been excluded from a study to begin with due to safety concerns.

And so that was essentially what we looked at very early on, and then the guidelines were released, and we went to our DERP partners to try to determine, you know, which products that were kind of being released to market were more favorable in certain conditions, in certain comorbidities or genotypes, or comorbidities that lend themselves to treatment at this level. And, again, we took

a deep dive into hepatitis C and how it affects the population, those that have active hepatitis C that go on to progress further or to start to see liver decline over time. And so those were some of the considerations that we had as these new agents were coming out, and then trying to get the medication to those sickest members of our population first. And we still, I mean even monthly, quarterly, take a look at what's available, any new information that's out there, and then just modify our criteria and our plan to review and provide access to that.

And so, yes, it was one of those high-impact drugs, meaning that it came at a high cost and touched a large part of the population nationwide. And so our approach was essentially when we don't have the guidelines or we don't have the evidence from our larger data gathering is to go simply to how it was approved to begin with and shape that, shape the criteria and coverage for that.

COMMISSIONER GORTON: So a quick follow-up. Two pieces. One, what was the impact of the "Dear State Medicaid Director" letter?

And two, did the fact that FDA's label was broad

and not particularly narrow cause you any particular challenges in approaching it?

DR. WILLIAMS: So the response to the letter, we read it and took it in for consideration and really felt that we had taken our approach and step was -- and aligned with what CMS has provided.

It did come as a surprise to us from our perspective, but we had to take a look at the scope of why the letter came and had those discussions with our DERP partners and with CMS as well around the reasoning behind it and still felt very much and aligned with -- and I -- with the letter and that we were doing everything that CMS was asking us to do, but I admit that it did catch us a bit by surprise.

I'm sorry. I forgot the second part of the question.

COMMISSIONER GORTON: The FDA label.

DR. WILLIAMS: Yes. So as far as the FDA label, in broad terms, I think more for us, it's more of a timing for us because we are required to cover these drugs as soon as they hit the market, and that means if a manufacturer came in and reformulated aspirin to gain their rebate

agreement with CMS, everything that comes after that, we are required to cover day one, when it hits our file. And so we're scrambling to try to find the best approach and the best way to apply clinical criteria that's safe for our patients but also allowing appropriate access, and so it is a very difficult process to try to scramble, get those studies.

And then with the study design now becoming less robust, fewer patients, surrogate markers, which I've mentioned before, it is still very difficult to try to place emphasis on the success of these studies, and many of them, quite frankly, are studying against placebo.

So timing certainly is more of a concern for us rather than the FDA warning around these drugs or FDA recommendation.

COMMISSIONER GORDON: On that point, Kit -- and I'm glad Renee made that point because we had a lot of discussion after this -- as soon as it hit the market, we had to cover it, and we actually made a request that in the future, not too dissimilar what you can do on -- the Part B plans can do is have the ability to look at what the studies actually indicated, take it to the P&T committee

before we issue our coverage criteria.

In the absence of that, what you really are doing, which I don't think is in everyone's best interest, is you're immediately covering -- potentially having coverage criteria that come with it some risk because you may be -- we're not talking about a $5 drug either. You may be giving a drug in cases where it is of no benefit and/or potentially even harmful because you have to quickly get it out to market. And I think that is something that was a concern to us and that we tried to raise with CMS, and under the current requirements, you're not allowed to do that. You have to push it out, and I think there's got to be some time afforded to actually looking to make sure your coverage criteria is consistent with the research.

CHAIR THOMPSON: There was also, Darin -- and Renee, maybe you want to comment on this -- some discussion about the idea that states needed to anticipate looking in the pipeline and getting ready in a better way as well. So I'm not sure how much of that solves that problem or there's still some of that problem that will inevitably remain by virtue of when something becomes available.

COMMISSIONER GORDON: The problem will still be

there because the evidence isn't necessarily available.

CHAIR THOMPSON: And you're always projecting when things would become available.

DR. WILLIAMS: Exactly. So that we are. A couple of things about that, even in Phase 2, Phase 3 trials, we know that if there is no benefit observed, in some cases, the trial -- or if there's harm observed, the trial is shut down. So we are spending a lot of resources trying to get a sense of that, but at the same time, there's after-market research. I think within about 12 to 14 months of these new agents coming on to market, we noted new drug interactions, and new things are being revealed every day in the hep C model, that hepatitis B can now be reactivated under the treatment of this course of therapy. So we're forced to then try to scramble back and see if we should have a line item of criteria that says, hey, if you're not testing and treating for HBV, then perhaps you'll get denied coverage for hep C.

So there are after-market reports that are really beneficial, and I think just given a little bit of time to even consider this in a more thoughtful manner would be of benefit to all involved.

CHAIR THOMPSON: I have Chuck, Toby, Stacey, Fred, Sheldon.

COMMISSIONER GORTON: Yeah. John owe me an answer to my NADAC question.

CHAIR THOMPSON: Oh.

DR. COSTER: So the simple answer is the rebates from manufacturers are based on AMP, average manufacturer's price, not average wholesale price. The AWP is what's been traditionally used to pay pharmacies. So back when it was created, it didn't seem fair to base manufacturer rebates on a number that really wasn't the revenue they were receiving. So rebates today are based on average manufacturer's price.

And NADAC wouldn't be -- I mean, we couldn't do it because the law doesn't prescribe it, but NADAC also includes wholesale and mark-ups as well because it's the prices that pharmacies are paying. So, again, it probably wouldn't be an appropriate benchmark to base rebates because it's not the actual revenue manufacturers are receiving.

COMMISSIONER GORTON: Thank you.

CHAIR THOMPSON: Chuck.

COMMISSIONER MILLIGAN: I want to thank all of you. This has been a great panel. I really appreciate what you've shared.

I have two questions. First one, John, is for you about 340B. There's been a lot of activity in the provider community about changes on the Medicare side, recently around 340B, and I'm curious kind of the state of play from your point of view. And there are issues about 340B has been expanded to providers that maybe shouldn't have received it or ways it's been used for some outpatient therapy that shouldn't have been approved.

And I'm curious to know sort of state of play from your point of view about 340B. So let me just tick off the other three, other couple of questions. So that's the first one.

The second one, I think, is probably, Doug, more for you, and it's around scale and rebates. You talked about some of the multistate pools. I work at a large managed care organization. I think there's a debate in general about who has the best scale to get deals, whether it's large national managed care organizations or carriers, whether it's states that pool all of their -- at the state

level.

Renee, I'm respectful of kind of what you said about Tennessee's decision to carve it out in terms of administrative and other considerations, but my question is really about scale.

I'm curious whether there's some minimum scale you think to get the best price or the best sort of purchasing leverage, sort of the state of play about that, and maybe at some point, things are so big that there's no marginal difference one way or the other. So I'm just curious about scale.

And then my third question, we've kind of touched around it in different ways. My third question, I think, is really probably -- properly to Renee and Doug, both of you, which is just if you could hit head on what you would recommend as changes to the Drug Rebate Act or some of the federal approaches.

Renee, you showed the letter from Arizona from mid-November. You've talked a little bit about this, kind of a speed-to-market issue with FDA. I'm curious about just where you see improvements that could be made in the Drug Rebate Act, just straight on.

So maybe if we could start with the 340B. John?

DR. COSTER: So my division's work with 340B is limited to how it interacts with the Medicaid program. So I know that most state Medicaid programs view 340B entities as an important part of their provider network, including providing access to prescription drugs, but that states have challenges with 340B with respect to preventing duplicate discounts.

So if a 340B entity purchases at the 340B price and provides that drug to a Medicaid patient, the state is not supposed to also bill the manufacturer for Medicaid rebate. And because of some of the complexities of the program, the retrospect of identification of patients, the growth in the number of entities, the growth of contract pharmacies, the lack of an exclusion file -- there's an exclusion file for fee-for-service providers who carve out a fee-for-service but not managed care -- that the states are facing challenges in trying to avoid duplicate discounts, which is unfair to manufacturers to have them have to pay both a rebate and discount.

So I think states are managing to the best they

can. We're seeing some states that are asking us to allow them to carve out contract pharmacies or certain entities which may not be in the best interest of patients, but they're doing it because they are struggling with this duplicate discount issue.

With respect to Medicare, it's not really my area, so I can't comment on that. I know there's a new OPPS rule that's going into effect in January with respect to reductions on the payment side of the hospitals. So that in my mind is the state of play with respect to 340B and Medicaid.

MR. BROWN: With respect to your question around scale, I think there's a critical mass that once you get to 2- to 3 million lives, I think you've reached kind of that critical mass.

And there's a caveat that I want to make here because part of what drives manufacturer participation in states is clinical criteria and how aggressively they manage their program.

Tennessee, not just because Renee is sitting next to me, but Tennessee does a very good job at managing their program. We saw the highlights today of all the things

that they do to manage that program. They're getting discounts as if they were 2- to 3 million life program.

The pools are big 4-, 5 million life programs. The other big states that we manage -- Texas and Florida -- are both about 4 million lives, between the MCO -- and they're both -- they are single PDLs, meaning that they have MCOs, but that their benefit for Medicaid applies to their MCO benefit, so there are single PDLs in both Texas and Florida, both of them around 4 million lives. The biggest state, obviously, is California, 6-, 8 million lives. I'm not sure of that number, but it's in that likely ball park somewhere. But I think to get to kind of critical mass, it's likely 2 million lives, in that range.

CHAIR THOMPSON: Can I just follow up to ask a question? Does that mean bigger doesn't make it better? Like once you achieve that threshold, you have all the purchasing power you can get?

MR. BROWN: I think you have enough purchasing power to do what you want to do as a state and go the directions that you want to go and get the contracting that you need to get. We don't see a lot of pricing differences between those different entities, but I think the

competition that occurs from a manufacturer's perspective of having those different programs in space and we see one state do something and change a drug for the different preferred status, meaning that the manufacturer has done something different with the pricing, showed up in the next bid that goes out, either for one of -- for any state, but mostly in these pools, you'll see the price drop. And it continues to kind of create a competitive environment between different states from a manufacturer's point of view in there, and the pricing continues to decline, which is a good thing that cost continues to decline.

DR. WILLIAMS: So, as Doug mentioned, we are -- and he didn't say this directly, but I'll accept it. We do aggressively manage our PDL and our resources as we have them.

But with regard to carving out the benefit and the nuances of our plan and how we leverage that, again, it's having the pharmacy benefit program under one tent, if you will. It takes time to set up the edits and direct the pharmacist behind the counter to use a brand as generic to get that benefit.

And having that discussion with our clinical

pharmacist and our provider educators and pharmacists that are out in the field targeting those providers to listen to those messages in this as information becomes available about changes to the program and plan are all very key and critical.

So I would have to say that solutions from my perspective definitely have to do with making sure that states have the resources in order to employ these types of tactics to manage aggressively, and that from a perspective of information sharing between states and then also having the staff and the individuals that are capable of maintaining the pace of such a rapidly changing environment.

And then the other thing, I think, and in talking to other states, the sense that I get is even with DERP and that evidence-based information coming out, short of going directly to the FDA and saying please don't approve these drugs or grant approval of these drugs so quickly without taking other things in consideration or could we get more -- could we require them to do more head-to-head studies against established therapy that works.

But for us, timing, as I said, is a huge factor

in all of this, and as I talk to other states and as we talk to our resource out in Oregon and the time it takes for them to sift through all of the studies that are available to them and try to make sense and gather those that are similar enough to conduct a meta-analysis that's appropriate and within guideline takes time, and so for us, it's just a few extra months, a couple of months, even, to try to get a sense of really where these drugs come into play and where they fit into our PDL and how we can manage them and get the access to the patients that really need them the most.

COMMISSIONER MILLIGAN: So I'm trying to extrapolate, Renee, changes to the Drug Rebate Act. More time, it sounds like not immediate, so some lag between the FDA action and the state action. Are there other statutory changes that you would want to suggest to the Commission around the Drug Rebate Act? Or, Doug, that, I mean -- as opposed to the state administrative side of this, the federal statutory side of this.

DR. WILLIAMS: I would only add -- and I know what you're wanting me to address. I would only add that there are nuances within every state. I know what works

well for our state, but I would only ask that if we are seeking to change it, that we explore it and take a deep dive and see what that means and have each state representative come with individuals that can help shape that determination and decision.

But specifics on what I would like to see changed about it besides a time and allowing potentially close formulary or flexibility to employ that type of access, I really don't have any other recommendations at this time.

CHAIR THOMPSON: We are coming up against time, but I wonder if the panel will forebear with us for another 5 or 10 minutes to just be able to finish off our questions and ask Commissioners to focus their questions, if they can.

I have Toby, Stacey. Fred, you're passing. Sheldon.

COMMISSIONER DOUGLAS: Chuck addressed my questions.

CHAIR THOMPSON: Okay. Well, we may have solved a problem here. See, I say we're coming up because of time, and everybody says, "Oh, I'm out."

Stacey, do you want to jump in?

COMMISSIONER LAMPKIN: I think most of what I was going to ask was captured by either Kit's line of questioning or Chuck's, but I really just wanted to make sure that we were identifying the barriers to the state flexibility in managing the program and understanding how much of them were in the rebate system, how much of them were statutory, and understanding where the levers are. If there's anything on that topic that you'd like to call out, any of you, that we haven't heard about, I'd welcome hearing it.

Oh, and thank you so much for coming. This has been fantastic to hear here.

COMMISSIONER GORDON: Can I just say we're -- you recapped a couple of things. I think Doug hit on the value-based purchasing -- or John did -- with regards to Medicaid best price and that that not be a barrier, I mean, however you address that, but I think Doug had touched on that.

CHAIR THOMPSON: Sheldon.

COMMISSIONER RETCHIN: Just before we leave, I just want to get back to Chuck's question and the response on the scale.

I think just listening, I understand that when you get to 3 million lives for traditional drugs, it seems like an adequate scale, and you're not going to squeeze out many basis points on that.

But when you get to the specialty drugs for rare disease, something that genetically is 1 in 10,000, where a million lives may actually only generate 50 patients, I wondered about your reaction about actually having a different pool for super-specialty drugs because when you put all these drugs -- I guess actually, as Yogi Berra would say, rare diseases are common.

[Laughter.]

MR. BROWN: It's certainly something that we're talking about as far as the contract goes. Working with some states that -- you mentioned rare diseases. They have four patients. You can't really do an outcomes-based contract on four patients for a state. So as part of that discussion, it's certainly being discussed about how many states do we have to put together in order to create critical mass for a particular product, and that's going to vary by product, depending upon how many recipients you think you're going to have that need that product in order

to put that type of a tool in place relative to outcomes-based contracting. We're just not there yet.

DR. WILLIAMS: I would only quickly add that there are certain conditions and disease states that are considered very much untouchable from a formulary management perspective, but there's room there to maintain access while leveraging positioning on the PDL.

And one of those classes that's traditionally not managed in that way -- hemophilia, chemotherapy, cancer agents, HIV. So there are certain classes that are, from that perspective, untouchable, but to be fair, if we were looking for support for the states from CMS or other entities, to be able to leverage those classes in a clinically thoughtful manner would be of benefit to us, quite frankly.

CHAIR THOMPSON: Well, let me just add my thanks to all of you for being here this morning. I think this has been extremely useful, and I think the Commissioners have benefitted a great deal from your insights and expertise, and your thoughts will help form some of the basis for our future discussion. So thank you very much.

And we will reconvene in 15 minutes to continue

the conversation. Thank you.

* [Recess.]

CHAIR THOMPSON: Okay. Why don't we reconvene, if everybody can take their seats.

ADDITIONAL DISCUSSION OF STATE STRATEGIES FOR MANAGING PRESCRIPTION DRUG SPENDING

CHAIR THOMPSON: Okay. This is time for us to continue the conversations and Commissioner crosstalk on the panel that we just heard, and other issues around prescription drug spending. Rick, Chris, are there any general comments or questions that you would like to start us off with here?

So you were not expecting me to do that? Okay.

MR. VAN BUREN: Yeah, no.

[Laughter.]

CHAIR THOMPSON: Okay. All right. Well, I think that we all found that panel to be extremely interesting and useful, so I wonder if I might invite the Commissioners to comment on anything that you felt was particularly noteworthy or what was suggested to you about future directions.

Kit.

COMMISSIONER GORTON: So two things. One, I just want to underscore what Renee shared, and maybe Darin can talk a little more about this, about the level of effort that Tennessee puts into manage this. And then I would like us to multiply that times 50 states and the District of Columbia and the territories, and then -- and I don't know the specifics of how Tennessee budgets its administrative costs and how some of the savings might be wrapped into the 1115 waiver. But in states that are operating under SPAs and that have rigidly controlled administrative budgets, they don't get the level of talent that we just saw in running their PDL. Now it's nice that they can hire it from Magellan, but you could be sure that the nice people from Magellan take a share for their shareholders.

And so I think it's worth thinking about how we administer this, and is there a role -- it's a question I don't have an answer to it, but is there a role un some centralized way for a clearing house for all this work? Because when I was in government, it was my job to do what it was Renee's job to do, and there were colleagues all over the country repeating this work, and that just doesn't

strike me as being cost-effective.

And so I think that we should give some consideration that maybe the staff can think about between now and when we talk about this next, getting our arms around just how much administrative effort between the PBMs, you could throw in the managed care plans, you can look at the states, you know, these pooled arrangements. I think there's a lot -- there's a huge amount of administrative costs, and every time we get a bump up in the trend, in this arms race with the manufacturers, in terms of controlling costs, your choice is really invest a whole bunch more money to try and control costs or come up with -- you know, or come up with some new approach.

But I just think it's worth thinking about, you know, 54 states, territories, and the district, and how much we spend trying to do that. That was one thing I wanted to say.

The second thing is, I've had the opportunity to manage side-by-side PDLs for a commercial product and for a Medicaid product, and to the point that Doug was making about scale, the states do get scale by pooling together and I think that's a great strategy. What you see, though,

is in carriers that provide coverage for both commercial and Medicaid populations, CHIP as well -- Part D is a different animal -- you can get scale by having a combined population. So if you have a contract with, you know, XYZ PBM, you've got all your lives. Your Medicaid lives are there, your commercial lives are there, your ACA lives are there. And when you pool that all together you can cross that two-million-member threshold pretty quickly, and you do see the benefits of that.

I also think that you see -- this is to the question that Chuck was asking -- you see there's stuff you can do in the commercial world that you just can't do in Medicaid. And our experience was similar to what Renee experienced. In the commercial world, in the state where I was operating when the hepatitis C drugs came out, the law permitted a six-month delay while managed care companies in the commercial market evaluated new drugs to market. So on the commercial side, we didn't cover them until we had a chance to study them, and we put criteria in place, and we did all of that other stuff. In Medicaid, day one, there it was.

And so I do think that leveling the playing field

between Medicaid and commercial in that way -- you're not going to do tiered copayments and that sort of thing because you can't do that in Medicaid -- but I do think there's some value to that.

And then the last point I would make, very quickly, is Medicaid is starting to put its toe into this value-based purchasing arena, because the drug manufacturers really like it, it creates -- it's interesting that they're the people who are pushing it, and I would just flag that for consideration. They've been pushing it for about five years in the commercial world, and what I would say is the commercial experience is decidedly mixed. There's a reasonable body of literature there and it may be useful for the staff to pull the studies that have been done, and I'm not talking about the industry-funded studies that have been done. I'm talking about the handful of sort of relatively unbiased work that's been done, and the folks at AHIP may be able to point staff in the direction of some of that work, because AHIP has led the charge in sort of taking a more measured approach to value-based purchasing.

But the problems that were pointed to in the

panel, and that Sheldon raised, are real ones, and I think experience on the commercial side is the manufacturers are really interested in these things when they think they've got a slam-dunk and they want to price it high. They're much less interested when the outcomes are iffy, when the populations are small. I'm not aware that they -- that maybe with the exception of Harvard Pilgrim that any of the hepatitis C manufacturers entered into a value-based contract, and Harvard Pilgrim has spent a lot of energy on this particular thing.

So I think we should not rush to judgment that value-based purchasing is a great solution here. In five or so years, on the commercial side, it has not been a silver bullet, very little uptick by the commercial plans, and certainly they have the incentive to undertake it if they thought it was a good idea.

CHAIR THOMPSON: Toby.

COMMISSIONER DOUGLAS: So one area that I feel I would like us to explore more is just around kind of this question of the carve-in versus carve-out. A lot of the discussion today was around the fee for service and what states could do within a fee for service environment. And,

you know, just from multi dimensions, one, from the question of -- from beneficiary or for the member, in terms of integrated care, the pros and cons of having a carved-in, carved-out, and then this issue of cost and scale, given kind of what Kit said. I mean, you can look at scale multiple ways. You know, a lot of the plans in Tennessee are national plans that have tremendous scale within the pharmacy across states, similar to a Magellan. So, you know, how does that compare to a state doing it? Then there's the administrative capacity, as Kit said, just really understanding, because this is an ongoing debate within the Medicaid and kind of what are the incentives for carving in and carving out the benefit and really understanding it from both sides.

CHAIR THOMPSON: You know, I also found the conversation around the timing issue to be very interesting. It was interesting to me, also, that Renee talked about 60 days as being a big help. I mean, you mentioned, Kit, six months. But, you know, I don't know if all the states would feel that way, but it was surprising to me how a little relief could make a big difference --

COMMISSIONER DOUGLAS: So if you --

CHAIR THOMPSON: -- in terms of different better ordered, in terms of serving the population.

COMMISSIONER DOUGLAS: -- even if -- even a 60 days, if you think about what the administrative process is to find out that you're going to cover a drug, enter in onto your file, gather any kind of evidence that you might want to do in terms of criteria, put together a draft policy, submit it to your P&T committee, go through the various steps -- you can't turn that thing on in less than 90 days, which is why it's six months in the commercial world. And that's if everything falls -- all the pieces fall into place and it's all straightforward.

So, essentially, what happens every time one of these blockbuster drugs gets approved by the FDA, is the Medicaid program across the country -- now, some people, the good people in Texas just said no on hepatitis C, or, I mean, stared down the "Dear State Medicaid Director" letter, as far as I know. But the more compliant folks just sort of say, okay, and then it's open season until you can catch up. And if you have a well-resourced team like Renee has in Tennessee, they probably can do it in 60 days.

I would say when I was in Pennsylvania -- now

this is years ago, and, you know, there weren't computers and all that stuff -- but, you know, we didn't have but a handful of people trying to do it, and if you got a couple of them at once, it was enormously difficult. And then you have all of the procedural steps, and I'm talking -- what I was talking about is from a managed care organization's point of view. If you're a state that has to do some regulatory guidance or something else in order to update your PDL, I mean, the timelines for those are long.

CHAIR THOMPSON: Darin and then Chuck.

COMMISSIONER GORDON: Yeah, and, you know, when we looked at it, because we felt we were not being responsible in developing clinical criteria that was supported by evidence, and that was not a great place to be, we did make a request to go up to six months, because it was consistent with what was done in Part D as well. But what we had suggested at the time of that request was, really, it was really until we could get it before our -- look at research and get it before the P&T committee, and the P&T committee say yes, this clinical criteria is appropriate. But the way the statute is written, you're not afforded that.

And again, I would tell you that everybody believes, well, you know, having this wide open and, you know, you pushing out these 100,000-plus-dollar drugs, you know, it's fine, you know, and if they have a diagnosis of hepatitis C, everything is going to be good. That's not necessarily true. And so, you know, you are -- it's not just -- you know, some people will look at that and, well, you're just trying to not push it out the door.

It's like, you want to make sure it's going, as Renee said, to the people who can truly benefit. The evidence is there that it benefits, but you also want to make sure you're not pushing it out, one, to where it won't benefit, because that's limiting resources that you have in the program, but, two, again, what I was always concerned about is, in fact, allowing someone to get it where it's contraindicated but, you know, your clinical criteria hasn't caught up to the evidence. And that is a legitimate risk.

But I'm glad that topic came up, because it is something you should look at, and, you're right, we didn't think saying just hard and fast six months, until you could get that particular drug, no longer the six months before

you P&T committee.

And I will say -- you had asked the other question that came up. The value-based purchasing thing, yeah, it's mixed. We're not sure where it's going and I'd say that, you know, in a lot of different areas. However, I would say that, you know, I was on the advisory group at Duke-Margolis as we're looking at value-based purchasing in the pharmacy space. Some of the barriers that were highlighted, Duke did put out a paper that says here are some changes that could be made to remove some of those barriers, to at least have the opportunity to pursue value-based purchasing. And, you know, am I saying that there are really clear paths on value-based purchasing? It's the harder stuff, for sure, but you'll never know unless you take away some of the barriers, whether or not it's truly something that could take us to a better place.

CHAIR THOMPSON: I think I saw Peter or Chuck. Which one? Chuck? Yeah.

COMMISSIONER MILLIGAN: Thanks. So I just -- I thought it was a great discussion. I want to, I think, tease out a few things. I do think this blockbuster drug delay lag time, like clinical, is real, and I think, you

know, if and when the Commission moves toward recommendations about kind of how pharmacies manage, statutorily and otherwise, I think this is something that's real.

Briefly, on the hepatitis C experience, because I was the Maryland Medicaid director at the time, it's not just -- you don't know what the medical necessity criteria is. I mean, there was, like, a lot of struggling about what's the right fibrosis score. There was a lot of struggling around, you know, what's the implication if somebody is still using, you know, substance use issues, compliance issues, in terms of efficacious drugs. There were issues around does it need to be administered and overseen by a board-certified infectious disease doc or not. All of those kinds of pieces.

It was -- you know, it was a moving target and, at the same time, states are getting sued for not immediately expanding it to everybody, and a lot of states were -- the perception was states were being very restrictive, for budget reasons, and so patient advocate organizations were filing lawsuits. And it's not a good policy environment to make, you know, evidence-based

decisions.

I want to -- the second thing I want to say is I think, you know, Renee's comment and the new formulation of aspirin and basically taking an old drug and trying to find a way of getting the price up, and it's always measured against placebo. Well, it's going to always be better than placebo.

So I think part, to me, of the delay-related issue is -- and it was -- you know, the Arizona letter that was shown on the screen is, you know, can we have some time to think about what the implications for PDL and otherwise. If it's not a blockbuster drug, it's just, you know, a new formulation of an old drug with, marginal, if any, benefit to the patient, and how do we handle that kind of situation, which seems to be occurring more often?

The third thing I want to -- my last comment, I asked the 340B question -- I want to just be explicit about it. You know, there's a lot of like price segmentation and all this stuff, obviously. The Medicaid price isn't the best price. 340B and, you know, the Department of Defense and VA, there are better prices out there. I think the issue is, the more you restrict those other prices, the

more you, in a hydraulics kind of sense, the more you can increase the Medicaid prices.

And so there is, I think, an interdependency, and so when Medicare does restrict availability of 340B and change safety net providers, and, Fred, I'm imagining this is affecting your system -- I know the safety net in academic medical centers in our market are scared to death about what's going to happen to them with the 340B issues on Medicare -- I think it will have effects on Medicaid. I think that there are -- these are not independent factors.

And so wherever Medicaid is going at the CMS level around potentially restricting which providers are allowed, and contracted pharmacies and all that kind of stuff, I think we have to keep an eye on the interdependencies with pricing of federal pricing structures.

So I'll leave it there.

CHAIR THOMPSON: Peter.

COMMISSIONER SZILAGYI: This is probably repetition, but to me the most -- this was a great session -- to me the most striking graphs were those two graphs about the flat line or declining traditional drug prices,

and then the specialty. And it just got me thinking more and more about the questions of scale that we're discussing.

I would love to see if there are -- and I don't live in this space at all -- if there are modeling studies where you really start considering your specialty drugs. I have this gut feeling there's no ceiling to this scale for the specialty -- in the specialty world, whereas there is for the traditional. And, you know, thinking about all of the administrative costs and the enormous effort that goes in this experiment of 50 states, I think that might contribute to our understanding of how we might be able to sort of both ensure access and potentially limit the cost.

So I don't know what kind of studies are out there, or modeling or economic analyses, really thinking about these super high cost specialties, like the SMA drugs, the spinal muscular atrophy, or, you know, these really rare drugs, because this is just the beginning of the biologics.

CHAIR THOMPSON: I'm wondering, you know, one of the reasons why I started off asking Glen about, like, really, explain a PDL, is, you know, in the end, it does

come down to a question of what a state can or cannot offer, or can or cannot withhold in return for a given price. And, you know, the Arizona letter, the Massachusetts waiver proposal, I mean, they start to touch on this question of -- and I'm trying to figure out if this is a practical difference -- is it a semantic difference?

Is it an important difference in terms of how accessible something is on a PDL versus closing a formulary, and allowing some kind of process by which a state could decide we're not going to cover this particular therapy, and, fundamentally, does a state need to have some kind of ability on that lever to be able to really be successful in negotiating in a market? And if it did, what would be the parameters of that, what would be the protections around that, what would be the corridor around that, that we might contemplate as being available for states to utilize?

I know that in our earlier conversation we said we did not have the appetite, sort of, for a full-scale revisiting of the entire Medicaid drug rebate program, and I don't know if this question starts to get us -- you know, because it calls into question the fundamental grand

bargain, whether we feel like it starts to get us too far in that realm. But I just wanted to test whether or not people had an interest or an appetite in thinking about what that could look like, as a matter of national policy.

COMMISSIONER CERISE: You kind of almost have to. We're sort of dancing around that issue, right? And, that is, give me a six-month delay, let us assess whether or not we want -- how we can restrict it or limit it to just those appropriate. But you're going to have drugs -- I see it as two groups. There's going to be the new drugs, the hep C kind of drugs that you know there's a benefit and there's a huge price tag to them. And then you've got a series of sort of new drugs in a space where you've got other drugs, where they may have a marginal benefit, and, you know, how much are you willing to pay for that marginal benefit, you know?

Health Affairs did something a few years ago that showed about a dozen new oncologic agents coming on, all of which are in that $100,000 range, none of which saved a life. But it was kind of the beginning of this wave.

But for those ones where you know there's a new added benefit there and you're kind of struggling with how

do you restrain it, the foregone conclusion is we're going to pay a huge price tag for that, and sort of absent what you're talking about, and that is, the hard, hard question is: Can you hold out and say that's just too much, you know, and sort of try to do something fundamentally to get more reasonable launch prices of the drugs? And that's a harder thing to do, but I think you have to talk about it.

COMMISSIONER LAMPKIN: Yeah, and the irony is that prescription drugs are an optional benefit. And yet once you're in, because you have to be in, you're kind of locked in. And yet all the discussion, you know, in Congress is about state flexibility, and this just seems like an area where there's very little of that, presumably because of the rebate structure.

COMMISSIONER CERISE: And to Kit's point, you know, rather than having 50 states and territories thinking about this individually, if you could do some collective thinking on this, it may be easier for a lot of states to have the collective thought on this.

CHAIR THOMPSON: Darin.

COMMISSIONER GORDON: Yeah, and just following up on that point -- and Renee mentioned that Oregon group,

Health and Science University, in essence is trying to be that entity that processes through all the research and help make that available to states. But, granted, you know, many states aren't involved in that, but several are. But that's the premise behind it, and a lot of folks said we can build our own capacity in this or we can leverage an entity that's already doing some of this and buy into their capabilities and their resources to provide that so it's helpful to all. But taking that even broader, I think obviously would be a benefit to states, to Kit's point.

CHAIR THOMPSON: Alan.

COMMISSIONER WEIL: Since you're just taking the temperature, I'll give my thermometer reading. I think the discussion was very interesting. I think the notion of some time for handling new entrants is reasonable, and I'm very interested in this notion of low frequencies or orphan-like drugs and trying to figure out how you catalyze the kind of analysis and pricing that is probably not possible at the 2 million level.

I think I'm right where Fred left us, which is I believe there is a place where we can overlap the resource issue and the state-to-state learning and the efficiency of

not having to replicate all these functions at the state level with the question of what would be the criteria for actually excluding from the formulary, without taking on the entire rebate structure.

So, I mean, I think it would be appropriate for us to start walking in that direction, you know, as a temperature read. But given the resources necessary to make those decisions, to just sort of say, "Yeah, states, go do this," doesn't seem like the right way to do it. So I think if we could pair these two together, it could be an interesting place for someone.

CHAIR THOMPSON: Sheldon, Kit.

COMMISSIONER RETCHIN: Well, I'm with everybody that I do think there's something here that we can contribute, and I was struck by Renee's last comment about looking for more support from CMS. So I think we should walk a pathway to be able to maybe come to some sort of consensus.

I will say, as I was listening to this, we're all looking at the untoward consequences of the costs of treating rare disease, much less the high frequency, high impact that the flip side is. I will say with the

explosion, you know, you can't predict discovering. And, you know, so there will be drugs that cure death.

But I think Sara Rosenbaum was talking about this as probably the biggest argument, the most cogent area where it will make very -- it will be very difficult as a policy for per capita caps. If there's any place where that pops the ceiling, it is in the biologics. The next biologic comes along, it's going to be very expensive, and it will be very effective.

CHAIR THOMPSON: Any other comments?

[No response.]

CHAIR THOMPSON: So I took down a long list here -- oh, sorry, Kit?

COMMISSIONER GORTON: So to Sheldon's last point, the name of that drug is Spinraza, and we'll see how it plays out. But I think there's a very good chance that it or one of its cousins down the road in fact does create a cure for spinal muscular atrophy, and so we're going to have to confront that. I say that as a parent of a child who died of spinal muscular atrophy. It's an enormously challenging thing.

One place that there might be an opportunity for

the Commission to say something about policy that might be helpful in all of this is Title 19 specifically excludes the coverage of experimental care. There's nowhere in regulation or in sub-regulatory guidance or anywhere else where experimental is defined. And so there is no -- the Brits have a very well developed system of deciding when something is approved in therapy and when it's not. We do not in the United States, and so one of the frontiers of this ongoing back and forth between industry, government, and the provider community about who should get what when and where is: Is it medically necessary? And at what point does it stop being experimental and does it start being established therapy? And I don't think there's a -- there's certainly not a consensus on that in the country, and I don't suggest for a moment that the Commission is going to generate that consensus. But I do think that it's an issue worthy of being flagged in terms of the qualitative descriptions.

One of the places where these discussions happen is on that frontier, and the whole question about labeling is if the -- and Renee pointed this out. If the drug is studied in a finite population but the label doesn't say

that finite population -- right? -- which was the case with Sovaldi. It was studied in a very defined population of people, and then the label came out and said anybody with hepatitis C. And then the CDC came out and said anybody with hepatitis C, and, you know, so then we got where we got.

The question is: If it has never been studied in a population, can it be established therapy just because it has been proved in some other population? If it has never been studied for a particular purpose, what the Commissions would call a particular indication, does that mean that its use for another indication means that it's established therapy for that indication? And I do think we could do some descriptive work about that thicket and the challenges that states face in trying to navigate that, I think it fits into this conversation about the administrative burden, because it's essentially what Renee and her team do every day, is say, you know, when is it good enough? And so I think that's worth flagging, and it might be a place where we could sort of shine a light for people.

CHAIR THOMPSON: Okay. Any other final -- Chuck.

COMMISSIONER MILLIGAN: I would just add to Kit's

-- and I'm repeating myself, but -- and also if it has never been studied against the other available therapies, it's been studied against a placebo.

CHAIR THOMPSON: So we have, I think, ticked through -- I at least have on my list -- about seven or eight different things that we might be interested in trying to attack. But I think what we will probably need, after we have the next conversation this afternoon, is to sort of circle back and sort through and prioritize among those, and also figure out where we can connect some of these different interests and themes in a way that gives us kind of some meaty views of some of the potential improvements that we can suggest. Thank you. And thanks again for organizing the earlier panel, which was so helpful.

Okay. Now we are going to move on to streamlining managed care authorities. I'll let the crowd fix itself here.

As we're getting prepared, just for the benefit of the public and also for the Commissioners, the way that we're going to work this conversation, we have previously been discussing opportunities for streamlining managed care

authorities. We asked the staff to construct some potential recommendations along those lines and bring them back to us. We will have Ben present the potential recommendations and justifications following on those earlier conversations. We will then have a Commissioner conversation, reaction, discussion. We will have public comment at the end of this session. And then we will come back at the end of today's agenda to review the recommendations again, inclusive of any kinds of adjustments or updates based on the earlier conversation, and hold a vote around those recommendations.

So, Ben?

REVIEW OF MARCH REPORT CHAPTER: STREAMLINING MANAGED CARE AUTHORITIES

* MR. FINDER: Thank you, Penny. And good morning, Commissioners. Today I'll present an overview of the draft chapter for the March 2018 report. Much of this will be familiar to you all. The Commission first discussed approaches to streamlining Medicaid managed care authorities at the March 2017 Commission meeting, and in October, you discussed some potential recommendations.

Based on your conversations in March and October,

we took your feedback and incorporated your thinking into the draft chapter. We also reflected on your conversation around draft recommendations and developed rationale around that for your consideration today.

So to that end, we'll begin today with a review of the draft chapter which, broadly speaking, can be broken down into three parts: The first part is an overview of the authorities under which states implement Medicaid managed care programs; the second is a comparison of the similarities and differences of these authorities; and the third is an analysis of some of the approaches to streamline Medicaid managed care authority. Following this, I'll present three recommendations and their rationale for you to consider.

There are two tasks before us today. First, I'd like your feedback on the draft chapter, so do we hit all of the major points? Is the tone appropriate? And have we characterized your thoughts in a way that reflects the Commission's view? And, secondly, we'll discuss the draft recommendations. Have we captured your thoughts on the recommendations and the rationale?

The draft chapter describes the authorities under

which states implement Medicaid managed care. In our June 2011 report, we described a history and evolution of managed care in great detail. This chapter goes into detail and describes the authorities of -- describes these authorities in greater detail. Section 1115 waiver authority was the only authority available to states to implement managed care in the beginning. Today many states implement Medicaid managed care programs under this authority in order to finance other program changes, such as uncompensated care pools or delivery system reform programs. Twenty-two states currently operate comprehensive Medicaid managed care programs under Section 1115 waiver authority.

Section 1915(b) authority allows states to waive certain requirements under Section 1902, such as freedom of choice of Medicaid providers, to achieve certain Medicaid program goals. Today states use this authority in one of three ways: first, to implement comprehensive managed care programs; second, to implement a specialized program or carve out, such as a non-emergent medical transportation benefit or behavioral health carve outs; and, third, and finally, to establish a home and community-based services

waiver program in conjunction with Section 1915(b) authority.

And, finally, 15 states implement comprehensive Medicaid managed care programs under Section 1932 state plan authority. One of the features of state plan authority is that the states can mandate enrollment for nearly all beneficiaries except for certain populations which I'll describe in a few more slides.

Medicaid managed care standards are applied based on the type of program -- for example, a comprehensive managed care program or primary care case management -- rather than the authority under which managed care is implemented. These standards are described at length in regulations, and they provide the federal government, states, and plans with different responsibilities and obligations. For example, regardless of authority under which Medicaid managed care is implemented, CMS must review and approve managed care contracts and rates. States must establish network adequacy and provider capacity standards, and plans must demonstrate compliance to those standards with supporting documentation.

Plans must establish an appeals and grievances

process developed within broad federal guidelines. States and plans must provide information that is easily understood and readily accessible. And states are required to establish a monitoring system for all managed care programs that address all aspects of the managed care program. All states must establish quality standards, including a quality review and improvement strategy, for their managed care plans.

This slides provides an overview of the ways these authorities are similar and different, and some of the key takeaways are that states use all these authorities to implement similar programs. For example, New Hampshire operates its managed care program under both state plan authority and Section 1915(b) waiver authority. Many aspects of program oversight are the same, too, as I mentioned on the previous slide. Communication standards apply regardless of the authority, and states must establish a monitoring system for all managed care programs that address issues, including appeals and grievances, marketing, program enrollment and disenrollment, provider network management, and accessibility of services.

On the other hand, there are some key

differences, too. For example, these authorities are different in scope. They exist along a spectrum. You can think of, on the one hand, state plan authority allows a state to implement a discrete comprehensive managed care program within Medicaid rules and requirements; and then, on the other hand, Section 1115 waivers provide broad flexibility to waive statutory requirements.

These authorities also vary in terms of who can be required to be enrolled in Medicaid managed care. Under state plan authority, states can require all beneficiaries to enroll in Medicaid managed care except for individuals dually eligible for Medicaid and Medicare services; American Indian and Alaska Natives; and children with special health care needs, including foster care children.

States can require these excepted populations to enroll in Medicaid managed care under Section 1915(b) waiver authority and Section 1115 waiver authority. These services are also optional under state plan authority. States can enroll these populations, but it has to be at their option.

Because of the variation in scope, the administrative burden required to implement each authority

also varies. For example, the time required to implement Medicaid managed care under a Section 1915(b) or state plan authority is more predictable because of the 90-day clock required for CMS approval. The budget or financial requirements vary, too. States provide a budget estimate with a state plan amendment, but must meet cost-effectiveness test under Section 1915(b) waiver authority and a budget neutrality test under Section 1115 waiver authority.

And, finally, the initial and renewal time periods are different under each authority, too. State plan amendments do not require renewal, and Section 1115 waivers can be approved for periods of us to five years. Section 1915(b) waivers can be approved for initial and renewal periods of up to two years, or up to five years if the waiver includes individuals dually eligible for Medicaid and Medicare.

At last month's meeting, I raised some straw man proposals for you to consider. Based on your debate at that meeting, we've refined the language and developed a rationale for you to consider. The three recommendations I am about to present are separate and not mutually

exclusive. I'll present the recommendations and rationale and then leave all three up for your reference as you weigh the merits of each recommendation.

So the first recommendation: Congress should amend Section 1932(a)(2) to allow states to require all beneficiaries to enroll in comprehensive Medicaid managed care programs under state plan authority. This would allow states to mandate Medicaid managed care enrollment for all categories of beneficiaries under state plan authority, including individuals dually eligible for Medicaid and Medicare; American Indians and Alaska Natives; and children with special health care needs.

Under current Medicaid program rules, states can and do require these sub-populations to enroll in managed care under Section 1915(b) and Section 1115 waiver authority. In fact, in fiscal year 2013, over 1.7 million dually eligible beneficiaries were enrolled in comprehensive Medicaid managed care programs. Also enrolled, about 235,000 American Indian/Alaska Natives, 400,000 foster care children, and over 825,000 children eligible for Medicaid based on an SSI determination.

The rational reflects the Commission's view that

Medicaid managed care has matured and become a conventional approach to providing Medicaid for all beneficiaries. States and the federal government have gained experience providing Medicaid coverage through managed care to all populations. As states have gained experience, federal standards were developed for managed care plans to ensure beneficiary access to needed care. Standards have also been established to ensure quality of care and the financial stability of Medicaid managed care plans. These standards have been codified in regulation and provide the federal government with an enforcement mechanism for assuring plan compliance.

So, in other words, the waiver application gives you permission to implement a comprehensive managed care program, but the requirements are the same as they would be under state plan authority.

This recommendation would simplify Medicaid program management for states and the federal government. Moreover, the rationale reflects the Commission's view that, with the additional administrative burden associated with waiver applications, renewals and reporting does not benefit beneficiaries and limits states' ability to pursue

other priorities, such as oversight and monitoring of their managed care programs.

CBO was not able to provide a formal cost estimate in time for this meeting, but based on previous estimates for the reauthorization of dual-eligible special needs plans, or D-SNPs, we can expect that these recommendations may increase federal spending to some extent.

For separate House and Senate bills, CBO estimated that the expansion of Medicaid participation and Medicaid-financed long-term services and supports programs would increase federal outlays by between $119 million to $123 million over a ten-year period.

The effect of this recommendation on states is likely to vary. Some states may choose to continue operating managed care programs under waiver authorities. On the other hand, the recommendation could simplify program administration for some states.

For example, states that operate managed care programs under multiple waiver authorities or multiple different authorities could consolidate under state plan authority.

The effect of the recommendation on beneficiaries is also likely to vary depending on where they live. Many dually eligible individuals, American Indians and Alaska Natives and children with special health care needs are already enrolled in Medicaid managed care, either voluntarily or by state mandate under a waiver.

And lastly, this recommendation is not likely to have a direct effect on Medicaid managed care organizations or providers.

Recommendation 2. Congress should extend approval and renewal periods for all Section 1915(b) waivers from two to five years. This recommendation would call on Congress to change Medicaid statutes such that all 1915(b) waivers could be approved for initial and renewal periods for up to five years.

The recommendation would simplify program management for states and CMS. First, there's already a precedent for longer approval periods. Section 1915(b) waivers that include individuals dually eligible for Medicaid and Medicare can be approved for up to five years.

Moreover, the approval period for Section 1915(b) waivers is short relative to other authorities. Section

1115 waivers can be approved for up to five-year periods, and state plan authority does not expire.

Reducing the burden associated with renewal applications could allow states and the federal government to focus their efforts on managing and monitoring these programs.

The Congressional Budget Office estimates that this recommendation will not affect federal Medicaid spending.

This recommendation is likely to simplify waiver administration and reduce burden for renewals for states that operate Section 1915(b) waivers that do not include dually eligible individuals.

And the recommendation could increase program consistency for waiver enrollees. States may be less inclined to change program specifics like benefits or eligibility requirements if the renewal periods were stretched out further than two years.

Finally, extending approval periods for Section 1915(b) waivers would ensure the plans and providers currently participating in a Section 1915(b) waiver could continue to provide services to waiver enrollees without

disruption.

Recommendation 3. Congress should revised Section 1915(c) waiver authority to permit Section 1915(c) waivers to waive freedom of choice and allow selective contracting.

Under current law, states must complete separate waiver applications to operate a single home and community-based waiver program if the state selectively contracts with a single entity to operate that program or if a state wishes to waive statewide-ness or comparability. Each waiver, Section 1915(b) and Section 1915(c), has separate reporting requirements. Moreover, the separate waiver authorities may not always be aligned in terms of their timing. Waivers can have different effective dates, different due dates for quarterly and annual reports.

The recommendation would add two Section 1915(b) authorities that are not already included in Section 1915(c) authority. This would simplify program administration for states and the federal government by allowing states to submit a single application rather than two and streamline the reporting requirements.

This recommendation also calls for CMS to

consolidate program rules such that beneficiaries retain the protections currently assured under both waivers.

The rationale reflects your comments from October, and that it does not preclude state's ability to operate and pursue home and community-based waiver service programs under Section 1115 waiver authority. Rather, there are distinct features of each approach, both Section 1115 and Section 1915(b), 1915(b)/(c) waivers that allow states to pursue different policy goals.

The Congressional Budget Office estimates that this recommendation will not affect federal Medicaid spending.

The recommendation would simplify waiver administration and reduce administrative burden of renewal applications for states that operate concurrent Section 1915(b) and (c) waivers, and in terms of the implications of this recommendation for enrollees, we anticipate that simplifying the application progress could create some incentives for states to pursue home and community-based programs. However, it's more likely that permitting states to waive freedom of choice and selective contracting under Section 1915(c) waivers would not have a direct effect on

Medicaid enrollees. Moreover, this recommendation calls for CMS to consolidate all program rules without reducing or eliminating assurances of access and quality made under each authority.

And finally, permitting states to waive freedom of choice and selective contracting under Section 1915(c) waivers would not have a direct effect on Medicaid managed care plans or health care providers.

I'll close here. I'm looking forward to your comments and thoughts on the chapter. Again, does it address the major points? Do we strike the right tone, and have I characterized your comments and the Commission's views accurately?

And I also look forward to your comments on the draft recommendations and the rationale. Do the recommendations and rationale also capture your thoughts from our previous meetings and discussions?

And with that, I will close.

CHAIR THOMPSON: Let me open it up for conversation.

I'll say, just to kick off, I think this is very helpful. I think it follows on our earlier conversations.

No doubt, there would like to be some -- we'll have the discussion that we'll have here, but I think you've done a good job of capturing what we last talked about and what we last contemplated in terms of potential recommendations.

I did want to ask one question, and then I've got Darin, who is going to jump in first, I think, Chuck, Sheldon, Bill.

In a couple of points -- and we sort of touched on this last time -- we talk about the idea that CMS has moved to create a regulatory framework that is not specific to authority, that it's about managed care, and it's about delivery. We also, a couple of meetings ago, talked about the fact that the administration, as is very common for new administrations, is taking a look at that regulatory framework.

So I just put it out for the Commission to discuss whether or not we want to -- if we proceed with these recommendations, to say something about -- not that it presupposes all the details of the current regulatory framework, but that it reflects an understanding that there is a desire to have an oversight mechanism, responsibilities and accountability mechanism that is not

specific to individual authorities. Even if we don't have 1915(b)'s in the future for comprehensive managed care, we would still have 1115s. You would still have SPAs. You would still have the opportunity to attach new terms and conditions under 1115s and so forth.

So to the extent that we think that is a part of the environment in addition to state's experience with managed care and the consistent performance and delivering managed care, then I think that's something we should discuss, whether that's a reference point that we want to make in the context of these recommendations.

All right. Darin.

COMMISSIONER GORDON: Echoing Penny's comments about well done, I mean, I think these are good recommendations, particularly looking at it with my prior state Medicaid director hat on. Sometimes it was hard to reconcile why you had to go down different paths to get to the same result and the complexity that came with that, and talking to other states as well as they were exploring managed care, heard some of that frustration about, as you talk about different reporting of -- different renewal periods and just managing that whole process, which not

everyone did all that well.

So I think simplifying the process, simplifying the authority is a good step in the right direction. So I just wanted to say thank you for pulling this together.

CHAIR THOMPSON: Sheldon.

COMMISSIONER RETCHIN: I guess one comment, and then maybe so I can clarifying what my understanding is.

The only comment I have is that only in America could streamlining cost more money. God bless America.

As I understand this, this is sort of -- we're moving away, as Darin just said, from a federalist view of the Medicaid program, just with this modest move to give states more flexibility.

So a state can choose not to mandate. So we're not mandating the mandate, so that the cost estimated by CBO, which should be followed by a pretty strong statement, that we're not taking into account the administrative savings at the state level. So that's not an offset, but that is something that -- so I just want to be sure to clarify that.

CHAIR THOMPSON: All right. So I have Chuck, Bill, Brian, Toby, Alan, Marsha, Martha. Okay. Thank you.

COMMISSIONER MILLIGAN: All aboard the bus.

Good job, Ben. A couple comments about the chapter. I think one of the things that would be helpful is to contextualize for the 1115s how many of those 1115s would still have been necessary, but for the managed care delivery system component, because a lot of times, there's lots of other stuff that are being demonstrated that require waivers. And I just think that we should tease apart the issue of a potential recommendation about not needing an 1115 authority from the fact that a lot of those 1115s would still be pursued by those states for other reasons. And I think that we need to make it clear that the public comment period, the public participation for those 1115s that have other design demonstration components would still have been required, however this recommendation shakes out.

The second thing for the chapter is sort of -- I'm going to give you the Native American and New Mexico kind of -- and my background piece of this. People can sometimes confuse IHS or ITU providers as being coverage. It's not coverage. It's a provider, and the way it works congressionally is funding is appropriated to those

providers. It's typically insufficient to cover their services for their catchment area, and so then they're required to go bill insurance companies to make up the difference.

But going to IHS isn't insurance coverage, and so I want to -- and it's a safety net provider. They get an appropriation. They need to bill insurance, and that's not coverage to me in an insurance sense. So I just think that we have to be careful in how we characterize that.

Lots to talk about with the recommendations, but I just wanted to kind of contribute that part for the chapter itself.

CHAIR THOMPSON: Bill.

COMMISSIONER SCANLON: Thank you.

Let me start by saying I'm in favor of sort of reducing administrative burden. I would guess I would characterize it more in the sense of improving efficiency, that we've got limited resources in which to manage these programs, and that they should be directed where they're going to be most effective. So something which is not going to do that, we really need to think about how can we modify that.

And in that spirit, I mean, the second recommendation just almost seems like it's clear-cut. Why wouldn't you take this longer period instead of repeating paperwork every two years?

The first one is also moving in that direction, but I have some concerns about it, and the question is whether or not sort of the rationale is strong enough to sort of justify it.

And the concern starts with the overall patient population. As you all know and have heard many, many times, there's about 1 percent of the people account for 20 percent of spending. Maybe 5 percent of people account for close to 50 percent of spending.

The reality is the population is incredibly heterogeneous. There are people that are very sick, and they sort of are the ones that need to be sort of a primary concern. And they're also the ones -- I mean, when we think about a quality mechanism of using complaints, they are the ones that are least likely to be able to use that as a mechanism to improve their care. We start there, I think, in my mind, and the question is, Are we doing enough to target people that are in greatest need?

The groups that are being excluded, maybe you sort of could think of them as an attempt to move there, the duals in particular, and children with special needs. I think it's, in some respects, revealing that disabled adults are not in that group, and who is going to be in that population in Medicaid? People that are in their waiting period before they become Medicare-eligible, and then people that are never going to qualify for Medicare who may be sort of a very vulnerable population that we should sort of be thinking about?

I start from this perspective of sort of who is being affected when we talk about changing the criteria for -- or changing the rules for dealing with sort of these groups of people.

In terms of the rationale, we sort of have reached a point of maturity with respect to sort of managed care. That to me is not sort of a strong rationale.

My sense is we never reach a point where we can reduce our vigilance. We've been doing with hospitals, physicians, skilled nursing facilities since time immemorial, and yet the need for oversight remains, remains strong.

GAO -- I guess this maybe 15 or more years ago -- designated Medicaid as a high-risk program. I was there then, and I don't think we ever believed that we would not designate it as a high-risk program. It's too expensive, too complicated. It always needs sort of to be sort of monitored carefully, and we don't have the resources to monitor it very carefully.

The second part of the rationale, our standards are now sort of uniform across the different authorities, again, sort of is not necessarily a sufficient rationale unless those standards are targeting -- and this is potentially a question -- are targeting groups that would be most vulnerable. If they are, then it does not make a difference.

But in requiring a separate waiver for these groups, we're calling attention to these groups. We're calling for monitoring of these groups, and so I think the issue is even though that is an incredibly second best approach, should we be thinking about sort of getting -- eliminating it now before we're comfortable with the standards really sort of targeting appropriate measurement and oversight of vulnerable groups within an overall

population.

Thanks.

CHAIR THOMPSON: Thanks, Bill.

A couple of things, and I'll be interested in the other Commissioners' view of this, which is I think you could say a lot of what you just said about fee-for-service, which we don't require any kind of special waiver for. To some extent, I think the issue is what are we doing to really ensure that those vulnerable populations are receiving the care that they need, and that is true, whether somebody is in a fee-for-service system or in a managed care system.

So I think maybe one of the ways to answer the question that you're asking is that we really should, instead of spending time on some of these activities between the federal and the state government, be directing our resources and our care and attention to that question in a substantive way.

A state that wants to move to managed care for those populations will be able to do so through a 1915(b).

I think the information that we've collected doesn't suggest that the 1915(b) authority itself provides

the protection that you're suggesting that we need to be thinking about.

So I'd be interested in some other perspectives on that question, but I think that's an argument for why, instead of spending time on the 1915(b) process, that the mechanism for overseeing care -- and not just in managed care, but in fee-for-service as well around these populations is so important.

COMMISSIONER SCANLON: Two things in response. One is, again, I'm sort of recognizing that the 1915(b) is potentially second best, and maybe we shouldn't -- I mean, the term "second" implies much more than it deserves because of the fact that it really may be sort of very weak, but it's potentially better than sort of nothing. I mean, that's sort of the point.

And I'll just say, I'll go on the record, if you've looked at what I've done over my time in health policy, I have never been kind to fee-for-service when there's been problems in fee-for-service. And it's both a question of dealing with individual providers -- and then there is an issue of the Medicaid policies. Are we depriving people of access just because we're simply paying

too little? That should be a focus and concern to.

CHAIR THOMPSON: Toby, Alan, Marsha, Martha, Brian -- oh, Brian. Sorry. I skipped over you. Start with Brian. Brian, Toby, Alan, Marsha, Martha.

COMMISSIONER BURWELL: So I want to focus on Recommendation 1 and being clear what we're considering here. So the recommendation, as written, is to allow these populations who are currently excluded from being able to -- states being able to enroll in mandatory managed care now could be -- could enroll in Medicaid managed care. And the primary population is duals. I just want to be -- but there's also, within the chapter, we want to exclude MLTSS services from this recommendation.

I don't see a whole lot of difference, I think. Medicaid spending on duals in 85 percent long-term care. You know, the rest is Medicaid cost-savings programs, copays, deductibles, et cetera, and a very small percentage of expenditures for services that Medicaid does not cover. So we're pretty much talking -- you know, there's no real reason to say let's put duals in managed care except for LTSS. That doesn't really make a whole lot of sense to me.

I don't buy the argument that we should exclude

MLTSS from this recommendation, based on lack of experience. Over about half the states have done it. I think there's a lot of experience that states have with MLTSS. I think there's a good body of knowledge and there really hasn't been any kind of major negative findings from the evaluations that have been done to date. So I would advocate for including MLTSS.

I also want to make clear that it appears to me that Recommendation 1 gives states the option of enrolling these populations in a comprehensive managed care program, but, from the state flexibility side, the B waiver doesn't go away. You can still use a B waiver to waive other components of Medicaid state plan requirements around statewide, et cetera. So if a state wanted to target certain populations for managed care or do something less than statewide, they could still use the B authority in that instance. So it's not like we're getting rid of B waivers, is my understanding. So that, you know, when we discussed Recommendation 1, those are the kind of things that I think get into play.

A second comment is, given all the activity in CMS around increased flexibility and administrative

streamlining around 1115s, et cetera, that have just come out in the last few months, I think we should acknowledge that in the contextual basis in this chapter. We really didn't have that information in October when we discussed this previously, and we should really kind of discuss our recommendations within the context of these other -- you know, the path that the administration is going down on the same issues.

CHAIR THOMPSON: I think Anne wants to jump in.

EXECUTIVE DIRECTOR SCHWARTZ: Yeah. I just wanted to clarify, to your first comment that you started making, Brian, I do think the issue of whether this recommendation is for comprehensive managed care only or LTSS is certainly something that the group can discuss. The staff took a little bit more, sort of a more conservative approach. But I did want to clarify, to your point of why would you do it if it didn't include LTSS, and the answer to that is many states are doing it now. So it's not like this is in states where there is no managed LTSS. So they are doing this. This is simply -- would be shifting it from one authority to the other, and I just wanted to clarify that it's not a hypothetical situation.

It is a real situation.

CHAIR THOMPSON: Toby.

COMMISSIONER DOUGLAS: Really good job, Ben, on these recommendations and the work. So first I just want to agree with Penny. I think the construct of the recommendations is really important that it is around foundational, around the protections, the oversight, the monitoring that exists, and that the recommendations could change if there is changes to that overall structure of how managed care now is in this framework of oversight and monitoring, both from a federal and state level.

I would say, you know, from being on the other side, as a state, really, there isn't, you know, difference in terms of the B waiver or the 1115 or the state plan amendment from the perspective of the monitoring and performance after that. There is definitely more, you know, stakeholder input on the front end on a waiver process, but in terms of if a plan is out of compliance, regardless of what, you know, pathway, there is corrective action, there is ability for CMS to come in.

And so it is just, you know, a question of, oh, we've created just a bureaucracy for the sake of, you know,

bureaucracy, or, you know, created, at the time, more ability for transparency for stakeholders. But then again, the framework now adds a lot more opportunity through the managed care regulation.

So, you know, I definitely feel like we should be moving forward with this. And on terms of the point on MLTSS, I agree with Brian. You know, this should be -- I find it hard to say that's one group that shouldn't be in it, but we are going to put others, like special needs, or the IDD population. I think there's enough -- again, back to the starting point of the framework and oversight, and enough evidence of MLTSS that it should be part of the SPA process.

I also, you know, for the record, think part of the reason why CBO is showing the additional cost is it's not taking into account the fact that if we had integrated a program between the D-SNP and MLTSS and shared approach for integrated savings across the two programs then it wouldn't cost as much. And so that's not -- it's just becoming two separate programs that are growing, rather than a realization of ability to coordinate and integrate and cut down on the costs on side or the other.

I also do think it's important to think about the SPA option in the event a state doesn't want to go statewide. There are plenty of SPAs, whether it's the health home or others, that don't have to be statewide SPA, so that that should be part of it. It shouldn't suddenly, now, require a B waiver for that.

So those were the main points. Thank you.

CHAIR THOMPSON: Alan, Marsha, Martha.

COMMISSIONER WEIL: Both of my reactions have already been stated but I just want to put my thumb on the scale for the two of them, primarily, depending exactly where you started, around the role of the regulatory regime. I think we need to be very strong in this area. I don't think we have to embrace the regs are currently written. That's not our role. But the notion of sort of relying on a statute -- endorsing a statutory change without it being clear that there needs to be a comprehensive, unified regulatory regime behind it I think would be a huge mistake. And so I wanted to be very clear on that side.

My second reaction is I want to align strongly with Bill Scanlon's comments regarding the rationale, and,

Penny, I'm going to differ, I think, a little with you. Maybe it's just a matter of emphasis. But I don't have any -- there's no question we have to do monitoring on fee for service as well as managed care, but the opportunities for mischief and the incentives for mischief are different in the two systems, and to sort of say, well, because we have to do it there, we don't need to call it out here, I think if we're speaking to managed care we do have to call it out here.

And so I would be hesitant to say that the rationale is this is mature and therefore everything is -- not to worry, which isn't exactly how you said it, but it does comes across to me a little bit that way, as to say, really, precisely what Bill did, which is we're trying to do some administrative simplification here and it doesn't help to have these administrative hurdles if you can do it anyway. But I think that's -- I would much rather emphasize that than some sense of because this is mature, you know, there's no need to worry, because I just don't think that's true.

CHAIR THOMPSON: I think that's a good segue for you, Marsha.

VICE CHAIR GOLD: Yeah. Thanks. You know, I've been studying managed care for ages in Medicaid, and I'm a supporter of it. I think that well done it has the potential to really coordinate care and be patient-centered. On the other hand, there are tremendous instances where, when there isn't a good regulatory framework or people don't have experience, or they take shortcuts, some big harm and scandals can happen that actually it hurts the managed care industry as well as beneficiaries and the program.

So I'm not going to repeat some of what Bill and Alan said. I am aligning myself with them. And just as a statement, I mean, I think the reason we're focusing on one is, from my perspective, I think Recommendations 2 and 3 are more straightforward, and I don't really have anything to say to them. I think, unless I hear something else, I'm supportive of them.

But I think 1 is a more complicated issue, and part of my concern, aside from the way Bill eloquently described things generally, is despite the managed care experience there is also considerable variability across states. And, you know, there are a number of states that

have absolutely no risk-based comprehensive managed care experience. There's some that have just a little, or maybe they've just had it on women and children. And so this doesn't recognize a state flexibility but it doesn't distinguish, I think, as it might, between states that have years of experience, like Arizona, running a managed care program that has, you know, everyone in it, and has done well, and there haven't been, you know, complaints and other things, and a state that has very little experience that, particularly, if they were budget constrained and they could put a -- you know, a state plan amendment might be tempted to rather than work on a managed care strategy basically capitate and offload the risk to someone else with some pretty vulnerable populations. So that's where I'm concerned.

I do think that regardless of whether waivers are effective, ineffective -- and I sympathize with the regulatory -- with the administrative burden that they create for states, and I have sympathy for the fact that there's a lot of paperwork associated with them -- I do think that, in my experience, it gets public attention when someone submits a waiver, and public attention, and getting

the advocacy groups and other people in is often important to thinking through whether the appropriate attention has been paid to coordination for special needs kids or for other things. So I have concerns with Recommendation 1.

I wanted to comment on the duals issue as well. I know, because Anne shared the data with me, that there are states that do this for acute -- I don't understand what capitated comprehensive capitated managed care is for dual-eligibles without the MLTSS, because -- especially if it allows still the Medicare freedom of choice. I mean, 80 percent, 90 percent of the funding on acute care is Medicare, and how do you comprehensively manage something when you're not dealing with that issue? And so I think there's good reason on the acute care side to, you know -- until we can get the Medicare-Medicaid stuff sorted out, there's a concern.

I have some sympathy for trying to deal with the managed long-term care part and make that work with the acute care side. I'm a little bit -- I don't know that this is the right vehicle for doing it. There was a proposal that CMS has had, that's out for comment, that I think staff shared with us, on the D-SNPs and trying to

work the duals out. It seems that until we can deal with Medicare and Medicaid on the acute care side, it's hard to sort out how you manage the two together. But there is more logic for managed care on the -- you know, the chronic care, but I can't see you doing it for the acute care.

So, anyway, and then the only final thing, which is sort of a speculation, is I'm not sure what CBO cost estimates you're looking at, but it's possible that if they were dealing with D-SNPs, a lot of the reasons that the cost costs more is because historically MA has cost more than Medicare fee for service. And so I'm not sure whatever you're thinking -- I'm not sure it would increase costs, but I do think it would have an effect on plans and providers. I don't think you can say not if you're moving to managed care, because they're going to do something differently.

CHAIR THOMPSON: Okay. I think, Darin, did you want to jump in before we turn to Martha?

COMMISSIONER GORDON: Yeah, only because it's come up a couple of times, and Marsha brought it up again, is, you know, about the populations, I mean, about, you know, whether LTSS should be in there or not. You know, I

could go either way. I think the thing that, on number 1, in particular, is everything you write, bring up about the different populations, a state can do today. We just make you go through other hoops to get there.

With regards to oversight, and, you know, back to Alan's point, and, you know, that -- you know, regardless of the vehicle, there's a managed care regulatory construct that will apply to all -- that oversight is still there as well. You know, and I may just be -- I'm just saying this from a person who ran these programs. I didn't get treated -- anything that was done through the state plan didn't mean I didn't have to deal with CMS. If it did, you would have seen, you know, Tennessee drastically move to --

VICE CHAIR GOLD: Did you have to deal with beneficiary advocate groups as much?

COMMISSIONER GORDON: Yeah. I mean, there's nothing you could do that substantial, like you were talking about with regards to a big swing to moving, you know, new populations or new services into comprehensive managed care that we couldn't do, or that we could do without that being in a very public process, going through the legislative process, getting input from advocates and

our medical advisory committee as well, and notice -- and doing public notice that that's the direction we're moving.

So the way that I -- we just talk about some of the populations and ability to adhere, it's like -- it's almost like, yes, because we're holding and coveting the state plan process as something very special compared to the waiver process, and you're basically saying, yeah, you can still do it, guys. Just don't do it through this vehicle. Do this for some populations, go over here and do a waiver for another, and you still are covering those populations.

So I just -- and again, I'm just looking at it as a person who had to make a decision whether we do SPAs or we do waivers, and the point that Chuck made is a very valid one, which, even with that, some states still may choose to do a 1915(b). They may still choose to do an 1115 for different reasons. It just begs the question today -- we have some artifact here on the state plan process that excludes things, that are being done in Medicaid, but in the state plan process we just haven't updated the authority to allow it to be done via that vehicle.

CHAIR THOMPSON: Kit, did you want to -- you were trying to jump in ahead of Martha, but I think --

COMMISSIONER GORTON: I just want to quickly --

CHAIR THOMPSON: -- you're trying to jump in on the same point, so we --

COMMISSIONER GORTON: -- align myself with --

CHAIR THOMPSON: -- can keep this string going.

COMMISSIONER GORTON: -- Darin. The SPA process is a process. I mean, isn't that a slam-dunk? You know, just lick the stamp and then you're done, ready to go? And there's full or more accountability within the SPA authority as there is within the other authorities. So I understand people's concerns, but CMS has more than enough tools to manage them in the 1915(b) waivers and they have more than enough tools to manage them in the SPA process.

CHAIR THOMPSON: Martha.

COMMISSIONER CARTER: Following up on Bill's question regarding monitoring of vulnerable populations, and speaking a bit to the rationale for recommendations and understanding that there's a lot more depth of knowledge on this Commission than I bring, I want to call out the fact that the opioid epidemic has really put a lot of children

in the foster care program that's really straining the states. And I wondered what benefit we know, for -- that has come to those children and to the providers that are caring for them in the states where they've moved them into managed care. And if there is a potential benefit, then call that out as one of the rationales for that first recommendation.

COMMISSIONER GORDON: Toby.

COMMISSIONER DOUGLAS: So I just -- obviously I align with Darin and Kit. I mean, I said all the requests for additional -- as part of the SPA there's a whole request for additional information, RAI, tons of questions, and, you know, a lot of those questions come from CMS but sometimes they come via lots of stakeholders sending information to CMS that suddenly show up in a request for additional information, and that we have to respond to them.

Bu I just wonder on kind of -- Bill and Marsha, what -- if there are pieces of the 1915(b) that aren't in the state plan amendment or in the current regulatory, if we add those in as recommendations, if there's some type of stakeholder process that isn't there, but I just wonder,

for highlighting certain monitoring. I mean, we're trying to streamline and create efficiencies around the process but not degrade the oversight in monitoring.

So I just wonder if there's some ability to thread the needle here, where we're not keeping two separate processes but if there are pieces that are not redundant in the 1915(b) that we could incorporate in. So that -- it would be like, is there a way now or if we think, as we go forward to --

CHAIR THOMPSON: Would --

COMMISSIONER DOUGLAS: -- highlight those pieces?

CHAIR THOMPSON: -- the statement, I think that was Alan's point, that general statement, which is our intention here is not to degrade the oversight or monitoring associated with these delivery systems, or with these populations so much as it is to streamline the process between the federal and the state governments.

COMMISSIONER DOUGLAS: Yeah, but it's also maybe if there's an up-front -- for example, a comment period, you know, or some just, you know, up-front if there needs to be, to make sure -- things like that, that might be there to allow the transparency that it sounds like Marsha

is concerned about, something like that.

CHAIR THOMPSON: Chuck, did you want to jump in before Bill and Marsha?

COMMISSIONER MILLIGAN: Whenever you want me to jump in.

I was early on the bus, but I was waiting, I guess, until the afternoon to do this part of the conversation.

Two thoughts to me -- and maybe this is kind of the Toby part of it. I'm going to just say having been a state person, I think these kinds of conversations often underestimate. There's so much more advocacy at the state level than these kinds of conversations presuppose. There are these conversations often presuppose that but for the bulwark of the federal government looking out for people, nobody is looking out for people. And I will tell you I've been run over many times otherwise.

So I just want to say that the advocacy organizations at the state level are stronger than you might think -- the appropriations, budget, legislative hearings, state legislators, all that stuff.

To me, the crux of it -- I mean, lots of people

have commented around the federal oversight and structure. If Recommendation 1 were to be approved by this group, there's some degree of reliance on the managed care regulations at the federal level as a framework for protection, and so the question I have, I don't have an answer to, and to me, it's something I will tee up for this afternoon, what does that framework have to look like? Because federal regs change, and so is it the managed care rule as finalized recently? Is it the managed care rule as being reviewed by CMS currently? So to me, the crux of it is to what degree does that framework have to have certain features for this recommendation to have a degree of comfort, and I think that's where I'll leave it for now.

CHAIR THOMPSON: Let me let Bill or Marsha respond to some of what the other Commissioners have said. We're running over time here, and so I do want to make sure that we have an opportunity to pause for public comment, and then we can talk about how we manage this and continue discussion in the afternoon.

COMMISSIONER SCANLON: Yeah. And my concern is really about continuing monitoring. It's not about the initiation of a program, approving sort of the concept, et

cetera. Realize that when you're talking about managed care plans, we're talking about smaller numbers as opposed to when we're thinking about how do we oversee hospitals or SNFs or anything like that.

But there still is the possibility we have what I'll call a rogue plan, one that just is not doing a good job for some segment of the population, and it's that issue of a segment of the population. I want the monitoring to be set up so that we focus on the most vulnerable, and that we're assured that we don't get an average. It's like the student got 80 percent of the things right, but got zero on math. I don't want that situation to be sort of repeated here.

If we can do that in the SPA requirements, we can do that in any one of the waiver requirements, but we've got to do that. That's the key, and right now, I'm concerned that the requirements are set up too generically and that that's what we need to be thinking about. Maybe it's a combination. I'm not sure if it's a second recommendation, but it's the idea that we really want attention to these populations that are vulnerable.

VICE CHAIR GOLD: The one thing -- I don't want

to repeat what Bill said. Maybe this is sort of the context I'm coming from, and it's what Chuck was sort of alluding to, without wanting to say it. We're in an environment where we're not sure what the managed care regulatory oversight will be at the federal level.

Certainly, from just reading the paper across all departments and areas, this is not an administration that puts a high priority on a strong federal role in oversight of policy. We don't know how that will translate. It's too new, but we do know that the regulations are being looked at.

So I'm sort of wondering why it's so important that we give the flexibility in one, given the risks. Part of the issue is there's so few people affected. I mean, there's small subgroups, and I'm not sure how much work they are, and yet there's risks that are quite large. So I'm nervous about that.

In terms of your question, Toby, the thing I actually was thinking of, I'm a lot more comfortable with a state that has a long track record in managed care, that maybe has over 50 percent of their people in there. There haven't been a lot of complaints. I'm more comfortable

with giving them authority, although I like Bill's idea to have more public and monitoring. It should be regardless of authority. It should be there.

But I'm more comfortable there than leaving at least open the possibility that some state that has never done anything, all of a sudden, will do it, and that has happened in the past at times. There have been proposals in Medicare and Medicaid that people have just wanted to do a lot, and depending on the politics in the individual state -- I think in most of the states we're familiar with, there's a lot of pushback from advocates and other things, but some states have more organized consumers than others. And so I'm concerned that states with no managed care experience essentially could just capitate their entire program with relatively little -- if there's not effective oversight.

CHAIR THOMPSON: Darin, did you have a point?

COMMISSIONER GORDON: Yeah.

Marsha, exactly what you just said, states are doing this.

VICE CHAIR GOLD: Some states are doing it. They're not all equal.

COMMISSIONER GORDON: Well, but what I'm saying is the pathway is still there to do everything you just said.

VICE CHAIR GOLD: Yeah.

COMMISSIONER GORDON: So the issue around having an oversight, appropriate oversight, I don't know anybody that's really disputing that.

VICE CHAIR GOLD: Yeah.

COMMISSIONER GORDON: My point is there are vehicles. The issue is whether or not -- are we saying that a great protection here is making them use multiple vehicles to get there versus having a more streamlined vehicle?

CHAIR THOMPSON: Toby?

COMMISSIONER DOUGLAS: I don't understand the problem. Let's just take a two-step. A state that wants to move to managed care, there's going to be tremendous advocacy against that in some cases. So that happens before it even gets to CMS.

But if they get over, if a state is able to coalesce and bring everyone together, then it gets to CMS. It never gets stopped at that point. It's either a (b)

waiver or -- so we're not stopping anything. We're just creating bureaucracy at that second step.

The first step is really about what goes on in the state and the dynamics of the stakeholders and the ability to either support or shape a policy around managed care.

CHAIR THOMPSON: Here's what I want to suggest that we are going to do.

First of all, it sounds like we have a lot of folks kind of ready and comfortable with Recommendations 2 and 3. So I want to see if I see any frowns or faces that dispute that.

The issue of No. 1, it sounds to me like we have three things to talk about in terms of getting this to a place where we can vote on a recommendation. One is addressing MLTSS. Is this in, or is this not in? It sounds like that's something that we should have a little bit more conversation about this afternoon to see if we can resolve that question satisfactorily to ourselves.

The second, I think, is this issue -- was it Brian who brought this up? -- about statewide-ness. I think that's a relevant question, too, to bring forward

with regard to No. 1.

And then the third is, is there anything that we can say today about our expectations with regard to oversight and monitoring that formed the framing around the understanding of why we're making this recommendation either as a general statement or a general expression of interest or attention as an ongoing matter from the Commission as we delve into some of these matters in more detail in the future, as the agency may take certain decisions or actions in the future, et cetera?

So those will be, I think, the three things that we'll try to spend a little bit of time talking about this afternoon before seeing if we can move ahead on a vote on all three or on just 2 and 3, if we feel like we need a little bit more time for those discussions.

Let me be sure that we pause for a second and allow public comment. So if there are any observations or comments from the public, that we can also take those into view this afternoon -- and by the way, invite any of the earlier conversation that we had as well.

PUBLIC COMMENT

* MR. MYERS: Thank you all for allowing me a

moment to speak.

My name is Jeff Myers. I am the CEO and president of Medicaid Health Plans of America. Our association represents plans that take full risk in the Medicaid space, and our members cover greater than 44 percent of all the managed care lives in America, in 39 states and the District of Columbia.

Our members include multistate, for-profit insurers with Medicaid lines of business, nonprofit, single, and multistate insurers, BlueCross BlueShield plans, community safety net plans, and quasi-governmental entities that are county-owned plans or behavioral health plans.

All take full risk in the populations that they cover in the Medicaid space and then joined MHPA because we are the only trade association that focuses solely and only on Medicaid.

I wanted to take a minute to chat with you about the Medicaid Drug Rebate Program. Our belief is that the MDRP, as it exists today, is outdated. It is not particularly efficient, and it now actually acts to drive up overall drug cost. It should be reformed using the

power of Medicaid plans and the massive changes that have happened in the Medicaid program.

In 1990, when the MDRP was enacted, Medicaid covered only 1 in 11 Americans, and of those covered, only 8 percent were in full-risk plans. That is not the case today.

As a result of the ACA, which MACPAC knows well, over one in five Americans receive their health care via the Medicaid and CHIP program, and more than 73 percent of those are in comprehensive full-risk plans, like the ones MHPA represents.

Given this, why should we continue to use a top-down state-driven model that does not leverage the value of these significant and fundamental changes? Why should we view providing outpatient drugs as an ancillary benefit and not as one of the core services that drive better health outcomes?

While the outpatient drug benefit is, in fact, voluntary, every state offers it because of its importance, and yet it is still not fully integrated into a comprehensive capitated model of care.

MHPA suggests -- and I heard one of the

Commissioners mention earlier -- that MACPAC look at the success of the MA/PD program as a construct for how to wrap this important benefit into a meaningful program enhancement. Under this model, incentives would be aligned to drive better care at lower cost to Medicaid enrollees.

Under the current MDRP, the rebate, whether applies to generics or branded medications, is actually a pay-to-play tax that life science manufacturers built into their pricing model. I know because I was in the pharma industry for 10 years.

Given the massive growth of Medicaid, pharmaceutical and biotechnology creators have every incentives to price as high as they can and avoid offering rebates above their calculated AMP or best price. This drives up the top-line cost of drugs to everyone, while reducing manufacturers' incentives to provide additional rebates. This is saving no one money, regardless of the total rebate that the government will claim under the MDRP program.

Under MDRP, the life sciences company pay the state a quarterly rebate. Government money is fungible, and those dollars don't really get recycled into the

Medicaid program. The encourage states to use higher-cost drugs to drive bigger rebates than they can use in other programs, and you don't have to take my word for this. A peer-reviewed study published in the Academy of Managed Care Pharmacy compared two real-world states before and after the imposition of a statewide formulary. It showed a 33 percent increase in drug spend and far greater utilization of branded drugs, even when generics were available.

Look at MACPAC's own data. The gross to net is significantly higher in fee-for-service than managed care because of the overall utilization of higher-cost drugs driven by rebate calculations.

Under MDRP, value-based purchasing arrangements are a mirage. CMS has provided no meaningful guidance to a life science company about how to design value-based purchasing arrangements that do not meet the risk of increasing their best price rebate should they not meet the goals of their VBP contract. All of the contracts of which I am aware are under their current AMP or best price.

The Department of Justice is currently looking at blended rate agreements over multiple therapeutic lines to

ensure appropriate allocation to each indices' AMP calculation. Life sciences company and managed care plans are obviously very weary of pushing the envelope to share risk and provide greater rewards for success if this risk taking leads to financial punishment later.

Lastly, under the MDRP and new managed Medicaid regs, plans have little ability or less ability to control drug utilization in a manner that drives better outcomes like they do in commercial or the Medicare space. This is tragic because the plans have invested significantly in creating care management programs that bring better outcomes at lower cost. Integrating the outpatient benefit into a comprehensive capitated model will drive down cost.

MHPA will be happy to provide greater detail to our suggested changes to 1927. In short, using an MA/PD model administered by the plans on behalf of the states will create better care for enrollees and promises to save tens of billions of dollars to the program. Again, do not take my word for this. The National Bureau of Economic Research, which is not funded or collaborated in any way with MHPA, released a recent working paper that suggests at least $22 billion would be saved by moving the outpatient

drug benefit into the MCO model.

So I am delighted that you all are looking at drug pricing and the challenges that Medicaid and Medicaid plans face. It is a very important issue to the plans, and anything we can do to help, we are delighted to do so. So thank you for giving me a couple moments of your time.

CHAIR THOMPSON: Thank you very much.

And I hope you will follow up and submit anything in writing that you have, so that we can study your commentary in more detail.

Any other public comments?

[No response.]

CHAIR THOMPSON: All right. We are adjourned and will be back at one o'clock.

* [Whereupon, at 12:25 p.m., the meeting was recessed, to reconvene at 1:00 p.m., this same day.]

AFTERNOON SESSION

[1:10 p.m.]

CHAIR THOMPSON: Okay. We have Madeline and Chris, who are going to give us MACStats highlights. So you can't get any more exciting than that.

VICE CHAIR GOLD: Absolutely.

HIGHLIGHTS FROM MACSTATS

* MR. PARK: Thank you, Penny.

MACStats is one of our major publications each year, and it compiles data on Medicaid and CHIP from a variety of sources, including federal and state Medicaid administrative data, federal and state budgets, and national surveys.

We look at these data periodically throughout the year, and as more recent data become available, we post them on the MACPAC website, and at the end of the year, we publish the collective set of exhibits together in a single publication. This published data book for 2017 will be released next week.

I'd like to acknowledge the contributions of the entire staff, particularly Jessica Morris and Martha Heberlein, as well as Kathy Ceja and Angelica Hill, for all

of their hard work in the production of this book.

I will now turn it over to Madeline to present some of the highlights from this year's MACStats.

* MS. BRITVEC: Thank you.

MACStats is comprised of five sections and a technical guide. Today's session will review some key takeaways from each of these sections. Additionally, due to the transition from MSIS to T-MSIS, for six exhibits in MACStats we report FY2014 MSIS data for 26 states as the B tables, and then we also updated FY2013 data for our A tables.

MACStats includes an additional table, Exhibit 23, on Medicaid benefit spending for full-year equivalent enrollees, for newly eligible adults, and all enrollees by state for FY2016.

Over 25 percent of the U.S. population was enrolled in Medicaid or CHIP for some portion of the 2016 fiscal year. Eighty-two million were estimated to be enrolled in Medicaid and approximately 9 million in CHIP. Medicaid's share of the state budget was 15.8 percent; whereas, elementary and secondary education held a greater share at 24.1 percent. Similarly to 2013 and 2014,

Medicare held a greater share of the national health expenditures at 20 percent compared to Medicaid and CHIP's, 17 percent. However, private insurance still continues to hold approximately a third of all national health expenditures.

This slide shows the major components of the federal budget as a share of the total federal outlays from fiscal year 1965 when Medicaid was first implemented to 2016. As you can see, Medicare and Medicaid have grown over time, but Medicaid has continued to attribute a smaller share to the federal outlays, and fiscal year 2016 is no exception. Together, Medicaid and CHIP account for 10 percent of federal outlays compared to Medicare that contributes 15 percent.

Medicaid and CHIP had an enrollment growth of 0.9 percent from July 2016 to July 2017 after experiencing high growth rates from 2013 to 2015. Enrollment trends always have varied based on eligibility group. For example, children experienced the largest absolute increase since 1975 at an increase of about 21 million additional children, but those eligible on the basis of disability quadrupled over these four decades.

This next graph illuminates how the trends in spending growth are complemented with the full-year equivalent enrollment growth. The trend lines for spending and enrollment run roughly parallel to each other, particularly during the expansion and recessions from 1986 to 1991, 2000 to 2003, as well as 2008 to 2010.

Medicaid's portion of the state budget depends on whether or not federal funds are included. When including federal funds, Medicaid is about 28 percent of the overall state budget. With just general funds included, as in what states raise through taxes or other means, Medicaid was approximately 20 percent of the state budget. And when just including state funds, so Medicaid and health-related providers taxes as well as local funding, Medicaid is approximately 16 percent. There was an increase in Medicaid spending in 2014, the bulk of which is shown through federal funds, mainly because of the newly eligible adult group, the adult population receiving 100 percent of the federal match, which is displayed on the exhibit. You can see that the top dark line, which includes federal funds, increases; whereas, the bottom two lines plateau.

Use of managed care continues to grow as well.

Spending rose on capitation payments for managed care to 46.3 percent in 2016, and enrollment in comprehensive managed care increased as well, from 60 percent in 2014 to 65 percent in 2015. Those eligible on the basis of disability and age 65 and older accounted for a quarter of enrollees, but two-thirds of program spending. Net drug spending increased by 15 percent over the last fiscal year, and drug rebates reduced gross drug spending by over 50 percent.

On this chart, the differences in spending categories vary by eligibility group. You can see that for those eligible on the basis of disability cost on average over $18,000 per enrollee, and average spending for those age 65 and older cost on average over $15,500. On average, those eligible on the basis of disability cost six times that of a child and four times that of an adult.

Another important aspect of this slide is the difference in service mix. You can see that the majority of spending for those eligible on the basis of disability and those age 65 and older went towards LTSS; whereas, the majority of spending for children and adults went towards managed care.

As previously mentioned, MACStats included an additional exhibit this year presenting Medicaid benefit spending per FYE enrollee for newly eligible adults in fiscal year 2016. Of the 75 million FYE enrollees, 11 million, or 15 percent, were newly eligible adults, and on average, spending per FYE enrollee among the newly eligible population was less than the average spending per all enrollees.

So, overall, eligibility criteria remained stable between 2016 and 2017. The National Health Interview Survey reported that in 2016, 42 percent of those enrolled in Medicaid or CHIP have an income below 100 percent of the federal poverty level, which was about $11,900 annually in 2016 for the lower 48 states, and that number has increased to just over $12,000 in 2017. In 2016, over 60 percent of Medicaid or CHIP enrollees have incomes less than 138 percent of FPL. Additionally, more than half of states covered the expansion adult group up to 138 percent of FPL, which was about $16,600.

Section 5 of MACStats focuses on access to care through utilizing survey data. Six exhibits use the National Health Interview Survey data, and two use the

Medical Expenditure Panel Survey data. From these exhibits, we found that children and adults were less likely to be in excellent or very good health than those under private insurance. Children reported seeing a general doctor more than those who were uninsured, but at slightly lower rates than those who were privately insured.

Overall, children and adults covered under Medicaid report having a usual source of care at a slightly lower rate than privately insured individuals, but were more likely to experience access barriers, particularly in the form of delayed care or trouble finding a doctor.

And this concludes our presentation. We look forward to releasing MACStats.

CHAIR THOMPSON: Thank you. We look forward to its release as well.

Any questions?

[No response.]

CHAIR THOMPSON: Okay. Thank you -- oh, Marsha?

VICE CHAIR GOLD: The usual-source-of-care question, is that with or without including emergency room? If I'm remembering how the survey question is structured.

MR. PARK: I've been notified that it is without

emergency room.

CHAIR THOMPSON: Okay. Thank you very much.

So we're going to have Nevena Minor and Joanne Jee talking about telemedicine.

REVIEW OF MARCH REPORT CHAPTER: TELEMEDICINE IN MEDICAID

* MS. JEE: Okay. So, Commissioners, you will recall that in September, we presented you with some background information on the coverage of telemedicine in Medicaid. Your charge to staff following the presentation was to develop a descriptive and foundational chapter on this issue, and that is what we are presenting to you today. And the chapter really sort of at a high level talks about the very basics of telemedicine coverage in Medicaid, and it also highlights considerations for its use.

Since September, we've done a little bit more digging into the literature that's out there on telemedicine, and there's a lot. And we also had the opportunity to speak with a handful of states to get their points of views and insights, and those views are sort of built into the chapter. You know, we don't necessarily

call out those states specifically, but they are accounted for.

So Nevena and I will go ahead and highlight the key parts of the chapter, and we look forward to your feedback on the chapter, and any sort of specific ideas you have for improvements or changes would be welcome.

Okay. So the chapter, which is in your meeting materials -- I think it's behind Tab 6 -- again, is a fairly high level overview of this issue. We cover a lot of ground in the chapter in terms of the number of topics that are covered. The chapter is organized into the sections that are listed on the slide here. We start with the description of modalities. We talk briefly about federal Medicaid guidelines. We talk about state policy design choices, and there are many. Then we go on to talk about some applications of telemedicine, highlighting specifically some areas of care that you all raised in the meeting last time, including behavioral health, oral health, maternity care, and then for some high-need populations.

The chapter then goes on to discuss some considerations for adoption, and then we just have a little

looking ahead and summary section.

Okay. So the first part of the chapter, the draft chapter, is the discussion of the modalities. We really just touch on the key modalities. Those are listed here on the slide: live video or synchronous telemedicine, which is real-time interaction using audiovisual technology. That is the one that most states are doing currently in their Medicaid programs in some form or manner. The second is store and forward, which is asynchronous telemedicine, which just means that it's not in real time. And it's the secure transmission of medical information about a patient from one provider to another. And then the last is remote patient monitoring. Again, that's asynchronous, and that is transmission of patient health information for assessment by a provider at a later time. And this is commonly used in chronic disease management, and the data that are transferred are things like vital signs and weight and that sort of thing.

Okay. So the chapter goes on to describe what federal Medicaid guidelines there are for telemedicine. The main sort of takeaway is that there really are few requirements or restrictions on states' use of telemedicine

in their Medicaid programs. Broad Medicaid rules apply, and those are listed in the sub-bullets under Bullet 2.

Comparability, statewideness, and freedom of choice do not apply, and state plan amendments generally are not required for states that choose to do telemedicine unless that coverage for telemedicine differs from face-to-face visits.

Okay. So state policy design choices, again, there are many. The chapter talks about six modalities, so what kind of telemedicine the state will cover; what specialties and services are eligible for a provision via telemedicine; which providers are eligible to provide services through telemedicine; what are eligible originating sites, meaning where can patients -- where do patients have to be in order to get a telemedicine visit; whether or not states impose any distance or geographic restrictions, that's something that's sort of commonly seen -- or it is seen in Medicare; and then we talk about a couple of other features, such as limits on services through telemedicine and payment, for example.

Okay. So I'll turn it over to Nevena.

* MS. MINOR: So in this next section, I'll review

the telemedicine examples which are of particular relevance to the Medicaid population that are discussed in the chapter, many of which you raised at the last discussion about this topic, and where available, the chapter includes examples of individual states' coverage policies, their approaches to covering these services.

So the first example of telemedicine use is in behavioral health, and non-institutionalized Medicaid enrollees have higher rates of behavioral health disorders than individuals in private insurance. There are several access barriers such as insufficient number and maldistribution of providers. So Medicaid agencies are turning to telehealth to help address the challenges since there are multiple applications of telemedicine throughout the continuum of care for behavioral health.

Research has shown psychotherapy to be effective when delivered by telemedicine, and there's a growing body of evidence that's demonstrating videoconferencing's effectiveness in assessment and treatment of myriad conditions, such as depression, PTSD, in some cases substance use disorder.

It is important to note, however, that the

generalizability, the availability, and the quality of research can definitely vary. It's really dependent on what telehealth application is being studied, what the specific clinical intervention is, the outcome metrics being studied, the population or the illness. And these limitations about the broader applicability of research, those are not unique to behavioral health and also apply to research on telemedicine and use for treatment of other diseases.

So all states cover telemedicine through videoconferencing in behavioral health to the extent they cover telemedicine in their Medicaid program. And psychiatrists, psychologists, and advanced practice nurses are most often eligible to deliver this care, although other behavioral health professionals such as licensed professional counselors and social workers can also be recognized in a number of states.

The chapter also discusses less often covered telemedicine services such as provider-to-provider e-consults and the hybrid education and consultation approach of Project ECHO.

So to address low dental service use and access

barriers in Medicaid, 11 states thus far cover some form of teledentistry. This includes videoconferencing between a patient and their general provider with a remote general or specialty dentist. Also store-and-forward technology is sometimes used for dentists to review and make treatment recommendations based on radiographs or photographs that they receive. The evidence to date is supportive of these approaches, but there is a need for additional research in this area of clinical care.

To address OB/GYN shortages and care needed in high-risk pregnancies, videoconferencing can be used to enable patient consultations with maternal-fetal medicine specialists, and videoconferencing can also be used for provider-to-provider consults, provision of genetic counseling. And remote monitoring can be used as well for women with gestational diabetes to track their glucose levels. And state coverage of these kinds of services does vary. Seven states at least explicitly call out coverage of services when they're provided by licensed midwives in addition to broad coverage of physician delivery of this care.

And, additionally, we also highlight the use of

telemedicine in provision of care for high-need populations. So this would be for individuals being served in health homes, through home and community-based service waivers, as well as dually eligible beneficiaries, and videoconferencing can be used to increase access to specialists or remote patient monitoring can help address ongoing management of chronic disease, chronic diseases.

The final section of the draft chapter covers issues that states contend with as they consider whether to adopt or to expand telemedicine use in their Medicaid programs. When telemedicine's aim is to expand access to care, states need to balance the potential increase in utilization with budget constraints and also ensure that the quality of care isn't compromised, or lead to, you know, potential further fragmentation of care with, you know, additional new providers participating in the delivery of care. And a few telemedicine studies thus far have specifically focused on Medicaid, so programs, you know, maybe working with some more limited information.

The use of telemedicine is also contingent on the availability of reliable and affordable broadband, which may actually not be necessarily available in remote rural

areas, which are -- where a lot of the provider shortages are, and costs for acquiring and maintaining equipment, which could potentially affect a provider's ability or willingness to adopt the technology, since states don't necessarily provide payment to help offset those costs.

Provider licensure, which is a state issue, can also affect telemedicine use, and currently 48 states and D.C. require physicians offering telemedicine to be licensed in the state in which the patient is receiving care. And providers can choose to get licensed in more than one state, but the effort and cost might deter providers from participating. There is a move for multi-state compacts in various specialties to expedite the licensing process, but as of yet none of those compacts have become fully operational.

The chapter also describes several other considerations, including how HIPAA regulations interface with telemedicine, state and federal laws and regulations circumscribing the prescribing of drugs to individuals via telemedicine, and states may also impose specific informed consent requirements around patients receiving care via telemedicine, and finally, states may also contend with a

provider's just general willingness to provide telemedicine and adopt it into their practice, and there's -- you know, sometimes providers may not be familiar with how telemedicine can be used in their respective specialties, or they may just need help coaching -- need coaching, in terms of actually implementing it and building relationships with other providers at distant sites.

MS. JEE: And then the chapter -- the draft chapter concludes, as I said, with a short Looking Ahead section, and in that section we highlight sort of states' continued and ongoing interests in using telemedicine in their Medicaid program. We note that although there is some research that supports the effectiveness of telemedicine in certain applications, it's a little bit -- the findings are a little bit mixed, sorry, and all of the researchers generally seem to be in agreement on the need for additional research on telemedicine, particularly with respect to access, quality, and cost, and even more specifically, among the Medicaid population.

Commissioners, some of you noted at the last -- or at the September meeting, that while telemedicine may help address many of the access problems that are sort of

commonly known, it won't necessarily address all of the access problems that are seen in Medicaid, so we note that as well. And, finally, we note that given the sort of general lack of information on implementing telemedicine in Medicaid, and the states' ongoing interest, it might be helpful for states who are looking to further their use of telemedicine if there were greater dissemination or state-to-state learning facilitated possibly by CMS, on strategies that have been tried and effective, or tried and not effective, that kind of thing, that that sort of dissemination might be helpful.

So that is our draft chapter. We look forward to your comments.

CHAIR THOMPSON: I've got Martha and Alan -- Martha, Alan, Toby, Peter, Sheldon, Bill, Kisha.

Okay. Martha.

COMMISSIONER CARTER: Thank you for your work on this. I have two things. One, as a former English major it just really bothers me that we still have discrepancies between telemedicine and telehealth, and Box 1 describes -- defines telehealth as a broader set of activities, like public health, but then Box 2 talks about telemedicine as

being clinical care. I would actually prefer that we settle on telehealth, because it is broader, because medicine is more medicine and telehealth includes behavioral health and other billable services that aren't necessarily considered medical care in the clinical world. So that's my two cents on that one. But I think we just need to reconcile these definitions.

The second is still the issue of the fact that CMS specifically prohibits FQHCs from being a distant site in telehealth, and to the extent that states have the option of adopting CMS's guidelines or creating their own guidelines, it's still a barrier to telehealth and FQHCs, and I think that needs to be at least called out, at least stated somewhere in here that it remains a barrier in many states.

MS. JEE: So what you raise is a pretty interesting point, because there are some differences between Medicare and Medicaid, obviously, and in Medicare they use the word "telehealth" and in Medicaid, on its website, it uses "telemedicine." So there is some reconciling that needs to happen.

But aside from just definitions, you know, there

are some differences in rules, and you're right, there are some states -- West Virginia, I think, is one of them -- that sort of just has generally adopted the Medicare rules, including the restrictions, even though they aren't required to do that. So your point is well taken.

CHAIR THOMPSON: And so, Martha, do you think that it is a situation where the state has just said, well, Medicare is figuring this out and so we'll just follow Medicare, and has not given it as much thought or appreciates that it could diverge from that, or that by virtue of what Medicare is doing it's kind of setting a standard and then people feel like they need to use that as at least a beginning point? You know, obviously we're not here to make recommendations about Medicare policy, and to the extent that states have the ability to exercise flexibility that they're not exercising, what do you think is in the mix in that?

COMMISSIONER CARTER: I'm not going to presume to figure out the minds of previous states' Medicaid directors, but I think it's a problem nationwide that the FQHCs have, so it's not just West Virginia. So I'm not sure what exactly the mechanism is, but it remains a

barrier. And maybe it's just that they don't have the staff to do the analysis, or -- I really -- I'm not willing to hazard a guess at why that happens, but it is, in fact, there.

Maybe some of the rest of you would have a better idea.

VICE CHAIR GOLD: [Off microphone.]

CHAIR THOMPSON: Alan.

COMMISSIONER WEIL: This was tremendously informative and somewhat bewildering. The number of dimensions along which state policies vary and the complete lack of any apparent evidence base for that variation is troubling, I guess, particularly to someone who edits a policy journal.

I'm not really sure that there's a next sentence after that, but I feel sort of the need to say it. My sense is that because of the relative newness of this -- sorry, English major -- that we are sort of at the messing-around stage and that you can't really learn a lot, or it's hard to even know what hypotheses you want to test at this point. But I will say I was struck in reading this that I'm not clear what the priorities would be, and I guess

that's often a problem at the messing-around stage, is sort of like what are the three most important things to know.

We published, I thought, a really interesting paper, but as you note, very little is on Medicaid, you know, talking about the cost-effectiveness. And it turns out to be very complex because, as you note, there is increased utilization when you reduce access barriers. And the implications of that for a frequently underserved population like Medicaid are very different from a population that might have better access.

So I guess, to me, what I'd love is, given, clearly, all the thought and research that went into this, to have a sense of what you think the key questions are, because, honestly, I came away with this -- with so many -- as I say, there are just so many dimensions along which the state choices vary, and I really don't have any sense of why different states took different routes.

CHAIR THOMPSON: Is that something you guys have any comments or reactions to?

MS. MINOR: I mean, I think, in part, in talking with states, I think some states just wanted to take a cautious approach in implementing telemedicine in their

programs, just not having experience, just maybe starting with just one kind of specialty, or just one modality, or just a subset of originating sites. And I think as they are gaining more experience I think they're looking at how to expand it. And I think that there doesn't seem to be a lot of research out there, even to the question about utilization, whether -- to what extent, you know, are you finally meeting an unmet need, or is -- you know, are you just substituting, potentially, or are you adding? I think that information we were unable to locate, and I think, in talking with states, they don't have -- don't seem to have a handle either, in the subset we spoke with.

MS. JEE: Yeah. I think that the notion of sort of cautiously sort of approaching this is something that we did hear for sure. But I think, you know, every year, based on -- you know, there are a couple of industry groups that are doing these compilations of Medicaid policies as well as private-payer policies, and every year it does seem to be that there's, you know, one more state, two more states that have expanded their coverage a little bit, you know, in some way. So there is, you know, this, you know, approach, including having to get, sometimes, some

legislation from state legislatures to do it.

CHAIR THOMPSON: Toby.

COMMISSIONER DOUGLAS: First, great job on this incredibly informative and comprehensive -- and I would use the word "telehealth" too rather than "telemedicine."

A couple of themes or just thoughts that kind of come together. One around the point that you make about states struggling with the issue of, you know, trying to do these new innovations but it being -- you know, how to prevent overuse within a fee for service environment. And what happens, and when I think back, whether it was eConsults or remote patient monitoring or video-to-video, the answer was we can't do it because we don't have ability to truly manage the utilization.

That being said, in the managed care environment, given that we would be capitating out, it was fine for the plans to try these different approaches. But the struggle now, for plans, is there's no -- because it's not in the fee for service there's no way to actually report on the encounters that they have that go back into the managed care rate setting, so it becomes kind of a -- you know, even if it's saving money because they are able to change

the care practices, whether through an eConsult or through remote patient monitoring, there's no way to capture that and it just becomes a net loss.

I was wondering -- so that's at least from the perspective of what I've heard, and some of our, you know, plans, and I think I remember Chuck bringing this up too. But did states ever raise anything? You have one sentence about -- I would like a little bit more in the paper about managed care. There's one sentence that says that there are struggles because of IT and financing. But the value within a capitated environment is very different than a fee for service environment, for advancements, and we're seeing, in procurements, actually, that a lot of states are actually pushing plans to do telehealth or telemedicine.

One is if it came up in conversation, and, two, I would recommend that we add a little bit more about that.

MS. JEE: So it didn't really come up that much in conversations. We did sort of poke at it a little bit. But we can, you know, go back to that issue a little bit more, for the next round.

CHAIR THOMPSON: Stacey, do you want to jump in on that?

COMMISSIONER LAMPKIN: Yeah, just a quick comment on this. So while I don't disagree that an ideal situation would have these encountered, there are other kinds of expenditures that managed care plans make that aren't easily encounterable either, but that doesn't mean that they can't be captured in the capitation rate. There are different ways to report those expenditures. So just a point of clarification, and I'm not disagreeing with your overall point, which is a way to get these encounterable would be ideal.

COMMISSIONER DOUGLAS: No, and I think the answer -- so you're absolutely right.

CHAIR THOMPSON: This is part of a larger conversation that we have sometimes touched on here, that maybe we should put more of a point on, which is how to ensure that alternative methods and means of delivering services, in general, are being captured and reflected in rates paid to managed care plans.

COMMISSIONER DOUGLAS: Yeah. It's just giving guidance that, I don't think you're right. There's not a one-size-fits-all answer to it, but rather giving guidance that here's a problem that's come up and here's a potential

-- a recommendation of how states could address this, of not having to add it into the fee for service but allow managed care plans to do it and still be captured in the rate setting.

CHAIR THOMPSON: Peter.

COMMISSIONER SZILAGYI: First, I agree. This is a really admirable job on a challenging chapter, but something that everybody is really excited about. You know, usually when you have a natural experiment with all these things going on, you learn really key themes or lessons. And I kind of agree with Alan that in this case that isn't the case, and I think part of the reason is there is a lot of research out there on telemedicine.

There are randomized trials. AHRQ published systematic reviews of telemedicine. But those are relatively small randomized trials, and states and ACOs and health systems are experimenting in very broad ways. So I'm not so sure that some of them lessons from the randomized trials can be generalized to the really large real-world experiment. So I think that's probably why we're left with this sort of gemisch about what is really the impact.

I mean, to me, the ultimate question is does telemedicine improve access to care, does it improve quality of care, and what's the implication to costs? Those, to me, are the three fundamental questions.

So I do have a couple of suggestions for the chapter. Do we have any data about how big is telemedicine in terms of what proportion of all visits? What proportion of costs? I mean, how big is this, is it currently? In a descriptive chapter like this, I think that would be very helpful. And then I have a couple of other suggestions.

MS. JEE: Yeah, you know, we did hope to be able to look at some of the data and get a sense of it, but in sort of talking with folks in some of the states about how the data are -- how telemedicine visits are tracked, I mean, they use a modifier code to -- that indicates that it was, you know, some kind of telemedicine visit. But our understanding is that sometimes those codes are not reported very faithfully, and so it's hard to know, in the data, like the extent to which the codes that are supposed to be there, or that are missing. And so that presents a challenge.

You know, we did, in reaching out to some states,

ask, you know, if they could share some data. We're still trying to, you know, get some of that. But your point is well taken, and, you know, it was kind of a challenge, to be frank.

COMMISSIONER SZILAGYI: To even put it into context.

MS. JEE: Yes.

COMMISSIONER SZILAGYI: So maybe the biggest suggestion I have is to work a little bit stronger on the park where it's called "expected outcomes," which, by the way, is a strange term to me. I mean, I think what we're really trying to get at is impact of telehealth here. And I would suggest creating --

EXECUTIVE DIRECTOR SCHWARTZ: They don't do that because I will strip out the word "impact" from anything they do.

COMMISSIONER SZILAGYI: So I don't know what -- "expected outcomes," to me, sounds like hypotheses, and what you're really describing is what are the results of evaluations of telemedicine. So whether not use the word "impact," you know, you could say "evaluation" or something. But I would suggest having little subgroups of

the evaluation on availability, or on access to care, or on costs, you know. It seems to be kind of jumping back and forth, you know, right now. So sort of maybe following our access framework, or some sort of organized approach within the chapter.

MS. JEE: So can I just ask for a clarifying question about that? Do you mean generally, like about telemedicine's effects, not impact, generally, or do you mean for the Medicaid population?

COMMISSIONER SZILAGYI: Well, there's little specifically on the Medicaid population.

MS. JEE: Right.

COMMISSIONER SZILAGYI: So it would have to be more general than that, because there's just little data for the Medicaid population.

MS. JEE: Right. And then there is some variation in the research in terms of the modalities, and even within that the -- sort of the care areas.

COMMISSIONER SZILAGYI: Right.

MS. JEE: So it sort of quickly turns into like lots of little subheads. But your point is well taken and we can see if there's something to build in.

COMMISSIONER SZILAGYI: Just to try to coordinate.

MS. JEE: Yeah.

CHAIR THOMPSON: Okay. Let me just review the bidding here -- Sheldon, Bill, Kisha, Chuck, Marsha. Who am I missing? Nobody, okay. So, Sheldon.

COMMISSIONER RETCHIN: I continue to think this is an interesting area, and it was a well-done review. Just one point and then maybe something to get into in terms of policy.

The first one is -- maybe I missed it -- did you discuss anything about the correctional system, prisoners? Which is an interesting area we don't really get into much here with the application of some of the Medicaid rules to the correctional population. This is one area, though, which actually -- I mean, not for any policy in particular, but because it saves so much money in transportation and security. I think it's worthwhile pointing out. I don't think there is any recommendation that is needed out of that.

But let me move to one area where -- it just sort of dawns on me that maybe this could be effective in terms

of policy, and that you did discuss it. And that was maternity coverage.

But one area there where it might be helpful is that -- and Rob will kill me on this one -- because I was actually thinking that there is a requirement -- Rob, correct me if I'm wrong -- to have two obstetricians on staff to be eligible for DSH. Is that right?

EXECUTIVE DIRECTOR SCHWARTZ: He is nodding.

MS. JEE: He is nodding his head.

COMMISSIONER RETCHIN: I felt it.

[Laughter.]

COMMISSIONER RETCHIN: Which never made any sense to me. Okay. So you can't afford obstetrical services. We're going to make sure you really can't afford anything else. We'll cut your DSH.

So this may be an area where telemedicine could actually -- it would require a change in the actual policy, but obstetrical services are closing, I'm sure everybody is aware, so rapidly in rural areas. We need some sort of a bridge, and maybe this is an area where you'd be able to say, "Okay. You only need one obstetrician on staff, but you've got to have telemedicine in place." Just a

suggestion.

CHAIR THOMPSON: Bill?

COMMISSIONER SCANLON: I agree that this is a really good report on a very complicated topic, and I think I'm going to develop a reputation of thinking the world needs to be stratified.

I'm going to agree with Alan and Peter. For me, that's the reason why there isn't kind of a storyline or a plot here because telehealth or telemedicine is not a thing. It's a category, and there's so many applications within it that if we're going to learn something, we need to study an application and discover what its consequences are. And when we find something there and we look at another application, it may not turn out to be the same sort of at all, so there's that.

And I think policy is always going to be about application. It's not going to be just telehealth or telemedicine. It's going to be very specific.

I had two things that I was more particularly interested in the chapter. One was the issue of why someone would be willing to treat Medicaid patients when they weren't willing to treat them in their office. Why

has access increased? To me, that, being the economist, goes to what are the fees that are being paid for telemedicine versus fees for an office, and you've got a very different practice expense for the two situations, and how much that's a factor that really improves sort of access was one.

And then the second area was the area where -- this is where Medicare struggles, and I think the Medicaid programs will struggle in the same way, which is how do you control utilization in a way that you find sort of reasonable. There seems like there is some implicit sort of geographic sort of limitations and sometimes more explicit that are in there. There's some kind of very simple things like annual cost limits, which that's kind of a crude device.

But the one that was of particular interest was prior authorization, and we could talk more about that because it often seems like that's too expensive to do, but can be potentially something where you really are being very discriminating in terms of this is appropriate or not. And so the experience with that, I thought would be something, if we knew more about it, it would be

interesting.

CHAIR THOMPSON: Kisha.

COMMISSIONER DAVIS: Thanks. I just want to echo that I really enjoyed the chapter again, and I think you guys did a really good job in thinking about telemedicine.

A few things that I just wanted to call out and thank you on, one regarding licensure and this issue of being out of state. If the goal in increasing access is that you are trying to be able to have this person consult with this super specialist who there may only be four in the country and you're restricted by state licensure, then it doesn't really increase your access if you're not able to then consult with that person. And so you have the added cost in time of traveling, whatever distance, to see that specialist.

Also, thinking about primary care and how that fits into this, and sometimes you need to think about primary care and telehealth a little differently than how you're thinking about it with the specialist, and so where telehealth is increasing the access to the specialist and that might be paid on an encounter basis, thinking about it for primary care in terms of increased ability to monitor

them as an outpatient.

So I am saving that person a visit with their primary care provider because I am now able to, you know, monitor their weight and their blood pressure at home without them having to come into the office.

So thinking about Medicare, which has done some of this with the CPC+ program, where you are then paying providers to provide those wrap-around services, gives a little bit more flexibility than when you're stuck with just the fee-for-service office visit we all providers have to do to see the Medicaid patients.

So when you open up that flexibility, whether it is a per member per month or some sort of wrap-around fee for providers to be able to then cover telemedicine and other outpatient services that don't require them bringing them into the office, you kind of get at some of the overuse issues and access and quality for patients.

CHAIR THOMPSON: Chuck, Marsha, Martha.

COMMISSIONER MILLIGAN: So echo the comments, it's a really good chapter.

A few things I wanted to just kind of punch for you all. Going back to what Toby said about encounters, it

is kind of one of the situations we're dealing with in my day job. We want to do remote patient monitoring. The state doesn't have that as a code or a service, and our encounter acceptance has to align to what their system is built to deliver.

I recognize, Stacey, that there are work-arounds to that, but it is barrier to the extent the state isn't building a work-around to that.

I want to come back to this provider licensure that Kisha was mentioning. In some ways, it goes beyond licensure, to the provider registering with the state too. So it's not simply having a state license.

I will give as an example, we've recently launched in my health plan the video, virtual visit. It's using a smartphone or tablet, having a Skype call, essentially, with a provider.

We have behavioral psychologists in our network to do that. They are licensed in New Mexico. They are not registered with the state. So we can't submit those encounters.

So one of the barriers is also the provider registration, provider registration, provider enrollment

with the state piece, to the extent that there's an encounter element to this.

I want to come back, Martha, to the comment about FQHCs. I'm not going to speculate where you didn't speculate, but I will speculate about my experience in Maryland around sometimes leveraging the Medicare rules, where you're scared about overutilization, where you can't set provider rates.

And so with the hospital waiver in Maryland, one of the issues that I always worried about was the second floor of Johns Hopkins doing a telehealth visit with the fourth floor of Johns Hopkins, and we had two professional fees and two facility fees in one visit that was an elevator ride apart. And so we piggybacked some of the Medicare geographic distance requirements because in a hospital rate-setting system, I had zero control over the fees, and I was scared about utilization. And so I think that where there's some of that concern about overutilization, it's especially acute where the state has no rate-setting influence.

I have two final comments. One of the things I've heard anecdotally -- and forgive me for bringing

anecdotal stuff to an evidence conversation -- is that -- and I'll give, again, this virtual visit, this smartphone thing. I very often hear about people who use that modality -- and we offer it to our members -- more likely to get an antibiotic than maybe if they were in person with their PCP. It leads to a good survey result at the end: "I got served. There is a prescription waiting for me at Walgreens." But I worry a little bit about overprescribing through this kind of modality, where it isn't quite the same relationship, and there's a survey right after the call. And I don't know if that's happening or not, but I do think that it can lend itself to over-prescribing in terms of the provider on the other end of that kind of encounter, delivering a good experience to the patient.

And the final thing is the comment about the correctional system. I want to give another example that we're soon to implement in my health plan. It is really linking nursing facilities better using telehealth. So that if somebody on Medicaid or in our D-SNP, for that matter, is at risk of maybe being put in an ambulance and sent to a hospital for something that could be managed with a telehealth visit, to have the originating site be at the

nursing facility so that somebody can stay in the nursing facility and not get put in an ambulance to the hospital.

So I'll stop there.

CHAIR THOMPSON: Marsha.

VICE CHAIR GOLD: Nice chapter.

I had a couple of comments, some of which parallel what I had sent you.

First, I want to go along with Toby and reinforce the importance of talking a little bit about telehealth in the managed care context, given how large a share of the population is in managed care. It's important, but also the incentives on managed care are different. So there's more potential there if the barriers aren't taken to learn stuff. So I just think expanding that a little is a good conversation.

The main question I had -- and I'd be interested in how other Commissioners react -- I sort of thought that both in the beginning and in the end, where we say, well, CMS should, maybe could get people together and help them learn in this learning thing, that we either should say more or less.

It seemed to me that if we really think it's

important and there are gaps, we should recommend it, and we should say what they should focus on or what the main issues are.

I didn't know, for example, if we need help with licensure and participation. So I didn't know how Commissioners felt, but I felt like as it stood, it didn't accomplish that much, and so I'd like us either to say, well, maybe it's not so important and not do it, or else be more specific and say why we think it's important and what the "it" is, where the priority should be to focus with the support to states, because CMS's money is limited. And they should know what their -- if we're doing it, we should have a sense of what it is.

CHAIR THOMPSON: I have to say I had a little bit of that same reaction.

There was a part of me -- and this kind of connects back to the earlier points that Alan, Peter, and others were making about there's still a lot that we don't know, and we have kind of this mishmash, and so in that circumstance, it's also not clear what state-to-state learning can really accomplish.

I mean, it can certainly take the ball a little

bit further, but if there isn't a variety of different experiences to draw on from which you can extrapolate the things that of most interest to you and then apply them to your environment, it may be less useful.

And so I actually wondered in a similar vein whether or not -- and it doesn't have to be for the March chapter, per se, but something for us to think about as to is this an area where there ought to be an explicit demonstration authority, an explicit approach to help organize, structure, test in particular areas where there is -- sort of going to Bill's categorization, I'm kind of the person that keeps talking about use cases, so maybe I'm in the same category.

VICE CHAIR GOLD: [Speaking off microphone.]

CHAIR THOMPSON: Right, which is to kind of say, picking up on Sheldon's point about rural areas and obstetrics, are there places where we specifically want to encourage, take up, with an evaluation framework, with an ability to collect data and so forth? So that may be something that we could consider as time goes on.

I think this chapter in terms of just setting the stage and providing kind of the survey information is a

sufficient ambition for our first big foray into this, but there may be others.

EXECUTIVE DIRECTOR SCHWARTZ: So would you take that out and just say we need more research, we'd like to learn more about why states do what they do?

COMMISSIONER RETCHIN: I know where you're going because I think this is incredibly comprehensive, really well done, and the discussion we've had is there are areas where we could come back based on this, leaving it in a chapter.

There's obviously a lot that we have to wrestle with, but I think it's really comprehensive and should stand as it is.

CHAIR THOMPSON: So we have Martha and then Fred.

COMMISSIONER CARTER: I wanted to go back to something that Bill said, and I may have misunderstood you, but you mentioned something about the cost of telehealth. And I think that points out how broad of a topic this is and how many different applications we're really looking at because there probably are several of us that have old robot-looking things in our offices holding up coats now.

But I think we're past that point, and I think

that there are differences -- now you can do retinal exams and have it read someplace. There's a cost there, but a lot of the cost of telehealth now is minimal because all you need is to secure technology because a lot of the applications now are psych or behavioral health or nutrition counseling or something that just requires a face-to-face, and that all you need is -- you know, it's a $1,000 a year for your secure connection, assuming that you already have broadband and an EHR that's operating with the same kind of technology requirements.

Did you want to respond?

COMMISSIONER SCANLON: I mean, I agree. I think that there are those kinds of costs.

It's basically a business analysis when you think about it. The technology initially is a capital cost, and then there's the issue of the operating cost. And when you're dealing with someone through some telecommunication, it's different than when you bring them into the office where you have to have a receptionists. You have to have space. You have to have sort of a medical assistant, maybe a nurse, and those needs go away or are diminished to some degree. And it comes down to the bottom line. Total up

how much things change and is it much different when you're doing it through a telehealth connection.

VICE CHAIR GOLD: But it's also whether it's a substitute or a complement. I mean, is it substituting for something that would have occurred in a different modality, or is it adding a different service which may either add or take away from cost and improve or hurt quality?

COMMISSIONER SCANLON: And I think those are the questions from the payer perspective. I was actually asking the question from the provider perspective, which is I'm willing to do this, but I'm not willing to have you come into my office because I basically face a different set of demands when you come into my office than if I'm dealing with you through the telehealth connection.

CHAIR THOMPSON: Fred.

COMMISSIONER CERISE: So, first off, I think it's a great chapter and summary and sort of a description of where we are.

I wonder, because there's so many questions around it, would it be helpful to dive into some case studies and look at places where you kind of have more aligned interest, like a big integrated delivery system?

Say you take a Kaiser or something, the payer and the provider, and you're weighing these things already, because you surely are concerned about inducing demand, but you're also worried about how can I improve access and make that as efficient as possible. And so I wonder if a few stories like that, looking into how some of these systems have handled it.

I heard Troy and Brian on NPR yesterday talking about Aetna and CVS MinuteClinics and where you can increase access there, but if that's not connected to some bigger plan, then to Marsha's point, are you just going to induce demand because it's easier now, but you're really not going to have an impact on your outcomes? And so I just wonder if some of these places that are struggling with this and own all the different -- you know, they own the competing demands, and just get an idea of how they're practically dealing with it might be useful.

CHAIR THOMPSON: Okay. So terrific chapter, terrific conversation. Thank you very much.

I think I sense on the part of Commission, in addition to the feedback on the chapter itself in some places where maybe if you can build up some more

conversation, that would be great, a desire maybe to look at integrated provider networks and plans and some of the ways in which they might be trying to take advantage of these kinds of technologies, using perhaps some more stratification or characterization around what does it take to get a provider interested, what does it take to ensure the provider has the appropriate incentives, and where are the places where this might have the most promise from a Medicaid context specifically. I think if we start to move in --

EXECUTIVE DIRECTOR SCHWARTZ: Is that for now, or is that for later?

CHAIR THOMPSON: No, no, no.

EXECUTIVE DIRECTOR SCHWARTZ: That's for later.

CHAIR THOMPSON: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Okay.

[Laughter.]

CHAIR THOMPSON: I think the chapter as it stands now in terms of a survey and an overview, yes. There was some specific feedback on the chapter, which I think you can take and use. Then in terms of the follow-on work, I think there might be some opportunities to do some dives

and to some specific contexts and use cases.

COMMISSIONER SZILAGYI: I think we're seeing that there may be a potential second chapter, opportunities for another chapter down the road.

CHAIR THOMPSON: Yeah. Well, we'll see where the work leads in terms of some additional work.

All right. Thank you very much.

Okay. We're back to Medicaid outpatient drug rebates, and Chris and Rick. Ready when you are.

POTENTIAL RECOMMENDATIONS ON MEDICAID OUTPATIENT DRUG REBATES

* MR. PARK: Okay. Thank you.

This session builds on the discussion of Medicaid drug spending from the September Commission meeting. We heard about the tools states currently have to manage the drug benefit this morning during the panel, and this presentation will focus on some of the more discrete policy changes to the rebate program. We will present background information and rationale for some potential recommendations on three of the policy options presented in the September meeting on how rebates are calculated and the oversight of the program.

The goal is for the Commission to make a decision on whether to move forward and make a recommendation on any of these options. You would not necessarily vote on anything today, but the staff can incorporate any feedback and can bring forward any of these options as formal recommendations for a vote in the future.

This slide is just a quick refresher on the Drug Rebate Program. I won't go over it. The main thing to remember is that manufacturers must pay statutorily defined rebates. In exchange, states must generally cover all the manufacturers' drugs.

A couple of the options today address the way rebates are calculated for brand drugs. There are two components: the basic rebate and the additional rebate. The basic rebate is the greater of 23.1 percent of the average manufacturer price or average manufacturer price minus best price. The additional rebate may be added if the increase in a drug's AMP exceeds the increase in the Consumer Price Index over time, and so this is a rebate -- this is also called the "inflationary penalty."

This additional inflationary rebate has become a very important part of the Drug Rebate Program. The Office

of Inspector General has estimated that over half of the brand drug rebates are attributable to the inflationary rebate.

So this first set of potential recommendations focuses on line extension drugs. A line extension drug is a new version of a drug that makes only minor changes to the originator product. An example of this is extended release formulations.

The line extension is considered a new product, so manufacturers can use it to establish a higher baseline price above the original version's baseline price. By moving volume from the original version to the line extension, the manufacturer can essentially reset the inflationary rebate to zero. Because the inflationary rebate is such a large part of the brand drug rebate, it can substantially reduce the manufacturer's rebate obligations.

To address this issue around the line extensions, the Affordable Care Act created an alternative rebate calculation for line extensions that are in an oral, solid dosage form. This alternative rebate reflects the inflationary rebate of the original version of the drug

expressed as a percentage and applies it to the line extension's average manufacturer price. The standard rebate for the line extension, which is the basic inflationary components, is then compared to this alternative rebate, and Medicaid receives the greater of the two.

However, there is an issue with this line extension calculation due to a drafting error that reduces the number of line extension drugs that will trigger this alternative rebate and limits the provision's effectiveness to yield additional rebate dollars. The discussion for the line extension rebate provision in the Chairman's mark for the America's Healthy Future Act of 2009, which was the precursor to the Affordable Care Act, indicated the desire to treat line extensions of brand-name drugs as if they were the original product, and calculate the additional inflationary rebate off the original version's baseline AMP rather than a new baseline price. However, the Affordable Care Act compares the alternative rebate to the entire rebate of the line extension instead of just comparing to the inflationary component.

Additionally, there is some uncertainty as to

which drugs meet the definition of a line extension drug. Although CMS proposed a definition in a February 2012 Notice of Proposed Rulemaking, it did not finalize the definition and sought additional comments when it issued a final rule in 2016. One of the areas of line extension definition that received the most comments in the proposed rule and contributed to CMS seeking additional comments was whether abuse-deterrent formulations should be excluded from the definition of line extension drug.

Later in 2016, the Comprehensive Addiction and Recovery Act of 2016 specifically excluded abuse-deterrent formulations from the additional line extension rebates, so that particular question was resolved under that act.

So to address these issues, MACPAC can make two potential recommendations.

To align the statute with the original intent of the provision, Congress should make a technical correction to the alternative rebate calculation for line extensions drugs in Section 1927(c)(2)(c). The correction would make the additional rebate the greater of the line extension's additional rebate or the highest additional rebate calculated as a percentage of average manufacturer price

for any strength of the original single-source drug or innovator multiple-source drug.

The second potential recommendation is for CMS to finalize the definition of line extension drugs. A regulatory definition of a line extension drug will help ensure that drugs are categorized properly and correct rebate amounts are collected.

These recommendations would produce federal savings. CBO has estimated that the recommendations would reduce federal Medicaid spending $1 to $5 billion over five years. However, states would not necessarily receive this benefit. The line extension rebate is subject to the federal rebate offset, which essentially remits the increase in rebates due to certain provisions of the Affordable Care Act entirely to the federal government. Due to the way many states calculation their supplemental rebates, an increase in the federal rebate can lead to offsetting decreases in the supplemental rebate. Because the states do not share in the line extension rebate, any shift between the state supplemental rebate due to the increase in the federal rebate dollars could ultimately lead to an increase in the cost to the states.

Additionally, an increase in the line extension rebate could lead to manufacturers reducing development of these drugs, and that could lead to a reduction in medication options for beneficiaries.

I will pass it over to Rick to go over the next two options.

* MR. VAN BUREN: Thank you, Chris.

So now we we'll talk about excluding authorized generics from the brand drug's AMP. The recommendation's intent is to prevent manufacturers from being able to essentially use artificial sales of authorized generic drugs to reduce the AMP of their brand product and, therefore, reduce the brand product's rebate liability.

So first some background that's important to understand in order to kind of follow the bouncing ball on how this is operationalized, some background on what authorized generics are, why manufacturers introduced them.

Authorized generics are a generic version of a brand drug that the brand manufacturer typically releases near the end of that drug's exclusivity period to compete with the first generic drug to market. Under the Food, Drug, and Cosmetic Act, the first generic version of a drug

enjoys 180 days of generic exclusivity before the FDA will approve other generic versions. This 180-day generic exclusivity period can be very lucrative for generic drug makers.

The Federal Trade Commission found in a study that the introduction of an authorized generic during this period can significantly reduce the profitability of generic drugs, which may affect the generic manufacturer's decision to introduce a competitor product.

Some information on what sales are included in calculating AMP. The Medicaid statute directs manufacturers to calculate AMP based on sales to wholesalers and pharmacies. The statute further directs manufacturers that make an authorized generic version of the drug to include those sales when calculating the brand drug's AMP. This is known as a blended AMP.

The Medicaid statute has a broad definition of what constitutes a wholesaler. Under the statute drug manufacturers that engage in the wholesale distribution of drugs can be considered a wholesaler. This means that if a brand manufacturer makes an authorized generic, sells it to another manufacturer for distribution, known as the

secondary manufacturer, that secondary manufacturer could constitute a wholesaler under the statute, and the sale of that drug would need to be included in brand drug's AMP. In that situation, the first manufacturer is known as the primary manufacturer.

In some instances, the primary and secondary manufacturer have a common corporate ownership or some other type of corporate relationship. In those cases the sale price of the authorized generic may not be a true arm's-length transaction, but it may be, in fact, artificially low and intended to reduce the brand drug's AMP, which in turn reduces the brand drug's rebate obligations.

A potential recommendation in this space would be in order to ensure that the brand drug's AMP reflects only the actual fair market value of the drug. Congress could remove the requirement that manufacturers blend the AMP of the brand drug with the authorized generic.

Some considerations in this space: The CBO did estimate there would be federal savings and that they would be less than $1 billion over five years. We expect these savings would come in the form of higher rebates from drug

manufacturers. Drug manufacturers would likely need to make systems changes to adjust which sales are included in their AMP calculations. If Congress were to pursue this policy recommendation, manufacturers may urge Congress to also exclude authorized generics' best price from the brand drug's best price in order for consistency across those two measures. We don't currently know if any brand drugs are paying a best price penalty based on their authorized generic. Finally, this provision could potentially increase the federal upper limits for pharmacies, which could result in increased payments to pharmacies.

The final topic we'll discuss would be to strengthen the oversight of the rebate program. So, currently, manufacturers that participate in the rebate program are required to submit certain data elements that are necessary for the proper functioning of the program. Some of these are specified in statute; others are included in the terms of the rebate agreement. This slide lists some of the data elements manufacturers are required to submit. They include AMP, best price, how the manufacturer classifies the drug, et cetera.

The Medicaid statute splits enforcement between

CMS and the Department of Health and Human Services Office of the Inspector General, or OIG. The OIG is authorized to audit manufacturers and issue civil monetary penalties, or CMPs, for manufacturers that fail to provide certain data accurately or timely. CMS is authorized to terminate manufacturers from the rebate program for noncompliance or other good cause.

Beyond these statutory remedies in Medicaid, manufacturers may be liable for violation of the False Claims Act or other government claims that would be prosecuted by the Department of Justice.

Beyond the statutory authority, CMS has an informal process it follows when it becomes aware that a drug is miscategorized. Specifically, CMS will usually contact manufacturers and attempt to reach an agreement regarding the drug's classification. CMS has issued sub-regulatory guidance regarding how manufacturers should classify drugs and codified much of this guidance in the covered outpatient drugs final rule. The final rule also established a process for certain manufacturers to challenge how their drugs are classified. And, finally, CMS has reprogrammed its Drug Data Reporting, or DDR,

system to only allow manufacturers to classify drugs consistent with the manner outlined in the final rule.

Despite these formal and informal steps, the rebate program still relies heavily on voluntary manufacturer compliance. There are limited tools to detect or enforce intentional noncompliance. For example, CMS does not have clear statutory authority to reclassify drugs that it considers to be misclassified.

The legislative language on civil monetary penalties includes what's likely a drafting error that leaves some ambiguity around what level the initial penalty is supposed to be. And while CMS can terminate manufacturers from the rebate program for noncompliance, this would exclude all of those manufacturers' drugs from Medicaid, which means CMS may be reluctant to take this step in the case of manufacturers who are the sole producers of vital medications. Finally, litigation can be time-consuming, costly, and administratively burdensome.

There are several recommendations MACPAC could make in this space to improve oversight and enforcement of the rebate program. The Commission could recommend one or more of the following:

That OIG conduct more regulate audits of the rebate program to ensure that drug manufacturers are reporting accurate information and Medicaid is receiving the correct level of rebates;

Congress could clarify the civil monetary penalties, including the penalties for misclassifying drugs;

Congress could give CMS clear authority to reclassify drugs, which would give CMS a tool to address instances of intentional noncompliance;

Finally, Congress could give CMS authority to terminate individual drugs from the rebate program for noncompliance. This would allow CMS to take more targeted enforcement action and may make the threat of CMS enforcement more credible. It would also be more protective of beneficiary access in the current all-or-nothing termination authority.

Some considerations in this space: The CBO estimates that there would be no budgetary effect from increasing the frequency of audits or giving CMS clear authority to reclassify drugs. It is worth noting that some of these steps can be administratively burdensome.

Audits could be time-consuming and involve going through lots and lots of information. Determining whether a drug has been misclassified can require digging through old FDA files, old manufacturer files. That can be time-consuming.

Terminating individual drugs from the rebate program would be a change from the current grand bargain of the program, which requires -- exchanges mandatory rebates for mandatory coverage. And, finally, if possible, that manufacturers would litigate if CMS took enforcement actions described that the manufacturer disagreed with, which would increase the administrative burden associated with those actions.

The next steps are to determine if Commissioners would like to pursue recommendations on any of these options. Alternatively, if the Commissioners are interested but need more information, what information or analysis would be helpful? And if Commissioners are interested in pursuing any of these recommendations, staff can prepare a draft chapter that Commissioners could vote on at a future meeting.

Thank you.

CHAIR THOMPSON: Okay, great. Thank you.

I had a couple questions. One is on line extensions. We make the case that -- or we reflect the reality that if we fixed line extensions in terms of the rebate, that all of those rebates go to the federal government. But couldn't we make a recommendation that that not be so and that, if we're in the neighborhood of fixing this particular element of the statute, we would also share those savings with states -- recommend sharing those savings with states in a different manner?

MR. PARK: Yes, we could make that recommendation.

CHAIR THOMPSON: Okay. So I just wanted to put that out there for maybe the other Commissioners to also think about.

And then with respect to CMS oversight, you know, we cite EpiPen, which doesn't seem to me to be an issue about any of the things that we say that we could do to strengthen CMS oversight. CMS knew about it; CMS told them that they were doing something wrong. I'm not exactly sure whether the follow-up happened. I'm not exactly sure kind of what followed from that, but it wasn't that they needed to do more audits to find something because they knew it.

I'm not sure if there are a lot of other instances that we could point to where there were failures in the enforcement regime such that we needed to give new -- I mean, I would always say intermediate sanctions are good to have because nobody ever wants to go to a full-scale termination, and nobody ever wants to go to, you know, litigation. And so if you're really going to have a meaningful enforcement mechanism, having some intermediate sanctions is always something good to have in your pocket, and so maybe that's the case. But are there other -- and CBO, of course, does not think that any additional steps with respect to oversight actually saves money or does anything.

So can you talk a little bit more about what we were thinking there and whether we have other examples where the lack of some of those tools or resources caused a result that we didn't want to see happen?

MR. VAN BUREN: Sure. I do think it's -- what you identified in terms of the lack of intermediate sanctions, it is currently, at least as it relates to what CMS can directly do, an all-or-nothing authority.

In terms of kind of examples beyond EpiPen, we've

analyzed the drug data and found there were 586 national drug codes approved under New Drug Applications, which would normally classify that drug as a brand drug but are currently classified as generics. So we can't -- we don't know how many of those are improperly classified or improperly categorized and how many are properly categorized. But there is a potential that some of those are miscategorized. The --

CHAIR THOMPSON: So we just don't think there's sufficient surveillance, period, to even have confidence in other than what the manufacturer is simply reporting. Is that kind of the key element or --

MR. VAN BUREN: I think that's fair, yeah.

CHAIR THOMPSON: Okay.

MR. VAN BUREN: And then scanning the OIG website, we found since 2009 there were 11 instances of the OIG issuing CMPs against drug manufacturers for failing to report timely data. I couldn't find any information on the website about failing to report accurate data going back to 2009, which is when there -- which is the earliest records they have.

CHAIR THOMPSON: And do you know what resources

are now available for those activities? So HCFAC funding, does that get deployed for this purpose?

MR. VAN BUREN: No, I don't know. We're trying to speak with OIG and want to find out more about kind of their activities in this space.

CHAIR THOMPSON: And I think in terms of making recommendations about resources, knowing what the federal government has access to, is it just a matter of priority, there are funds available but the priorities are greater in other areas, which may not be a bad thing, versus there needs to be some kind of different resource allocation or availability where we could contemplate recovery auditing or something else without having to necessarily invest all of the money up front, as against, you know, ongoing surveillance and then the availability of sanctions that one would actually want to use or employ.

Other questions or comments from the Commission on this topic? Kit.

COMMISSIONER GORTON: So I think we should move -- I think we have some more work to do, as Penny has laid out, and certainly I would want to think long and hard about moving forward with the recommendation regarding OIG

and their activities without having talked to them about what they think their priorities are and get their perspective, at the very least, you know, sort of "nothing about me without me" kind of a conversation. We ought to see what they think about that.

But I think there's -- to the extent that they agree that with more resources or with more tools, I do think intermediate sanctions, with respect to EpiPen, the manufacturer in question, you couldn't put out of the program. So the nuclear option is simply not an option in that particular case, not if they ever wanted to have the flu vaccine paid for.

So it's simply -- so I do think that there may be a recommendation about intermediate sanctions that we ought to think about, if nothing else to be able to say that you could have a drug-specific exclusion as opposed to a manufacturer-level exclusion. And so that, I think, is worth moving forward.

I think the piece about authorized generics, I think we -- it certainly feels like the system is being gamed there, and it seems like we could point that out. We have talked, in past meetings, about the need for the

Commission to identify savers, and I think this is potentially a saver.

I agree with Penny that I don't think the federal government should get all the savings. You know, the manufacturer might not mind if the savings came out of the states' supplemental rebates. So I do think that we ought to potentially address that piece of it as well. But this feels like a whole lot of, you know, loophole-jumping to me, and maybe we could close some of those loopholes and save the taxpayers some money there, and I think that would be a good thing.

I am inclined to believe that any regulatory regimen which is based largely on self-reporting of the regulating entity may not have as many teeth as it should have, particularly when there's this much money at stake. And so I do think that we should think about enforcement and what we can do -- and again, I think we need to talk to CMS and find out what they think. But what would be valuable to close these loopholes and save state and federal taxpayers some money. And so I would like to see that, you know, fleshed out.

I guess the last thing that I would say is the

conversation this morning talked about the issue of timing of adding drugs to state formularies, and that's absolutely relevant here because it is the rebate law that requires that. So I think that I would like to see at least an attempt to putting together a recommendation on allowing states some flexibility around timing so that they can study the drugs that they are intending to add to the formulary and come up with relevant policies and procedures, before the drugs goes on the formulary rather than after.

MR. VAN BUREN: Can I ask a clarifying question? You mentioned the state claw-back issue. So that's an issue for the line extension fix. I don't believe that's an issue for the authorized generic fix. Are you --

COMMISSIONER GORTON: That was my read as well, but I think we should be explicit about that --

MR. VAN BUREN: Okay.

COMMISSIONER GORTON: -- so we don't cause panic in 50 state capitals. But I do think that to the extent it needs to be fixed in the line extension that we should talk about fixing it.

CHAIR THOMPSON: Chuck.

COMMISSIONER MILLIGAN: Nice job, guys. I was scared when I read the materials, but you've talked us through it.

The line extension -- I would want to have a sense of how much the federal gain on the rebates is offset with the state potential loss of supplemental rebates. Is it dollar for dollar? Is it -- I mean, what is the leverage point there? I mean, it kind of gets to what Penny said about sharing or not. But I just -- I'm curious -- the more we can know about that, the more informed we would be to consider a recommendation like that, is my point of view.

With respect to the second recommendation, about authorized generics, it seems to me that that's a recommendation personally I'm comfortable supporting for the reasons that, you know, it feels like gaming, and it is an opportunity for the Commission to recommend some savers that I think are not detrimental to beneficiaries, et cetera.

With respect to the third, I agree about the -- you know, "nothing about me without me" kind of element that Kit introduced. I do think, though, that all of the

intermediate sanctions are not necessarily have to be considered as a package. And, for example, giving CMS the authority to reclassify a drug with, you know, appropriate appeals rights and whatnot, is something that would have been beneficial for the EpiPen, without having to go to other, perhaps, more severe forms of sanctions.

So I just think that the more we can kind of unpack some of those -- and maybe eventually we are going to want to kind of review it and recommend it or not as a package. But I think the ability to reclassify with appeals rights does not, to me, seem particularly onerous, and it seems to me that it would have an impact on compliance. And I do want to align to what Kit said earlier. I think the discussion this morning lends itself to some framework for recommendation.

CHAIR THOMPSON: You know, my pause, Chuck, on allowing CMS to reclassify was the question of whether or not that makes it CMS's problem if it's inaccurate. And I don't know that it does, but it -- I worried a little bit, in just reading that, that a manufacturer would say, well, you know, I made my best judgment and if you felt it was wrong you should have reclassified it, as opposed to the

manufacturer is responsible for making the correct submission and owns the responsibilities of correcting that, adjusting that, and dealing with the penalties and consequences if it's not correct.

And if CMS doesn't not -- you know, John, earlier today, talked to us about the division of pharmacy and the variety of different things that they're responsible for, if they don't have the adequate resources to do some of that surveillance, does that invite, you know, some further diminution of responsibility on the manufacturer's part, that they won't be able to step up and really fulfill.

But obviously, it would be nice to be able to -- I'll just go in and change it, is also a pretty quick fix to a problem that you otherwise can't resolve.

COMMISSIONER MILLIGAN: I guess I -- the fact that you have kind of -- have lived inside of the CMS land, I defer to your expertise. It seems to me, just as a layperson looking from the outside, that it's not a zero-sum game, where, you know, if CMS is accountable, the manufacturer isn't, like, you know, I'm going to turn in my poorly written report and it's now your job to edit it. I don't -- that seems --

CHAIR THOMPSON: Yeah. Any other comments?

So what I would like to suggest is, I think it could be great if you can -- I don't know if we'll have the room on the January agenda, but it would be nice to come back with some updates on this, and maybe even being prepared to make some recommendations. I don't know that we'll be in a place where we can pull all of these thoughts together, or we feel like we want to have them all together.

There's the timing issue that we discussed earlier. I think the line extension piece is definitely ready to go with the additional information about like who gets a share of the savings and how do those get distributed, with some of that additional research. The authorized generic.

And then I think maybe some more discussion around the enforcement regime. What's the most effective enforcement regime? Where does that money come from? What are the tools that are used to ensure this is being done accurately? My suspicion is we're not going to be in a place in January to kind of formulate a very set of specific things around that, but you may be able to help

point us more in a direction for at least discussion in a chapter of some of the things that we think could be useful, and maybe some subsequent recommendations.

EXECUTIVE DIRECTOR SCHWARTZ: So I'm not sure how much we can get accomplished --

CHAIR THOMPSON: For January?

EXECUTIVE DIRECTOR SCHWARTZ: -- for the January meeting, and we'll see. We certainly -- you know, the meeting -- we meet towards the end of January and then we meet like March 1st, I think it is.

CHAIR THOMPSON: Yeah.

EXECUTIVE DIRECTOR SCHWARTZ: But if we meet March 1st and we are well developed, we're still good for June, for the June report, and this is not going to make that March report, in any case.

CHAIR THOMPSON: Right.

EXECUTIVE DIRECTOR SCHWARTZ: So we can figure out whether there's some little piece that we would want to do in January, and otherwise March shouldn't be a problem.

CHAIR THOMPSON: Mm-hmm. I just -- it just occurs to me from a congressional standpoint, a congressional calendar, that the more that we can feed in

cost-saving ideas as we go along, even if we bundle it all together in a comprehensive discussion in the June report, I think that could be helpful to come to --

EXECUTIVE DIRECTOR SCHWARTZ: Well, sure. Any time we act --

CHAIR THOMPSON: Right.

EXECUTIVE DIRECTOR SCHWARTZ: -- I mean, it's news and it's information that they can use, even if the report isn't out. It's just, you know, the December-into-January period is always less productive.

CHAIR THOMPSON: Good.

EXECUTIVE DIRECTOR SCHWARTZ: People aren't around.

CHAIR THOMPSON: Okay. Great. Chris, Rick, again, thank you. Very technical issues but appreciate the English language translations.

All right. So we're going to take a break and we will reconvene at 3:00.

* [Recess.]

CHAIR THOMPSON: All right. Why don't we go ahead and get started, and we are going to push through the rest of the afternoon.

So we're kicking off this last section of the agenda with Rob Nelb and DSH allotments.

REVIEW OF MARCH REPORT CHAPTER: ANALYSIS OF DISPROPORTIONATE SHARE HOSPITAL ALLOTMENTS TO STATES

* MR. NELB: The one topic that's a little less complicated than drug policy.

Today, I am going to review a draft chapter for our March report that provides the Commission's annual analysis of disproportionate share hospital allotments to states, known as DSH.

The chapter begins with a brief background on current DSH allotments and payments and then provides the data elements that MACPAC is statutorily required to provide, which are listed here.

The chapter also describes DSH allotment reductions, including the first round of reductions, which took effect on October 1 of this year.

And finally, the chapter concludes with a brief discussion of next steps for MACPAC's work in this area.

I am going to walk through these findings

relatively quickly today since there aren't too many surprises here and since most of the findings are similar to the data that we reported in previous years, but as always, feel free to stop me as we go along if you have any questions.

First, some background. As you know, states are statutorily required to make DSH payments to hospitals that serve a high share of Medicaid and low-income patients, known as Deemed DSH hospitals.

In addition, states have the ability to make DSH payments to virtually any hospital in their state.

In this chapter, we analyze the latest available DSH audit data from 2013, and we find that 44 percent of hospitals received DSH payments in that year.

In 2013, about 14 percent of all hospitals met the deemed DSH criteria, and these hospitals received more than two-thirds of DSH payments.

As you know, DSH payments are limited by annual federal DSH allotments, and states have up to 2 years to spend their allotments.

In 2015, a total of $11.9 billion in DSH funding was allotted to states, and about $1.6 billion in federal

DSH funds were unspent.

In the chapter, we further discuss some of the reasons why states don't spend their full DSH allotments. In some cases, states may not have available state funds necessary to put up the non-federal share to draw down their full federal DSH allotment. In other cases, some states have DSH allotments that are actually larger than the total amount of uncompensated care in their state, so they couldn't draw down the full DSH allotment, even if they had available state funds.

In the chapter, we provide more background about sort of the underlying context for all this, which is really this wide variation across states in terms of state DSH allotments, which are largely based on state spending in 1992, wide variation in state DSH targeting policies, and more recently variation in the effects of ACA coverage expansion on hospital uncompensated care and other factors.

In the report, we provide information about a number of uninsured, levels of uncompensated care, and the number of hospitals that provide essential community services.

Using Census data from 2016, we find that the

number of uninsured declined by 13.7 million since 2013, which is a 33 percent decline.

In using Medicare cost report data, we find that between 2013 and 2015, total hospital uncompensated care for uninsured individuals fell by about $8.6 million, which represents a 23 percent decline.

However, according to the American Hospital Association Annual survey, we find that during the same period, Medicaid shortfall increased by about $3 billion, which is a 23 percent increase.

Medicaid shortfall, as you'll recall, is another type of hospital uncompensated care that DSH pays for and is equal to the difference between a hospital's cost of serving Medicaid patients and the total amount of Medicaid payments it receives for those services.

Lastly, to identify hospitals with high levels of uncompensated care that also provide essential community services, we examined the share of deemed DSH hospitals that provided some of the types of services listed in MACPAC statute because this concept of essential community service really isn't defined anywhere else in statute or regulation.

This year, we found that 95 percent of deemed DSH hospitals provided at least one of the services in our working definition, and that about two-thirds provided three or more services. And more information about the specific services is in your materials.

Some of the declines in uncompensated care that we've seen have the potential to improve hospital margins, and so the chapter includes some updated data about hospital margins using Medicare cost report data.

Looking over the years, it's a bit difficult to identify any trends. We do find that aggregate hospital operating margins increase between 2013 and 2014 by about 1.8 percentage points, but they actually decreased by about 0.4 percentage points between 2014 and 2015.

In 2015, as in prior years, we did find that the deemed DSH hospitals reported lower operating margins as well as lower total margins compared to other hospital types, and for these hospitals, their margins would have been much lower without DSH payments.

The chapter notes that when assessing hospital margins, it's important to recognize that -- especially these year-to-year trends, it's important to remember that

many factors can affect hospital margins, such as hospital consolidation, managed care penetration, hospital costs, factors other than the payer mix, the ACA coverage expansions.

In addition to reporting on those various data elements, the draft chapter provides information about DSH allotment reductions. In October 1 of this year, the beginning of fiscal year 2018, the first round of DSH allotment reductions took effect. It was a reduction of $2 billion in federal funds, which is about 16 percent of states' unreduced allotment amounts.

Under current law, the allotment reductions are scheduled to increase each year up to $8 billion in 2025, which would be a 55 percent reduction.

This summer, CMS proposed a methodology for distributing DSH allotment reductions among states, but so far, this methodology has not yet been finalized. As a result, the projections in our draft chapter are based on CMS's proposed methodology, which may change if this regulation is finalized.

This figure shows the change in state DSH allotments this year as a percentage of states' unreduced

allotments. You can see that the amount of the reductions vary widely by state, from 1.8 percent in South Dakota to 31.6 percent in Massachusetts.

In future years, as the size of DSH allotment reductions increase, the percent reduction for states will also increase. However, the distribution of DSH allotment reductions among states is expected to be largely the same.

As in our previous reports, we continue to find little meaningful relationship between DSH allotments and the various factors that Congress asked us to consider, even after DSH allotment reductions take effect. This is primarily because, as I said before, DSH allotments just vary so much by state because they are based on state spending from 25 years ago in 1992.

However, in addition, we also find that the ACA coverage expansions are adding to the variation that we observed since the ACA is having different effects in states that have expanded Medicaid and those that did not.

Because the DSH allotment reductions are premised on the fact that the ACA coverage expansions would reduce hospital uncompensated care cost, the draft chapter focuses on analyzing the relationship between DSH reductions and

uncompensated care.

We find that 18 states have 2018 DSH allotment reductions that are actually larger than the state's decline in uncompensated care between 2013 and 2014, which suggests that the decline in funding for DSH hospitals in those states from DSH cuts may actually outweigh some of the gains from reductions in uncompensated care in those states.

We also find that in 2015, 11 states have 2018 DSH allotments that actually exceed the total amount of uncompensated care in their state, which means that the state may not actually been able to spend its full DSH allotment, just adding to that $1.6 billion in unspent DSH funds that I mentioned earlier.

In terms of next steps, the chapter outlines a two-track approach that builds on the Commission's discussion at our last meeting.

First, in the near term, we plan to continue to monitor the effects of DSH allotment reductions on states and providers. Because of the timing of this report, we don't have too much information yet on how states are distributing DSH cuts among providers. However, by next

year, we should know more and could further examine policies to better target the remaining DSH funds.

When CMS finalizes its DSH allotment reduction rule, we can also examine how CMS responded to comments that the Commission provided in August of this year. Specifically, we could consider whether CMS or Congress should take further action to better distribute DSH allotments among states.

All of these analyses may be affected by congressional action to further delay DSH cuts, and so we'll continue to keep an eye out for any potential changes. It's too early to tell what might happen right now.

And then in the longer term, we also plan to conduct a more comprehensive analysis of Medicaid hospital payments more generally. As we learned from our recent round table on DSH policy, there are many different types of Medicaid payments to hospitals, and these payments are often interchangeable, and so Commissioners expressed interest in learning more about how DSH interacts with non-DSH supplemental payments as well base payment rates to hospitals.

So that concludes my presentation for today. I look forward to your feedback about ways to improve this chapter and any suggestions for our ongoing work in this area.

Thanks.

CHAIR THOMPSON: All right. Thank you. As usual, Rob, thank you very much for an excellent overview and an excellent chapter.

Marsha.

VICE CHAIR GOLD: Yeah, really nice job. I continue to think this work we're doing, which in the beginning, I wondered where it was going, actually is some of the most useful, very useful stuff that we're doing, so good job.

I had a question. I don't understand the operational on-the-ground fact of a delay in the decision on the 2018 rules. My concern is that sometimes when something gets pushed like into the fourth quarter versus happening all over the year, there's really some bad effects on states or providers or other things. And I don't know if we should be concerned about any of that and discuss it in the report or whether that's a reason where

if it doesn't get done by X time, then maybe you want to delay it, or maybe it isn't because practically it doesn't have an effect.

I mean, I don't quite know what states are doing since they haven't finalized the policy anyway, and what happens if they finalize it this month or April or the summer? Does it make a difference?

MR. NELB: So I can just answer briefly. In terms of the rule, CMS has given states preliminary allotments for 2018 based on their preliminary methodology that was proposed this summer, so that's sort of what states have that they're working with. They know it might change a little bit if the methodology changes.

The bigger wildcard is the DSH cuts themselves, and this is where it's sort of hard to tell exactly what's happening. We've heard anecdotally that some states are already kind of reducing their DSH payments based on current law. Other states may be sort of holding off making payments to see if the cuts get delayed. It definitely adds to uncertainty for states and providers.

CHAIR THOMPSON: I have Sheldon, Brian, Kit, Martha.

COMMISSIONER RETCHIN: I think that's a great addition, Rob, and I don't know anybody on the planet who knows more about DSH than you do, which I'm not sure what that says.

[Laughter.]

COMMISSIONER RETCHIN: As I understand it, as part of the House bill, the DSH cuts would be delayed for 2 years. That actually saves money.

So let me get it straight. Streamlining costs money; delaying cuts saves money. I'm just trying to get that straight. Okay.

[Laughter.]

COMMISSIONER RETCHIN: What I did want to ask was -- I mean, I do agree. We've made progress in understanding the DSH cuts. My fear maybe is what you were saying, Marsha, is that this is sort of starting to feel a little bit like SGR, and you get to a point where you've got billions of dollars that you've built into the cuts.

By the same token, the assumption in building in these reductions, the one failed assumption is it was always assumed that Medicaid would expand universally, and it didn't. So that is one, I think, salient reason to go

back to the drawing board, and maybe there is a compromise here that some reductions could go ahead. But we still have to figure out how to target, and right now, I'm definitely not -- and I keep thinking that we should come back. Instead of trying to target places that don't need it, which I do think there's some of that, rather targeting the safety net institutions that provide comprehensive care, with ambulatory care, physician care, and I realize DSH was never intended for that. But it ought to be a part of the reception of it.

CHAIR THOMPSON: I just have this sigh that comes across my visage when I think about trying to spend more time talking about how to target DSH, and it's not that what you said is not true. It's just that we have had a conversation about this in a variety of different ways, and I guess the question is, do we think that conversation just in terms of helping the staff prioritize where they're going with some of this? It feels like at an earlier point we kind of came to the conclusion, we need the totality of the picture about what's happening with hospital payments. We can't make sense of DSH because we don't know what else has been embedded in these state systems over these past 25

years about how they worked around what DSH was to them with compensating other policies and pools, and only then when we can see the totality of what the various kinds of streams of funding are -- and maybe with that idea about focusing on certain kinds of institutions so we can see the complete picture. Can we understand what changes might be needed in DSH policy alongside of those other structures that have built up over time?

COMMISSIONER RETCHIN: So I don't disagree with you, Penny. I think, though, that it's almost like approaching -- I mean, it seems to me like the Commission really has some -- I won't say obligation, but responsibility of addressing this, and I think it's almost like it should instead -- if we let it go, it's almost like sequestration.

What I would say would be maybe one of the issues, because we can't see any natural seam on the targeting the reductions, maybe we should -- and I've been an advocate for this -- is targeting the allocation; that is, looking for qualities of care, comprehensive care, mostly vertically integrated, that is a requisite for receiving DSH. That's all.

CHAIR THOMPSON: Brian, Kit, Marsha, Chuck. Oh, Martha. I'm sorry. I can't read my own writing.

COMMISSIONER BURWELL: So my comments are along similar lines. The lack of uniformity across states and the size of the reductions jumps out at me. So we have Massachusetts getting a 31 percent reduction, Vermont a 26 percent reduction, while the number of states getting less than percent, and then I see that Tennessee is a footnote.

[Laughter.]

COMMISSIONER BURWELL: Did you have anything to do with that?

It just doesn't make any sense to me, and you have sentences in here like, "Because of the reduction methodology is only partially based on what states receive, the states with the largest allotments are not necessarily those that are experiencing the greatest cuts." Is there a role for -- I mean, there's a methodology here that you nicely lay out. Is it within our purview to comment on that methodology and the results that it produced? I mean, is there -- can you follow this methodology and see how it ended up with these reductions?

MR. NELB: Yeah. So, as I recall, we did provide

a comment letter in August on the methodology and sort of why CMS could potentially change within the existing statutory factors, and so some of the variation is lower reductions to low DSH states and some of these things. Massachusetts has a very low uninsured rate. It gets a larger hit under that uninsured factor and different things. So, yeah, there's more analysis we could do kind of building off of what we did in our comment letter to look at these things.

The other issue that we raised in the comment letter was this issue of unspent funds, which is a factor that was not in the current statute, and so we'll see how CMS responds to our comments, the extent to which they think they can address that within their existing statutory ability. But there may be room for thinking about other factors that would probably have to get added to the statute or think about that would result in a distribution you might think better reflects the way you think the fund should be distributed.

COMMISSIONER BURWELL: You could follow this methodology and quantitatively end up with the same results?

EXECUTIVE DIRECTOR SCHWARTZ: Sadly for him but luckily for us.

MR. NELB: Yeah.

COMMISSIONER BURWELL: SO it does kind of make mathematical sense.

MR. NELB: Yeah. We calculate the reductions for each of the factors, and I can get that for you if you like. We can even talk about it more in the report, the extent to which these differences are due to the uninsured factor versus the targeting factors.

CHAIR THOMPSON: It might be helpful.

MR. NELB: Yeah.

CHAIR THOMPSON: Anne was just suggesting this too. I think one is it might be helpful to remind the Commissioners of the earlier comments that we sent in, and the other would be to maybe embed some of the modeling that we -- if CMS took some of our commentary in the directions that we had suggested, what would that mean in terms of some of these results, that might be helpful as well.

VICE CHAIR GOLD: And if I remember right, our comments also were, to some extent, constrained because of what we thought the guidance CMS was assuming they had to

follow in doing this. So things we might have wanted to say, we weren't sure we could say, if that's the case, because statutorily, they were supposed to follow X, Y, or Z, but if we're then looking at the effect of the way the reductions were, those things we were concerned about come back into play.

Am I remembering right [off microphone]?

CHAIR THOMPSON: Yes, we did try to appreciate that CMS was working within the statutory framework to implement their recommendation --

VICE CHAIR GOLD: Right.

CHAIR THOMPSON: I mean to implement their regulation, yeah.

Kit, Martha, Chuck.

COMMISSIONER GORTON: So I just have a suggestion for future work. Massachusetts, New York, Colorado, Oregon are all places where deemed DSH hospitals and other essential community hospitals are being rolled into accountable care organizations where they are beginning to be paid on a different basis and where they may be able to cover their Medicaid shortfall, one, by dropping encounters, but then by getting paid risk payments on the

back end. And I just would suggest that going forward -- and I don't know whether we'll begin to see that in the next year's data or after that, but I would suggest that going forward, we may want to flag those organizations and think about treating them as a different subset for analysis to see whether their experience -- I mean, the talking points around this are it's okay, you're going to make your money over here, you don't need to drive fee-for-service business in order to keep your margins up and meet your payroll. I think that there will be an opportunity for the Commission to make observations about that. In fact, we may be uniquely situated to make observations about that, and so I just think that going forward, we ought to consider that factor.

CHAIR THOMPSON: Martha.

COMMISSIONER CARTER: I've got sort of a fundamental question and maybe could just use some enlightening, but you can do it another time. But I notice that there's a difference in the definition of uncompensated care between Medicare and Medicaid DSH, because DSH doesn't include charity care and bad debt for people who have insurance, which, as we see that increasing

because of more low-income people having insurance, then causing more bad debt. So how does that factor into this whole constellation of payments to hospitals? And is there a -- maybe I'll stop there.

MR. NELB: Sure. So what you highlight as a limitation of our data is that to get information on uncompensated care for all hospitals, we have to use Medicare cost reports, which define uncompensated care a little bit differently than Medicaid DSH. So it doesn't have an effect on payments to hospitals, so for Medicaid DSH it's only for individuals who are uninsured without other source of coverage, and then there's also the piece for Medicaid shortfall. But there is this portion that's in our sort of overall numbers of uncompensated care that's charity care and bad debt for people with insurance.

COMMISSIONER CARTER: So is that one of the supplemental payments that hospitals get to cover that shortfall? Where does that come into the equation?

MR. NELB: Let's see. So on the Medicare side, there was a recent change that there's a portion of Medicare DSH payments that will be based on your uncompensated care that's reported on your cost report.

It's a separate stream of funding that's a Medicare DSH funding, and that does not affect the amount of uncompensated care that states report on Medicaid DSH audits and the amount of Medicaid DSH funds that they're eligible to receive.

So for the Medicaid purpose, sort of what we're looking at, Medicaid DSH doesn't pay for individuals with private coverage that maybe you can pay a copay or have a deductible or it's bad debt. It isn't covered by current Medicaid DSH policy.

CHAIR THOMPSON: Did you want to jump in on that, Fred? Then Chuck.

[Comment off microphone/laughter.]

COMMISSIONER CERISE: You know, just one quick comment. It's not particularly on that, but more along the lines what Sheldon was talking about, and perhaps Kit. That is, you know, DSH, the purpose was to make sure hospitals were seeing low-income people, and over time this evolution, hospitals will see people. You got to the hospital and you get seen, and the greater need now is if you've got some chronic condition, if you've got things that need care outside of an emergency department but that

you typically depended on the health system, that's -- I guess that's where I would focus efforts rather -- you know, DSH payments have become just one more supplemental payment. States will work around -- if you try to steer, states have ways of working around this. And so if there's going to be payments targeted really for trying to guarantee some access to care, I might look and focus more on what do you want that access to look like, and I don't think you want it to look like an emergency department, but that you would try to focus on ACOs for low-income people or, you know, more comprehensive systems of care. Maybe we can kind of come at it from that angle a little bit as you look at policies around DSH.

CHAIR THOMPSON: Chuck.

COMMISSIONER MILLIGAN: Just a couple of comments and then a question. I think that was really helpful. You hear anecdotally about increases in high-deductible plans and people not paying the deductibles. Is that uncompensated care? I mean, it is, it isn't. People have insurance. They're supposed to pay the deductibles, all that stuff.

I do think that, to Kit's point, Fred's and

Sheldon's point, we are seeing more expectations around whether it's ACO or value-based purchasing or, you know, integration with outpatient systems, I think there's more of that model that I think will be important to kind of track over time.

My specific question about the chapter, you have a -- it's great, Rob, and Chris and Rick are thinking, "Thank God pharmacy isn't as complicated as DSH."

[Laughter.]

COMMISSIONER MILLIGAN: The comment is you have in the chapter sort of a Medicaid payment-to-cost ratio figure, and you have it kind of in quintiles or -- so it's, you know, base payments, supplemental, non-DSH supplemental, and then, I mean, DSH. So you have kind of stratified tiers of states and payment-to-cost ratio. So in some states, you add all those components together, the base payments, non-DSH supplemental, and DSH, and you don't get to 100 percent of cost, and in some states you get way above 100 percent of costs.

In the appendix, I didn't see that stuff at a state-specific level. There's a lot of tables in the appendix that have state level detail. I didn't see that

in the state level detail. And I think that would be helpful in terms of a contribution to this discussion because then in some states the hospital association can say, you know, all of this stuff rolled together doesn't equal my costs. And in some states, they'll say that, but if you're reporting that you had all the components, it's 127 percent of cost. It's a helpful, I think, contribution, and I would -- I guess my question and my comment is: Was there a reason not to have that at a state-specific level in the appendices? Because I think it would be a good contribution.

MR. NELB: No, I think we definitely could add it. Actually, this Health Affairs article, I guess last year, where we provided some state-specific information in an appendix to that article, and so we could use similar tables here. It adds more appendices, but, you know, we get longer every year, so --

COMMISSIONER MILLIGAN: Well, but there's so many state-specific tables in the appendices already. It seemed noticeable by its absence to me.

MR. NELB: Sure. We can work on that.

CHAIR THOMPSON: Yeah, more tables are always

nice.

[Laughter.]

CHAIR THOMPSON: I had a little bit of the same question about hospital margins and some of the relationship to this, but I think that's probably best -- I will set some of that aside for our totality conversation, because I think the relationship both of what we see in this table that Chuck is pointing at and what we saw in the tables that you presented about hospital margins I think need to be put together in a way that gives us more insight into what's actually happening, and what do we really mean by costs and what do we really mean by payments.

Any other comments for Rob on this chapter?

[No response.]

CHAIR THOMPSON: Okay. Hearing one, thank you, Rob. Appreciate it.

Okay. Now we're going to hear about implementation of Section 1115 Medicaid expansion waivers. Kacey?

IMPLEMENTATION OF SECTION 1115 MEDICAID EXPANSION WAIVERS: FINDINGS FROM STRUCTURED INTERVIEWS IN FOUR STATES

* MS. BUDERI: Thank you. So in this session, we'll continue the Commission's discussion of how states have used approved Section 1115 waivers to expand Medicaid to the new adult group. Specifically, I'll be sharing findings from a study MACPAC conducted with the State Health Access and Data Assistance Center at the University of Minnesota, or SHADAC, to conduct structured interviews in order to learn more about state experiences implementing these waivers.

So I'll begin by providing some background on the expansion waivers and prior MACPAC work in this area, describe the study approach, and outline some key takeaways. I'll provide further details on the administrative capacity considerations states needed to make and the challenges they encountered in setting up their programs. I'll conclude by outlining some steps interviewees suggested CMS could take as other states pursue similar approaches.

So as a little bit of background, seven states are currently operating their Medicaid expansions through Section 1115 waivers. They cite a desire to implement policy changes to more closely align Medicaid enrollment

and benefit design with those used in commercial insurance and create incentives for enrollees to use resources more efficiently.

Prior MACPAC work in this area has included fact sheets on each of the state waiver programs, which are available on our website, as well as a presentation at the April 2017 meeting discussing findings from available interim evaluations.

As part of that discussion, Commissioners expressed interest in learning more about how states approached implementation and the administrative capacity elements that were needed.

So in response to that, MACPAC contracted with SHADAC to conduct structured interviews with individuals responsible for implementation in four states: Arkansas, Indiana, Iowa, and Michigan. We identified five key waiver provisions based on Commissioner feedback at that meeting, as well as the available interim evaluations, and these include exchange plan premium assistance, enrollee contribution requirements, health savings accounts, healthy behavior incentives, and graduated copays for non-emergency use of the emergency department.

For each of these, we were interested in what administrative capacity elements were needed, the challenges that arose and how states responded to them, and what other states and CMS should take into account when pursuing similar programs. To answer these questions, SHADAC conducted interviews with 33 individuals representing state agency staff, both current and former, and health insurance plans, and these interviews took place in September and October of this year.

So interviewees identified several key takeaways from their experience, and I'll go through those. Waiver programs are more administratively complex than traditional Medicaid but worthwhile in order to expand coverage. The overall value of the waiver programs is not in cost savings but, rather, in carrying out policies that promote consumer engagement.

Directives from state legislatures to incorporate specific program elements can create administrative and operational difficulties for those who have to implement them. Short timelines between when waivers are approved and when they need to be up and running may require a phased implementation approach, which can be inefficient

and create challenges.

Implementation requires significant work and investment to set up and administer, even in states delegating responsibilities to managed care plans. Significant information technology systems work is required to develop, test, operationalize, and maintain programs. Targeted ongoing beneficiary outreach and education are essential for program success, and plan representatives generally felt equipped to take on additional administrative responsibilities associated with the waivers, although some noted that negotiations over future rates and responsibilities were ongoing.

So in setting up their programs, states needed to consider the administrative capacity needs, which generally fell into four categories: staff time, coordination and communication with other organizations responsible for implementation and with beneficiaries; systems, processes and IT infrastructure; and then the associated costs.

All study states, with the exception of Indiana, reported using considerable staff time, although the extent to which each state delegated responsibilities to contractors varied. For example, Indiana delegated nearly

all responsibilities to plans and other vendors; whereas, Iowa has been able to keep most functions in-house.

While state agencies generally did not report increasing staff, at least one interviewee in every state reported having to scale up member services resources, generally through increased cost center staff.

Coordination needed to occur across different entities with implementation responsibilities, especially in the initial stages, but also on an ongoing basis. For example, Medicaid staff in the premium assistance states, Arkansas and Iowa, spent a lot of time educating state regulators and exchange plans about Medicaid members and requirements. Interviewees in all states also really stressed the significant amount of time required to educate beneficiaries about how the new policies would affect them.

The amount of work that needed to happen in terms of systems processes and IT infrastructure varied depending on the level of capacity that was already there. So, for example, health plans in Indiana already had a lot of the capability they needed to do things like invoice members and collect payments because of their experience with the previous iteration of their waiver, Healthy Indiana Plan

1.0 By contrast, Iowa faced a much heavier IT lift in setting up these kinds of capabilities. And then in terms of the costs of administering these programs, there was little information available, often because they were built into plans' capitation rates and couldn't be separated. However, interviewees generally agreed that the costs of administration outweigh savings or revenue from the waiver policies.

So now I'll turn to some of the challenges interviewees experienced implementing specific programs, beginning with premium assistance.

So premium assistance in this case refers to the state purchase of exchange coverage on behalf of Medicaid enrollees, in place in Arkansas for all expansion enrollees, and initially in place for Iowa enrollees over 100 percent of the federal poverty level, although Iowa has now discontinued its premium assistance program.

One challenge that was true in both states is that plans had a hard time pricing the population, and this was because they had insufficient data to forecast the costs of covering them.

In Iowa, the key challenge, though, was really

plan participation. Both plans dropped out by 2016, partially because they were struggling in Iowa's larger marketplace. They also weren't required to participate in Medicaid. By contrast, Arkansas required all of its exchange plans to also participate in Medicaid premium assistance, and so the influx of Medicaid enrollees there may have actually helped stabilize the Arkansas marketplace.

However, Arkansas faced considerable coordination challenges, and one reason was that it hadn't been using Medicaid managed care prior to expansion, so it had no existing relationships with the plans to build on. And this resulted in what interviewees called a "cultural divide," which had to be overcome under a tight timeline.

So in turning to enrollee contribution requirements, which refers to premiums and cost sharing, I'm going to discuss Iowa and Michigan.

Iowa collects monthly premiums for expansion enrollees over 50 percent FPL, and Michigan collects retrospective cost sharing, billed to expansion enrollees based on their prior three-month service use, and additionally collects premiums for enrollees over 100

percent FPL.

Interviewees in both states reported challenges calculating the contributions because of changes in income and in Michigan service use. Each state also reported different challenges in terms of collection. For example, Michigan interviewees noted that enrollees could not pay premiums by credit card, which was a barrier. And then as another example, Iowa's system for collecting and applying payments didn't have the capacity to process late payments.

Additionally, both states had trouble coordinating with their respective Departments of Treasury to collect unpaid contributions as debts to the state recoverable through things like tax refunds.

So moving on to health savings accounts, which are closely linked with required enrollee contributions, I'm going to talk about Arkansas and Indiana.

So Arkansas initially implemented Health Independence Accounts for individuals over 100 percent FPL, and they planned to phase in the use of these accounts for other enrollees, but ended up terminating the program because of low participation and high costs per enrollee.

Indiana built off its existing account structure

under HIP 1.0 to establish Personal Wellness and Responsibility, or POWER accounts, which cover the first $2,500 of enrollee claims and are jointly funded by state and enrollee contributions.

The challenges here were similar to the ones Iowa and Michigan experienced in terms of calculating required contributions, and this was particularly true in Indiana where the contributions are 2 percent of income and have to be recalculated even for small fluctuations in income. And I'll just note here that this is an example of where a state sought to address a challenge. Indiana is proposing to change its premium requirements to a tiered structure rather than this 2 percent of income system.

So one of the challenges that was unique to the POWER account structure had to do with determining each enrollee's account balance at the end of the benefit period, which has implications for whether the plan or the state owes the other. And this involved reconciling information on service use and contributions across plans, the state, and the fiscal agent, which didn't always match up.

So interacting with both enrollee contribution

requirements and health savings accounts are healthy behavior incentives, and I'll talk about these programs in Indiana, Iowa, and Michigan.

So the programs differed in terms of their incentives and their requirements, but generally allow enrollees to reduce or eliminate their contributions by completing a health risk assessment or preventive care visit.

States face unique challenges based on how their healthy behavior incentives were set up and tracked. For example, Indiana and Iowa reported that challenges sprang up in terms of reconciling claims with a fiscal intermediary or payment system used for crediting beneficiaries, and Michigan experienced a backlog of paper-based health risk assessments because providers didn't always know which plan to submit them to.

Despite these challenges, though, I do want to note that the stakeholders we spoke to generally felt that the healthy behavior incentives were a bright spot in their waiver programs and they were happy with participation rates at this stage.

The last waiver program element I'm going to talk

about is the use of graduated copays for non-emergency use of the ED, which is currently only in place in Indiana, and the goal of this policy is to encourage beneficiaries to substitute non-emergency use of the ED with less-costly alternatives, and it involves charging beneficiaries in the test group $8 for the first non-emergency visit, and $25 for subsequent visits.

Neither the state nor health plans in Indiana reported significant challenges with this one, because the health plans already viewed it as part of their business functions, and they had the systems and processes they needed in place. However, providers were the ones actually responsible for collecting the payments from beneficiaries, and interviewees expressed doubt about whether this was actually happening.

So beyond the challenges unique to specific waiver elements, interviewees also noted some more general challenges. Ones that were related to short implementation timelines as a result of long waiver approval wait times and last-minute legislative decisions. For example, Arkansas had only a few months to set up its premium assistance program, and some interviewees felt that the

health independence accounts had been added at the last minute. Also due to short timelines, stakeholders in all states cited a tension between setting up IT systems quickly and completing full testing and development, often resulting in additional staff time being spent resolving problems manually.

Another set of challenges had to do with communicating with beneficiaries, both in terms of educating them on the more complex waiver provisions and in reaching them in the first place because of problems like bad addresses, which is not unique to the waiver programs but because of waiver provisions such as disenrollment for nonpayment of premiums the consequences were greater.

And then, lastly, interviewees across states expressed some concern about the administrative capacity and coverage impacts of potentially upcoming changes to their state waiver programs.

Finally, I'll just raise some of the levers that interviewees pointed to as ways CMS could help states improve their implementation process. While many of the interviewees felt that CMS was responsive during waiver discussions and helpful in making connections to other

states, they did propose a few new steps CMS could take, including to allow more time for implementation through faster decision-making or a process to automatically approve waiver program elements that have already been implemented in other states; clarify which specific program elements it's willing to approve; and provide more opportunities for information-sharing so states can discuss their experiences, like how they work through common issues, why they chose not to implement certain provisions, and associated costs.

So to wrap it up I will look forward to hearing your thoughts on the findings, as well as how best to disseminate this information. We could publish SHADAC's report as a standalone piece, which includes much greater detail than what I've presented here, or, if the Commission wants to share its perspective on the findings we could issue a MACPAC publication or series of publications. And with that I will conclude.

CHAIR THOMPSON: Thank you. Wonderful. You know, from my standpoint, I think that when we're talking about trying to share information about operational details and implementation, more detail is always better. I think

that is where the value comes in for states or stakeholders or state legislators to be able to look at some of that detail and get a feeling of what is this really going to be like for us, what is this really going to take, what are some of the things that, you know, for us, in our state, we can maybe have a shortcut, because we already have that in place, or we have something like that.

So I think the detail matters, and while I think it would be great to do some fact sheets around the different categories, as you've laid them out, which can be helpful for people who want a very short view of it, that I think making the underlying SHADAC information available would be a very important and helpful contribution to other states.

I did want to say one thing about our characterization of administrative capacity, and test me on whether I'm interpreting this correctly. It sounds like what we're saying is, that capacity has to exist somewhere in the system. In the case of Indiana, we sort of have this characterization of, well, they just handed it to the plans. But the plans still had to come up with all of that, right? They still had to do it. It may not have

been something on the state ledger, where they had to hire state employees, and similarly with other states there is an awful lot of reliance on contractors and others and not just people in the state agencies.

So I just want to be careful as we characterize what does it take to administer this, that when we talk about capacity, I think it's fine to recognize states organize that differently and have different ideas about who can come in and help, and sometimes they do it in-house and sometimes they look to others to do it, but I think it's important not to suggest that there wasn't a lot of administrative cost in one state because they transferred it to a different cost center per se. I'm just making sure that we're clarifying that.

Darin.

COMMISSIONER GORDON: Yeah, and I think -- good information. I think another point along those lines with administrative capacity and operational capabilities, you hit on it with Indiana. It's also for where you're starting from. You know, they had HIP 1.0 and so they were building on top of an existing infrastructure. I mean, they still added some new design elements, but it all

really depends where you're starting from, if you don't have some of these capabilities.

So if you go all the way back, pre HIP 1.0, I mean, there were obviously some administrative things they did in implementing that program.

CHAIR THOMPSON: Very good point. Thank you.

COMMISSIONER GORDON: So just something to keep in mind, where you start from.

CHAIR THOMPSON: Brian, then Kit, then Chuck.

COMMISSIONER BURWELL: My comments have to do with the bigger picture. I mean, this is a great chapter and, you know, we've learned a lot about the implementation of these new types of waivers with these new kinds of provisions in them. But one of my takeaways, I feel like we're seeing only a very -- if we're trying to generate information about these new demonstrations and what we can learn from them, this is a very small window into what's going on in these programs.

These programs are about trying to change behavior about how people are accessing health care, among a very poor population. So when we're talking about, you know, people paying premiums at the federal poverty level,

these are people who make $12,000 a year. They make $250 a month. We're trying to get them to change their behaviors. We're trying to get them to participate in the cost of their health care, take health risk assessments, change their behaviors.

I mean, so I almost see this as a chapter, you know, it's like if we were to write an evaluation -- you know, a comprehensive evaluation of these experiments, this would be one chapter out of 10 kind of thing, because it just gives -- focuses on the state implementation issues.

So I don't -- you know, is that our intention that we just want to --

CHAIR THOMPSON: Well, you might not remember but when we sort of last left this topic and we were talking about evaluation findings, the Commission was very interested in implementation experience. So I think the staff is coming back in response to that conversation, not because we believe this is all there is to say about these areas.

Now I think --

COMMISSIONER BURWELL: Yeah. I mean, so I'm saying, I would hate to just leave --

CHAIR THOMPSON: -- there's another question --

COMMISSIONER BURWELL: -- our work alone --

CHAIR THOMPSON: -- yeah.

COMMISSIONER BURWELL: -- at this.

CHAIR THOMPSON: Mm-hmm.

COMMISSIONER BURWELL: I think it's a very small percentage of the total picture around these 1115s.

CHAIR THOMPSON: Yes, because we asked for them.

COMMISSIONER BURWELL: I understand that.

CHAIR THOMPSON: Right. Right. So I think that, you know, there's another set of questions that we maybe want to think about, which is, is there more work to be done here and what would that look like with respect to, you know, the substance of these experiments and what have they actually resulted in.

EXECUTIVE DIRECTOR SCHWARTZ: I just want to add onto that. I think -- one of the themes that came out when we talked about this in April, and Kacey presented the available interim waiver evaluations, -- there's an evaluation going on in each state. Mathematica is doing a federal evaluation. They have access; they've designed their evaluations. They hold the data. And while we can

be synthesizers of that as it comes out, there's not much we can do to sort of goose that along.

This seemed to be like something -- you know, 33 interviews is -- you know, it took work, but it's something that we could do relatively quickly and get out. So I think while we saw it as a complement, our ability to do more does depend somewhat on the available information.

VICE CHAIR GOLD: Can I just make a suggestion on that, because it may be that, from what we've done, there's a little more we could tease out without more work, which is, one of the reasons one usually is looking at implementation experience -- and I think it's important, because if it's not implemented, how can it have any effect?

And so one of the questions you might ask, given the information that's in the report, is to what extent were these provisions implemented, and when, and what does that mean we will or won't learn about their effectiveness, assuming they were implemented? Because if they're not implemented, the evaluation won't find anything, and you should know, at least for each of these kinds of provisions, where they came in, and whether it didn't, and

what it means. So that might help pull a little bit of it together.

I mean, I'm not surprised that we found out -- I mean, every -- the most robust finding in health services research is it takes long, it's more expensive, and it's usually more complicated. And we found that here. But it is important, I think. People promote some of these as excellent models. Well, it would be good to know to what extent they are theoretical models or actually exist on the ground, and as of which date, with how many people affected by them.

CHAIR THOMPSON: I am wondering if some of that detail is found in the SHADAC report.

VICE CHAIR GOLD: Yes, that's what I was thinking.

MS. BUDERI: I think it's in there. I think we could try to pull it out a little bit more prominently if that's something you'd like us to do.

CHAIR THOMPSON: Okay.

EXECUTIVE DIRECTOR SCHWARTZ: I also think -- I hear what you're saying, Marsha, but I also think it's somewhat of a moving target, because we picked one point in

time. Some of these things are still evolving. We didn't design this to sort of have a -- you know, at the one-year mark, you know, in a very systematic way. So we can see what we can do to sort of pull together, but I don't think that we can say -- like we can say now that health independence accounts didn't work. They terminated the program. But some of these other things, they're still sort of -- they're still ongoing.

VICE CHAIR GOLD: But you might be able to do a timeline. You know, you know when you interviewed people, and you know when they were supposed to start, so you at least know as of -- in that window, where things were. And that's all I was thinking. It's more -- I was trying to get at the question that Brian and others had. I'm not asking for more work, really, or more data collection. I was just thinking that if you looked at the data in terms of timeline and what was originally intended versus what happened when, it may tell you a little bit more than you've taken out of the information you have so far.

EXECUTIVE DIRECTOR SCHWARTZ: We can see what we can do, but I don't fundamentally think that we were set up to really answer that question. But we can see if we can

figure out from what we've learned if we can comment on it.

CHAIR THOMPSON: Kit and Chuck.

COMMISSIONER GORTON: So I agree with Penny that -- one, I agree with Penny. Thank you for doing what we asked you to do. I think you did a -- at least as far as my understanding, what we asked you to do, I think you did a fine job doing what we asked you to do, so thank you.

I do think that releasing the SHADAC report -- it contains valuable detail, and, quite frankly, I think given the state of the Commission's knowledge about all of this I think releasing the SHADAC's report as the SHADAC's report is the way we should do that.

I agree with Penny that it is important that we not overlook the fact that if states delegated something to some third party like a health plan, said health plan perhaps wanted to be paid for it, or perhaps already had been paid to build the infrastructure, whatever. So the fact that the state didn't incur new cost doesn't mean that there weren't costs associated with the work. So I think I would underscore that either we know how that was managed or we don't know how that was managed and we should be clear about that, or SHADAC should be clear about that.

The last thing I will say is that I hope that SHADAC and everybody else will be careful about the qualitative comments made by a very, very, very small number of organizations. We're talking about 4 states, 33 people. Those people don't believe for a minute that CMS won't know who said what. And so the fact that they said CMS was very helpful, of course they did, and who would blame them? We would say the same thing.

As well, there are vendors who bid on business, and why would we expect them to say anything other than, "Of course we're equipped to do this work"? Right? Because that's what they put in their bids so they better be equipped to do the work, and if they're not yet, they will be soon.

So I just think the qualitative stuff, particular that sort of squishy stuff, I hope we don't make too much of that because that's just people being -- and there's an awful lot of Midwestern nice in this sample.

CHAIR THOMPSON: Which we do not object to.

[Laughter.]

CHAIR THOMPSON: It's just a general matter.

COMMISSIONER GORTON: It's very, very sweet, but

I don't know that it's always scientific.

CHAIR THOMPSON: Chuck.

COMMISSIONER MILLIGAN: Oh, dear God. So I think two more Commission meetings and I get my honorary doctorate, although I don't know what in at this point.

[Laughter.]

COMMISSIONER MILLIGAN: Nice job, Kacey. A couple of things. One is, just to contextualize, in April -- you know, it sounds like a long time ago, at this point -- Medicaid reform congressional action, it was important to do this work and I'm grateful that you did this work, to try to get a sense of if states have more flexibility. If Congress did something over the summer, what are these programs starting to look like?

And so I think, as a research enterprise, we need to kind of have a long view of that, because that issue is going to return -- entitlement reform, state flexibility, if states have flexibility what's going to look like in terms of these kind of factors and others that are in play, eliminating retro-eligibility, work requirements, all that kind of stuff. So I think the contextual part of why this work was commissioned and when it was commissioned was very

much to anticipate flexibility, and I think that we still need to have that in the long view.

My specific comment about the chapter, on top of what's been said so far is, some of the comments that people offered were requests of CMS to accelerate things or, you know, like give a wink about kind of what's likely to be okay. Given the bulletins that CMS released about a month ago, given some of the waiver reforms CMS has released recently, I think it would be just helpful to kind of incorporate to what extent any of those informational bulletins or guidance about, you know, 1115 waiver review timelines, project plans, that kind of stuff reflects or doesn't reflect some of the feedback some of these informants offered.

Does that make sense? Okay.

CHAIR THOMPSON: I'm also wondering, because it's inevitable that people will say "I wish I had more time. I wish I had more runway." And to the extent that, you know, I wish the federal approvals or signals had come in sooner, or I wish the state legislature or the governor had told me sooner, or -- I wonder if there is some way that we can also -- I don't think -- I mean, we had a little bit of

this here, but, like, how much time it actually did take between when they started and when they hit certain milestones.

And I think that's maybe a reference point, because it might be -- lots of people who could help create that runway. If you said this kind of an effort -- again, sort of to Darin's earlier point, depending on where you start -- but say you're starting from zero, it's going to take you this amount of time because you've got to get this done, and this follow that, and this is dependent on having completed those first two steps. To the extent that we can have some of those kinds of benchmarks available to people, then regardless of who or how the group of people are that can create that room and that time and that schedule to be more successful, that might be helpful to people. Like this is a three-month effort; this is a nine-month effort.

COMMISSIONER MILLIGAN: Well, I agree with -- and it seems like that was some of the feedback, and I think it was feedback, also, like this is this going to be a viable policy approach to CMS. Is this something they're likely to approve within these parameters? Because we're building on a parallel path, and we're building with, you know, an

implementation schedule in mind, and with a design in mind, but it's got to iterate with CMS about the waiver process.

It seems to me that the states that pursued these were proving feedback that, in some ways, CMS tried now to address with informational bulletins of like five weeks ago. It's probably not going to go necessarily further than that from CMS.

So I'm just -- I just think a little context about to what extent those bulletins address the feedback offered by the informants would be just helpful context.

CHAIR THOMPSON: So that they could feel a little bit more confident about planning and investment ahead of finalization of documents.

Marsha.

VICE CHAIR GOLD: This is just a reality thing. There's a mismatch between the political and policy setting agenda process and the implementation work. And some of it you can figure out how long it takes, and, yes, you can tell Congress that you really need to give them more time. And, yes, you should tell CMS that they have to do it faster. But to some extent, there's something in the nature of the approval processes that results in more

complicated initiatives that really are inconsistent with the timeline. And I don't know how we deal with that because it's a reality. And these were pretty complicated initiatives that had to be implemented pretty fast because people were going to get coverage based on them in a complicated environment where there was a lot of other things going on.

You know, that's always the sausage making that always bothers me about when you look at the policies, because you almost could have told half the time going forward what you'd find a year or two later. And I don't know how analysis can be helpful in that or not. I don't know if other people have thoughts on it, but there's something about the policy process that, you know, legislators have time horizons, people want to be overly optimistic, people want to commit to accomplishing more than they can. They come up with solutions that are infinitely complicated because that's the way you cut the sausage to get all the people and interests involved. And you end up sort of messy policy.

CHAIR THOMPSON: I used to think about like you would have Step 1, Step 2, then magic, then finish. That's

a project plan.

VICE CHAIR GOLD: I like magic.

CHAIR THOMPSON: Magic. All right. Any other feedback and comments? I just want to clarify what we think we're doing with the chapter.

VICE CHAIR GOLD: [off microphone] chapter?

CHAIR THOMPSON: Well, this document. So one is that we're saying we do want to see the SHADAC report released under SHADAC nomenclature. I think we're hearing that it would be helpful to have some fact sheets for the website that could summarize by the kinds of initiatives that we're talking about some of these elements of the implementation experience, maybe appreciating some of the points that have been made so far about recognizing the totality of the administrative capacity needed, how much was dependent upon what you started with and how much of that needs to be taken into account, the extent to which we can connect this with timelines or key operational plans and milestones. Those would be helpful.

VICE CHAIR GOLD: I thought your -- my suggestions and yours with timelines is very much interrelated and getting at some of the same thing.

CHAIR THOMPSON: Okay, great. Thank you, Kacey.

We'll move on to our final topic of the day. We are back to Medicaid managed care authorities. So this section we are continuing from our earlier conversation. We had a little bit of a back-and-forth about issues around MLTSS and also kind of the regulatory framework in which we're planting these recommendations, and I think, Ben, you have some additional thoughts and information to share with us about that.

REVIEW AND FINALIZE RECOMMENDATIONS ON STREAMLINING MEDICAID MANAGED CARE AUTHORITIES

* MR. FINDER: That's right. I think this morning some questions were raised about whether the regulations address specific targeted populations or specific vulnerable populations or populations with complex health needs. And there were other questions about how the regulations treat plans that offer or provide long-term services and supports to their enrollees.

With respect to the former, these are provisions that target specific populations. There are not very many requirements that target specific populations either in the managed care regulations or in the 1915(b) waiver

applications.

There is one provision that addresses American Indians and Alaska Natives, and it has specific provisions about network adequacy and coverage, how payment is to be made to providers, to IHS providers, and special provisions around the enrollment in Indian managed care entities, or IMCEs.

EXECUTIVE DIRECTOR SCHWARTZ: And that's in the reg, right?

MR. FINDER: That's in the regulation, yes. Thank you.

There are also some requirements in the regulation that address coordination of benefits or coordination issues with Medicare specifically for dual eligibles for all managed care plans, regardless of whether they're implemented under 1932 state plan authority, Section 1115 waiver authority, or Section 1915(b) waiver authority.

With respect to standards for plans in states that provide LTSS through managed care programs, there are several places where the statute calls out specific protections or specific standards for those plans or

states. For example, the requirement that states establish a monitoring system, one of the requirements of the monitoring system is that it must address areas around LTSS that are not otherwise specified in the litany of requirements that their monitoring system must have. There are also some specific requirements around stakeholder engagement, specifically that when you are developing a program that provides LTSS, states must ensure that the views of beneficiaries are solicited and addressed in the design, implementation, and oversight of the state's managed LTSS program. Moreover, plans that provide LTSS must also establish a member advisory committee that has a representative sample of beneficiaries that use LTSS services.

Some of the other provisions include the states must implement a mechanism to identify people who need LTSS, and states must establish a beneficiary support system that includes special requirements for individuals who express -- who use LTSS or express an interest in using LTSS services. And there are also some specific requirements around network adequacy that reflect both the complex needs of this population and that LTSS is not

necessarily delivered like other acute-care services.

So that's just sort of a quick overview of what is in the managed care reg. Again, those apply regardless of what authority the plan is provided under, and we can come back with more information if Commissioners are interested later.

CHAIR THOMPSON: Any comments on that or -- so the first -- can we put up the recommendations again? The first recommendation, there were sort of two different questions, I think, that we were focusing on here. One was is this inclusive of MLTSS, that we're saying a state wants to do long-term services and supports, that they can do it through a state plan amendment, though we should discuss whether that ever happens, which is, Would a state ever use a state plan authority without also invoking (c) for MLTSS? And then the second question was whether or not we felt comfortable or wanted to say something more about the regulatory scheme that ensures there's proper oversight and monitoring, particularly for some of the populations that had been previously exempt under a state plan authority from mandatory enrollment.

So let me just open it up for any conversation

with that additional input from Ben to see what people's reactions or thoughts are on that first recommendation. Toby?

COMMISSIONER DOUGLAS: I think to me it strengthens the argument of bringing in MLTSS if there's already -- you know, again the existing -- the point of this is all constructed around there is a structure of enforcement and monitoring, but if the managed care regulation has that for MLTSS -- it does raise for the other populations that are already in there that maybe there needs to be some -- you know, if there isn't anything in the regulation that specifically calls that out, have a little bit more segmentation of those populations and monitoring, or, you know, any type of ongoing reporting and transparency on those.

CHAIR THOMPSON: Chuck?

COMMISSIONER MILLIGAN: I want to take on the two comments that you made in order, Penny. I think to me including MLTSS in number one makes sense because I do think that the likelihood is that states are still going to need a waiver. It may not be a 1915(c). It may be an 1115, because if the state is trying to pursue a way of

offering HCBS waiver-like services but without it being an open-ended entitlement -- in other words, capping enrollment somehow -- you're not going to be able to do that through a state plan authority by itself. So I do think the likelihood is that MLTSS would, in spite of the fact whether it's a state plan amendment or not for managed care as a delivery system, you're still going to need some form of waiver in all likelihood.

With respect to the second about managed care kind of oversight and protections -- and I want to ask the question I meant to and neglected to this morning. The managed care rule has, you know, been finalized. The 1115 waivers that are out there now, they have special terms and conditions that include beneficiary protections of various sorts. To what extent are those 1115 beneficiary protections found in the managed care rule as it has been finalized?

MR. FINDER: So I think I'd need to do a little bit more work to come back with a more well informed response to that. I think the STCs tend to vary by state and by the program that states are trying to implement, and so they can be wide-ranging. But that being said, they

tend to be consistent for similar parts of the program, for example, the fact that states are implementing managed care, they tend to be similar along those lines.

COMMISSIONER MILLIGAN: Just the reason I ask the question is if the concern among some Commissioners or members of the public about number one is that if it's a state plan authority, there's the potential for access or quality risk to beneficiaries, to the extent that there's a bulwark in the managed care rule to protect beneficiaries, do we need to have a waiver for purposes of that beneficiary protection? And I think that that's an important question for me about the extent to which we still need waivers or not because of potential STCs, special terms and conditions, in those waivers.

CHAIR THOMPSON: So, Chuck, just to make sure I understand your question and what you're trying to get at, the STCs, as I think most people know, have always evolved over time, which was one of the --

VICE CHAIR GOLD: Special terms and conditions, right?

CHAIR THOMPSON: Yes. Have always evolved over time, and so -- which to some extent kind of cuts both

ways, right? I mean, on the one hand, it's sort of like that's an argument for why states gets frustrated, because State X came along and got this deal, State Y comes along a year later and, well, that deal is no longer on the table, right?

Now, there's some new thinking and some additional thoughts about what the terms and conditions really ought to look like.

Certainly, I think it's true to say that the current managed care rule attempted to take kind of the best of that thinking as it existed at that moment in time and embed that in that regulation. But that always could change in the future. So is your thinking that you want to see to what extent states with current waivers and current STCs no longer need to be under a waiver because they could have a state plan and effectively pour it over all their obligations that they have been previously meeting under the current reg? Or is it that to the extent that state have been asked to meet a certain level of requirement, that those requirements exist in regulation today?

COMMISSIONER MILLIGAN: So I will share just my thought process for myself, okay? Having worked at the

state level in a few states and seen advocacy at the state level, I'm confident that advocacy at the state level occurs and that we don't need a waiver to generate state-level discussions among advocacy groups, provider associations, state legislators, and others.

For me personally, I'm comfortable with Recommendation 1 as written, but for me personally, if we get to a vote at some point in time, part of what I would offer as an explanation for my vote in support of Recommendation 1 is that because of the now existing managed care rule, recognizing all this stuff always changes over time, but because of the managed care rule as it now exists providing beneficiary protections, I'm comfortable that we don't need the waiver to provide those protections.

So that's where I am, but I'm not sure if that answers your question, but I do think that the context between the protections in the rule and the relationship to special terms and conditions is a meaningful one.

CHAIR THOMPSON: Brian and then Bill.

COMMISSIONER BURWELL: In regard to ensuring that we have adequate protection of vulnerable populations, I'm

less concerned about the LTSS population, obviously, than I am about children with special health care needs. And I think one of the reasons they're excluded from mandatory managed care at this point is access to the high specialty services. So I think there's a concern about network adequacy for those children with highly specialized needs. We want to ensure that they have access to specialty care, you know, whether it's in network or out of network. I don't know if the managed care rules do that.

MR. FINDER: Yeah, so the managed care rule for network adequacy, you have to provide -- you have to document that you have enough providers in a couple of different areas. They call out specialists specifically and then pediatric dentists, and I think there's one other pediatric specialty that is called out under the regulation.

CHAIR THOMPSON: And I do again want to come back to the point that those requirements today do not differ from if you are exercising your authority under a SPA or under a 1915(b). So this is, I think, a little bit of the conversation that we started earlier today, which is -- and it's hard to keep these things separate, and maybe they

aren't. But it is the idea that today there is a SPA and a 1915(b) and 1115s, and comprehensive regulatory regime applicable in all those circumstances for whatever decision states have made about what services and populations are going to be covered under managed care.

And so what we're attempting to do is have a conversation about that circle, which is the regulatory regime, covering all of those populations and services, simplifying this top-level of how states and the federal government interact for states to exercise the available options available to them today and the requirements that are placed upon them as they exercise those options.

To some extent, your comfort level, as we talked about earlier today, with what we're doing up here -- and I think several of us have said rest on this idea of this comprehensive, robust oversight and monitoring regime, whatever those details are, but that contain beneficiary protections, contain requirements around network adequacy, contain requirements around quality and performance that give us confidence that these populations are being properly served in these environments.

EXECUTIVE DIRECTOR SCHWARTZ: And those contracts

are eligibility group-specific, so we're not throwing kids with special health care needs -- like the pricing of those plans is going to be different than the pricing of a plan for a kid who's just a low-income child who doesn't have a disability. So the contracts would be -- you know, that's part of -- the review of the contracts and the rates have to be in accordance with whoever the population is. So, you know, you can argue about whether you think that is sufficient or not, but saying kids with SSI just are going to be treated like a kid who gets, you know, sniffles, it's going to be a different animal.

Can I just say one more thing? Which is this issue about we look -- Ben and I talked about this, and Moira too, yesterday around the 1915(b)s, and we went to look to see about the special terms and conditions, and they point -- the ones that we looked at, which was like spot check, they point to the rule. And the issue on the 1115s, if we wanted to look at that particular portion of 1115, which may not be the reason why the state was doing the 1115, we can do some spot checks to also see if in the newer ones they also just point to the rule; whereas, in the olden days they would have had other kinds of things

because they didn't exist elsewhere. But that's something that we can do if it will make people feel more comfortable.

CHAIR THOMPSON: Right. Bill, Kit, Marsha.

COMMISSIONER SCANLON: This last conversation has left me confused because I thought I was going to react to sort of what Ben said in terms of saying that it seems to me that asking for more specific targeting of oversight is an appropriate thing, that Congress can tell CMS that they need to structure the regulatory regime in a way that there is that kind of targeted sort of oversight, and there's assurance.

Now, what Anne just said about the people are going to be segmented into different contracts and that's going to kind of accomplish the goal in some respects is potentially an answer, but I guess it's also -- I would worry that it may not always work out that way. I mean, things could get combined.

And my sense was that this recommendation, which is essentially saying you could put the people into a single sort of option, but you've got to -- when you do that, you've got to target your oversight.

Again, we're making this recommendation to Congress, not to CMS, and there's more permanence in that, just because of how much inertia there is in terms of statutory change.

We have to do a comfort level if we are sort of talking about this targeted oversight, and I thought that's where Toby was too sort of earlier. We can simplify things on one level and hopefully not complicate things too much in terms of the other, but even if we add some complications in this targeting, it may be so important to do it.

One of the things, as I observed earlier this morning, we've got adults with disabilities who are not in one of these, what I'll call protected groups, and one could think about them as being a very complex population that needs some protections, that go above what you might think of as average protection.

CHAIR THOMPSON: Kit.

COMMISSIONER GORTON: So, first, I want to build on what Bill just said. You have children with disabilities who are not part of these protected groups. So if you look at any TANF population, you've got a bunch

of kids with disabilities in them. They turn up all the time because they haven't gone through this. So I process whatever else.

So those children rely on the monitoring oversight schemes that are in place, and they have for a generation now. And I just want to point to what Chuck has said very articulately on several occasions. The states are not immune to this kind of input, and at this point in my life, I have participated in managed care bids in about a quarter of the states. Now, that's not all of them, but it's a reasonable sample size. And there's not a one of them that doesn't have a page-long list of pediatric subspecialists that are required in terms of the geo-access requirements.

And so I think the states have taken very seriously their responsibility for children with special health care needs. There is no louder group of advocates than the families of children with special health care needs if things are not going well, and that's appropriate because people should advocate for their children.

I think the states are very sensitive to that, and I think they have, by and large -- not always perfect,

but I think they have, by and large, done a pretty good job with that.

And there's a fundamental question of federalism of does something have to be in a federal rule in order to feel comfortable that it's getting done, and I guess what I would say, as I look back on 25 years of experience in Tennessee and Pennsylvania and some of the other trailblazer states, where kids with disabilities were put in these programs, and it's been okay. And it is currently the situation, right?

So right now, today, you can put a kid in a 1915(b) waiver. CMS will say yes. So once you've convinced the parents and advocates -- and God bless them, the Academy of Pediatric chapter in that particular state, that it is okay and safe to put children with special health care needs in a managed care program. CMS does not get in the way of that, and everybody is paying a lot of attention to it.

So I think that I'm more than happy if we need to do more diligence and make people more comfortable with that, but I'll align myself with Chuck. I'm ready today to vote for this. I think that there's more than enough

protection in place, and I think we have a lot -- again, 25 years' worth of experience saying that that's the case. And I'm glad that people care and are worried about it, but I think these populations are well addressed. And just because something didn't happen and make it into the mega rule doesn't mean it isn't in place on the ground working perfectly well.

CHAIR THOMPSON: I'll also say with regard to thinking about some of this conversation, as I've been trying to take it in as well, some of the requirements of the rule -- and of any regulatory regime -- are meant to be specific to the purpose and the populations and the services being covered. So when we talk about network adequacy and we're talking about a plan or a set of services focused on a certain population, then obviously your view of what that network adequacy is or is not depends on that population or set of services.

Same with quality measurement. That's going to depend on what kind of population do we have here, what kind of services are we including here.

So the fact that they are -- that there isn't another level of scrutiny or oversight -- and the rule is

pretty comprehensive. I don't know what some of those additional -- that additional scrutiny or oversight might look like that would take into consideration the special needs or issues associated with a certain set of services or populations that doesn't already have kind of the meat on the bones from the sort of general category of requirements that needs to be met.

So as I think about this, I'm having a little bit of difficulty also trying to think about what that -- even if we wanted to propose some additional sort of monitoring or federal steps, what exactly, how that would play out exactly in this framework that we're talking about.

Marsha, I know you want to jump in, and, Darin, you're next.

VICE CHAIR GOLD: Okay. I'm not going to repeat what I said this morning. I do have some concerns with this, and I hear people coming back as well.

I want to suggest one thing, which may be consistent with some of what Chuck was saying and others. I think something is missing in the chapter right now that is making it harder for us to make a decision on these recommendations.

I have a sense that it was a very generic discussion. There are these exclusions, but we didn't talk about the people who are the exclusions. I would like to see who this subgroup is, why they were excluded to begin with, how many of them there are, what we know now about which waivers they're included in or not, and what protections there are in the existing managed care regulations that are specific to this population or under the different waiver authorities.

To me, that's the evidence base that lets me decide whether I'm comfortable with it, but I don't know that we've gone through that detailed work. We've talked about it sort of generically, and I was thinking more about state plan amendment versus 1915(b) or 1115 than I was thinking about specific vulnerable subgroups and where they stand today in the program.

So I don't know if that can be done, but I would feel a lot more on a sounder evidence base thinking about this if I had that along with what we know from any research on the performance of people if they've been in managed care, but I don't think there is any research much.

CHAIR THOMPSON: Darin.

COMMISSIONER GORDON: You know, we're having this discussion about that if you do things through a SPA that you are somehow weak, there's a weakened oversight or weakened protection for populations if we have a SPA pathway, which state plan amendments have never -- state plan --

VICE CHAIR GOLD: There's a general problem with --

COMMISSIONER GORDON: My point is it's interesting. We're basically saying if it's a waiver that there's so much more protection because, again, all these populations are covered in waivers today. This is an issue about a vehicle, and if we have a concern that a state plan is a lower level or a lower bar for a vehicle, that's a whole different discussion. It's broader than anything we've been talking about today.

I don't think that's the case. I don't think there is anything that you can point to that would show that a state plan is you can do whatever you want, nobody is watching out for you, there are no minimum standards or expectations. That's not -- that's just not existent.

The state plan, you have the same oversight --

CMS has the same oversight responsibility and same expectations. If we don't think that's the --

VICE CHAIR GOLD: Well, I'm not averse to saying there's a generic problem.

COMMISSIONER GORDON: Well, I was going to say if we don't think that --

VICE CHAIR GOLD: I'm not averse to that if that's the factual thing we come up with. I just don't know that we've done the analysis. I appreciate your experience and you're telling us that's how it works, but there's --

COMMISSIONER GORDON: It's a --

VICE CHAIR GOLD: Yeah.

COMMISSIONER GORDON: The state plan, it's an obligation. Same -- similar waivers. It's a different contract vehicle with the federal government of here's what I will do, and here is how I'm going to do that. And there's a back-and-forth. You're still interacting with CMS on your functioning there, my point being the concern about these different populations, you're going to put them -- they're in managed care.

VICE CHAIR GOLD: They're not in managed care.

COMMISSIONER GORDON: They are in managed care.

VICE CHAIR GOLD: Some of them are, and some of them aren't.

COMMISSIONER GORDON: Yes. And my point is whether you do this or not -- there's some are; there's some not -- they're going to -- if you made a decision in your state that you're going to cover this population of managed care, that is your threshold question.

VICE CHAIR GOLD: Yeah.

COMMISSIONER GORDON: The vehicle, you find that you do second, which is I'm going to either do part of the state plan, part in a 1915, I'm going to do an 1115. I've had states after they made the conclusion that they're going to do managed care for all populations ask the question, "So now that we've passed that, which vehicle do I follow?" This is about a vehicle, another vehicle, or a simplifying vehicle that a state could use to get to where they can get to today. It's just a simple -- it's another path that simplifies basically an artifact because you're talking about why were those populations -- they're at a time -- and I remember that time -- there wasn't a state plan pathway at all for managed care.

Just again, it's -- so, again, I'm with Chuck, and again, I think it's because I've been in the states. I've seen the states. I've done state plan amendments. I've done waivers. It's a vehicle. It isn't a matter of whether or not you are sacrificing protections for certain populations.

CHAIR THOMPSON: Toby.

COMMISSIONER DOUGLAS: Well, I think we're done. I think we have just --

CHAIR THOMPSON: Yeah. We've exhausted ourselves on this, yeah.

EXECUTIVE DIRECTOR SCHWARTZ: That's a good point.

COMMISSIONER DOUGLAS: Thank you.

[Laughter.]

CHAIR THOMPSON: Why don't we do this. What I would like to suggest is that we carry over Recommendation 1 into January, with the additional analysis that Chuck has proposed, some more meat on the bones to follow up on this issue of what does monitoring and oversight really look like. I think that to the extent that we have some additional ability to talk about MLTSS and how that fits

into Recommendation 1, I think that could be helpful.

At that point, people will either get more comfortable or not. We'll take a vote, and we'll proceed, but I think we can put some more information on the table for all of the Commissioners. I don't think there's a reason that we need to rush ourselves to a vote today if we have some Commissioners who are feeling uneasy. We can build in some more language and justification apropos some of the earlier comments that we had this morning about focusing on the oversight and regulatory regime that is in place and the key constituent parts of that, that make us comfortable moving ahead with this recommendation.

VICE CHAIR GOLD: Penny, on that, will we get a revised chapter that incorporates the logic of the recommendations and any changes to look at so we can understand how, if we voted X or Y, it would be presented in the report to Congress?

CHAIR THOMPSON: Sure. I do think that you have an opportunity to still feedback on -- you know, I think we should strengthen this aspect of it or I think we should address this aspect of it.

VICE CHAIR GOLD: Right. Sure. But we see what

the staff proposes.

CHAIR THOMPSON: Yes, we can see that ahead of time.

What I would like to do is see if we can go ahead and have a discussion or a vote on Recommendations 2 and 3.

Toby.

COMMISSIONER DOUGLAS: One that was the other issue that Brian raised around statewide-ness. Is that coming back?

COMMISSIONER BURWELL: [Speaking off microphone.]

COMMISSIONER DOUGLAS: Okay.

COMMISSIONER BURWELL: You have the option of doing comprehensive managed care, but you can still waive state --(b) waivers do not go away.

VICE CHAIR GOLD: Correct.

COMMISSIONER BURWELL: You can still have a (b) waiver --

COMMISSIONER DOUGLAS: But the question is, are we allowing for -- will the state be allowed to use a state plan amendment to do it just in a certain geographic region?

COMMISSIONER BURWELL: I would say no.

COMMISSIONER DOUGLAS: And I thought that was where a vote -- we can take it into January, but again, I don't know why we wouldn't allow that, why that would then require a (b) waiver, why we would be forcing them to do a (b) for something that could be -- it's the same thing. They're just doing it in certain geographic regions. As I said earlier, there's state plan amendments, like the health home option, where you can do it. So it's not like there isn't a precedent there.

CHAIR THOMPSON: Yeah. That seems a little bit -- I mean, that may be right that we should think about that, but I'm not sure that is what was contemplated in our initial instructions to the staff about focusing on choosing managed care as a delivery system as opposed to some of the other elements like statewide-ness.

So you're saying, though, it would undo some of the benefit of it.

COMMISSIONER DOUGLAS: Yeah, it would undo the benefit. I mean, a lot of states aren't doing statewide because there are certain areas where they just don't have the capacity or they want to test it in certain regions.

Yeah, I thought Brian brought that up earlier.

EXECUTIVE DIRECTOR SCHWARTZ: Can we explore that as part of --

COMMISSIONER DOUGLAS: Yeah. Perfect.

EXECUTIVE DIRECTOR SCHWARTZ: We can also take a look at the waivers and see how much --

COMMISSIONER DOUGLAS: I said we were done.

EXECUTIVE DIRECTOR SCHWARTZ: And then we can also have an assessment about whether that's a bridge too far for this moment as opposed to --

CHAIR THOMPSON: All right. So let's turn to Recommendations 2 and 3 and see if there are any questions about what those recommendations mean or any discussion the Commissioners would like to have before trying to bring at least those two to a vote.

COMMISSIONER WEIL: I have a silly question, which is wouldn't we want to take these all up together, even if we're ready on part of them, but I have a strong feeling that it just seems neater. Maybe you'd probably like to be done with it, though.

[Laughter.]

CHAIR THOMPSON: I try to check the box, get things off the list. But if that makes more sense to the

Commissioners, we can do that.

It seemed as though there was less of a question in people's minds about 2 and 3, and if we can dispense with that and focus our attention on the first, that seemed like a more efficient use of time to me. But I'm willing to go with whatever the Commissioners would like.

COMMISSIONER CARTER: Would we put them all out at the same time?

EXECUTIVE DIRECTOR SCHWARTZ: Yes. They would all come out.

COMMISSIONER CARTER: So we would just vote on those, 2 and 3, today and then hold them until we had resolved No. 1?

EXECUTIVE DIRECTOR SCHWARTZ: Yes.

VICE CHAIR GOLD: In the March report.

CHAIR THOMPSON: Leanna.

COMMISSIONER GEORGE: All right. I'm not nearly as well informed about these programs as most of you are. So I'm just verifying that No. 1 basically makes it to be able to do what (b) does, and No. 3 basically makes it be able to do what -- makes (c) do what (b) does. Am I right? Because I see the waive freedom of choice. I remember the

arguments back at home when we went into -- renewed the (b)(c) waiver to go into a managed care plan, and that was like, oh, there was a big concern. And fear was they're taking away our freedom to be able to choose our providers, to be able to choose what kind of services we want, things like that, and so that's what I'm trying to clarify.

EXECUTIVE DIRECTOR SCHWARTZ: So what's contemplated here is that in doing a combination (b)(c) waiver, the pieces of the (b) waiver that you would still need if you were allowed to mandatorily enroll these other populations are a waiver to waive freedom of choice and selective contracting, and you would still have to go through your rationale and describe that. You just would have one waiver to do it in. You wouldn't have to do two waivers with two sets of reports with different schedules. It's just it allows -- it's meant to allow consolidation of those activities into one activity. It doesn't change what states are doing or give them new permission to do new things. It's an administrative consolidation.

COMMISSIONER GEORGE: Okay.

CHAIR THOMPSON: Any other questions on Recommendations 2 and 3?

VICE CHAIR GOLD: Can we vote?

CHAIR THOMPSON: That's what we're about to do.

Okay. So we will call for a vote. Before we -- before doing so, I want to represent to the public that our conflict of interest rules apply when it comes to a vote. Our conflict of interest policies are posted on the MACPAC website. That policy is intended to ensure that certain kinds of financial and other interests and affiliations, should they rise to the level of potential conflict, will be disclosed during a voting meeting.

Under our policy, a reportable interest has to be particular, directly, predictably, and significantly affected by the outcome of a vote on a specific recommendation. It is not a generalized interest. There are a variety of other requirements associated with disclosing conflicts of interest.

We have a conflict of interest committee. The committee, in anticipation of taking a vote on these recommendations, met in advance of this meeting. The committee did not find any reportable conflicts from any of the financial and interest disclosures of any of the Commissioners.

Okay. So, Anne, would you go through the vote and we'll take each recommendation in turn?

EXECUTIVE DIRECTOR SCHWARTZ: Yes.

CHAIR THOMPSON: Thank you.

EXECUTIVE DIRECTOR SCHWARTZ: Okay. So this one we're going to vote first on what is Recommendation 2 on the slide, Congress should extend approval and renewal periods for all Section 1915(b) waivers from two to five years.

And so I'm going to go down the list. Brian Burwell.

COMMISSIONER BURWELL: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Martha Carter.

COMMISSIONER CARTER: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Fred Cerise.

COMMISSIONER CERISE: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: I'm marking Gustavo Cruz as not present.

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.

COMMISSIONER GORDON: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: 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.

COMMISSIONER WEIL: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Penny Thompson.

CHAIR THOMPSON: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Okay. Adopted. All right.

So Now this is on the recommendation marked Number 3 on the slide, Congress should revise Section 1915(c) waiver authority to permit Section 1915(c) waivers, to waive freedom of choice and selective contracting.

Brian Burwell.

COMMISSIONER BURWELL: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Martha Carter.

COMMISSIONER CARTER: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Fred Cerise.

COMMISSIONER CERISE: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: I'm marking Gustavo Cruz as not present.

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.

COMMISSIONER GORDON: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: 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.

COMMISSIONER WEIL: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Penny Thompson.

CHAIR THOMPSON: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Okay.

CHAIR THOMPSON: Thank you, Commissioners.

So then we will carry over Recommendation 1 for additional justification and refinement as discussed in

this meeting, and we will look forward to a vote on that revised recommendation into the January meeting.

We can open up for public comment to end the day, on any or all matters under discussion before the Commission.

PUBLIC COMMENT

* MS. GONTSCHAROW: Hi. Zina Gontscharow with America's Essential Hospitals. First I'd like to thank the Commission for this opportunity to comment, and its continued work and focus on Medicaid DSH. We also thank the Commission and its staff for all of their hard work on the annual Medicaid DSH report, and we are really looking forward to its release in March.

Medicaid DSH support ensures our hospitals are able to provide primary through quaternary care, and vital services such as top-level trauma care, burn care, and neonatal intensive care. Our overall goal, as always, is to ensure that essential hospitals have the financial resources they need to keep their doors open and provide all the services to all patients, particularly the low-income and other vulnerable populations. This is consistent with Congress's stated intent in the DSH statute. We

continue to advocate for better targeting of DSH dollars, and by which we mean concentrating the DSH dollars to targeted hospitals. We welcome the opportunity to work with the Commission as they continue their work and we prepare for the release of the third annual report.

So thank you.

CHAIR THOMPSON: Thank you.

MS. HAVENS: Hi. I'm Laurie Alban Havens, representing the American Speech-Language-Hearing Association as Director of Private Health Plans and Medicaid Advocacy. I want to address the issue about telemedicine and just to comment. There is also telerehab, telepractice, and telehealth, if you want to add a few more terms to it.

We'd like to encourage the inclusion of all therapies that were not mentioned in the chapter, because this is a very growing and significant area. And in terms of what is being done and the capturing, or inability to capture what's not being done, it's very interesting that because of the coding there are some states that specifically, because it's considered a different platform but the treatment is the same, don't even include the code.

So we don't know what we don't know. In fact, telepractice is being done but may not be reported.

And just incidentally, anecdotally, in the state of Hawaii they have approved Medicaid provision for telepractice -- or telehealth, or whatever. However, because they use the coding that Medicare uses and because Medicare doesn't accept that code, they can say it's approved but they can't file any claims or have acceptance of any services that are being provided via telehealth. So I just want to explain that, and because there aren't explicit regs in some states, it is being done because they accept it.

And then, finally, as you consider, and you talk about later, work that you will be doing, we at ASHA are following very closely what's happening with telepractice for our clinicians, and we're certainly happy to provide you with any information on that.

Thank you.

CHAIR THOMPSON: Thank you. I'm sure we would like any information that you would like to provide. We

would find that very useful. Thank you.

Any other comments from the public?

[No response.]

CHAIR THOMPSON: Thank you very much and we are adjourned.

* [Whereupon, at 4:49 p.m., the meeting was adjourned.]