

PUBLIC MEETING

Via GoToWebinar

Thursday, April 8, 2021 10:30 a.m.

COMMISSIONERS PRESENT:

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1 PROCEEDINGS 2 [10:30 a.m.] CHAIR BELLA: Good morning, everybody. We will 3 give others a few seconds or a little bit longer to join 4 5 us. 6 [Pause.] 7 CHAIR BELLA: All right. Let's go ahead and get 8 started. Welcome, everyone, to the April MACPAC meeting. 9 Thank you for joining us, and welcome to all the 10 Commissioners. 11 We are going to start with our session on high-12 cost specialty drugs. Chris is going to lead us through an overview of the chapter and our recommendation. So Chris, 13 welcome, and I will turn it to you. 14 15 HIGH-COST SPECIALTY DRUGS: REVIEW OF DRAFT ### 16 CHAPTER AND RECOMMENDATIONS 17 MR. PARK: Thank you. Okay. So I don't see the \* 18 slides right now, so let me wait until they pop up. Okay. 19 Okay. Thank you. 20 Today I'll provide a quick overview of the draft 21 chapter and go over the draft recommendations on 22 accelerated approval drugs prior to tomorrow. The chapter

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includes discussion on high-cost specialty drugs, including a summary of the work the Commission has done over the past year with a technical advisory panel to develop new models to address the challenges of high-cost specialty drugs.

5 The chapter will also include a section on accelerated approval drugs and the Commission's 6 7 recommendations, which will be the focus of most of this 8 presentation. It also discusses design options and 9 considerations for a new benefit for cell and gene 10 therapies that was identified by the advisory panel. As a 11 reminder, we are not making any recommendations on cell and 12 gene therapies at this time.

For the draft recommendations on accelerated 13 14 approval drugs I will go through the rationale for the 15 recommendations and the potential implications on various 16 stakeholders. If you have minor comments or edits on the text of the recommendation you can send us those later so 17 18 that we can incorporate them for tomorrow's votes. But if 19 there are things that you think need to be added or 20 clarified in the chapter feel free to raise those today. 21 The first section of the chapter provides

22 background on Medicaid spending on high-cost specialty

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drugs and how the shift in spending towards these drugs 1 creates challenges for states. From 2010 to 2015, net 2 spending on specialty drugs in Medicaid almost doubled from 3 \$4.8 billion to \$9.9 billion. Specialty drugs have also 4 been the main driver of recent drug spending growth. For 5 example, from 2018 to 2019, Medicaid fee-for-service net 6 cost per claim for traditional drugs fell 0.4 percent while 7 8 the net cost per claim for specialty drugs increased 8.6 9 percent. Additionally, in 2019, specialty drugs accounted 10 for 48.5 percent of fee-for-service pharmacy spending, but 11 only 1.3 percent of drug utilization.

Over the past few years, the Commission has heard from states about the challenges high-cost specialty drugs present. They have commented that the current utilization management tools are not effective for high-cost specialty drugs and that they need new strategies and models to address the unique challenge of these drugs.

18 The next section reviews the Commission's ongoing 19 work on high-cost specialty drugs. The Commission has been 20 discussing the issue of high-cost specialty drugs over the 21 past few years and working to identify potential models 22 that can help states address these challenges.

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1 Although states have started to develop some innovative strategies to deal with particular high-cost 2 specialty drugs, such as those to pay for hepatitis C drugs 3 4 or outcomes-based contracts, the Commission has heard how these models have been administratively challenging to 5 implement. Thus, states have only been able to use these 6 models on a smaller number of drugs. States are seeking 7 8 new authorities to address high-cost specialty drugs more 9 broadly.

10 To assist in the Commission's work in examining 11 the effect of high-cost specialty drugs on Medicaid, MACPAC 12 worked with a contractor over the past year to conduct an analysis of the drug pipeline, and convening a technical 13 advisory panel to examine these issues more closely. The 14 15 advisory panel included drug policy and pricing experts 16 from academia and the private sector, state Medicaid and federal officials, beneficiary advocates, providers, health 17 18 plans, and drug manufacturers.

The goal of the panel was to bring together a diverse group of experts to help us prioritize which drugs in the pipeline could have a significant effect on Medicaid over the next few years, identify what challenges these

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1 drugs present, and develop new Medicaid payment coverage 2 policies that could help address those challenges.

This slide highlights the findings from the TAP 3 4 meetings which were presented before the Commission in January, so I won't spend too much time here. The panel 5 prioritized three types of drugs with particular challenges 6 to states, including accelerated approval drugs, cell and 7 gene therapies, and drugs for sensitive populations, which 8 9 include drugs for conditions such as HIV/AIDS. The panel 10 discussed the pros and cons of several different models for 11 each type of drugs, as shown in the figure, and ultimately 12 identified a differential rebate for accelerated approval drugs and a new national drug benefit for cell and gene 13 14 therapies as the models with the most potential. The 15 findings from the panel were helpful in informing the work 16 of the Commission. After deliberating on the various policy 17 options and key design considerations from the panel, the 18 Commission ultimately agreed to proceed with recommendations for a differential rebate on accelerated 19 20 approval drugs. The Commission also agreed that a new drug 21 benefit for cell and gene therapies has potential, but we

22 are not ready to make a recommendation on this model at

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1 this time.

I will quickly skip forward to the new benefit 2 for cell and gene therapies briefly, since we will be going 3 through the accelerated approval drugs recommendations in 4 5 detail. Building on discussions of the panel, the chapter presents a framework for a new national drug benefit for 6 cell and gene therapies that could help address the high 7 up-front costs, budget volatility, and the uncertainty in 8 9 the long-term benefits that cell and gene therapies 10 present.

11 A new benefit could carve cell and gene therapies 12 out of the Medicaid Drug Rebate Program, or MDRP. It would 13 allow for new coverage, payment, or rebate requirements without disrupting the existing structure of the MDRP for 14 15 other outpatient drugs. The chapter discusses key design 16 options and the potential tradeoffs that would need to be considered when developing such a benefit, including 17 potential implications for certain stakeholders. 18

So the accelerated approval pathway allows FDA to grant accelerated approval based on whether a drug has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit. The surrogate endpoint is a

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market that is thought to predict a clinical benefit, but it is not, itself, a measure of a clinical benefit. For example, tumor shrinkage in certain cancer types has been considered to be reasonably likely to predict improvement in overall survival, and is a commonly used surrogate endpoint in accelerated approval of cancer drugs.

7 The FDA has acknowledged that using surrogate 8 endpoints creates a risk that patients will be exposed to 9 drugs that ultimately will not be shown to provide an 10 actual clinical benefit. It was also noted that the 11 smaller and shorter clinical trials may mean that there is 12 less information about the occurrence of rare or delayed 13 adverse effects. When the FDA approves the drug through an accelerated approval pathway, it requires manufacturers to 14 15 conduct additional postmarketing studies to verify that the 16 drug achieves a clinical benefit. However, these 17 confirmatory trials are often delayed.

One analysis found that results from confirmatory trials for over half of indications granted accelerated approval, between 2009 and 2013, were not available after a median of five years of follow-up. This means that it takes longer to complete the confirmatory trials for many

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of these accelerated approval drugs than the average of one to four years it normally takes for Phase III clinical trials under the traditional pathway. Because of these issues, states are concerned about being required to cover accelerated approval drugs and paying high prices when the clinical benefit has not been verified.

To address these concerns, the Commission is
considering two recommendations. Recommendation 1 is to
increase the minimum rebate. It reads:

10 Congress should amend Section 1927(c)(1) of the 11 Social Security Act to increase the minimum rebate 12 percentage on drugs that receive approval from the U.S. Food and Drug Administration (FDA) through the accelerated 13 approval pathway under Section 506(c) of the Federal Food, 14 15 Drug, and Cosmetic Act. This increased rebate percentage 16 would apply until the manufacturer has completed the postmarketing confirmatory trial and been granted 17 18 traditional FDA approval. Once the FDA grants traditional 19 approval, the minimum rebate percentage would revert back to the amount listed under Section 1927(c)(1)(B)(i). 20 21 Recommendation 2 would increase the inflationary

21 Recommendation 2 would increase the inflationary 22 rebate. It reads:

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1 Congress should amend Section 1927(c)(2) of the Social Security Act to increase the additional inflationary 2 3 rebate on drugs that receive approval from the U.S. Food 4 and Drug Administration (FDA) through the accelerated approval pathway under Section 506(c) of the Federal Food, 5 Drug, and Cosmetic Act. This increased inflationary rebate 6 would go into effect if the manufacturer has not yet 7 8 completed the postmarketing confirmatory trial and been 9 granted traditional FDA approval after a specified number 10 of years. Once the FDA grants traditional approval, the inflationary rebate would revert back to the amount 11 12 typically calculated under Section 1927(c)(2).

These recommendations do not affect FDA authority 13 14 or processes. The recommendations do not dispute the FDA's 15 decision to approve a drug and thus require the Medicaid 16 program to cover these drugs. They are merely a pricing policy focused on lowering the cost to Medicaid. Changing 17 18 the rebates under the Drug Rebate Program strikes a balance 19 between addressing state concerns of paying high prices for 20 products that do not have a verified clinical benefit while 21 maintaining Medicaid coverage for these products.

22 These recommendations would lower the net price

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of these products until the manufacturer completes its 1 confirmatory trial and verifies the clinical benefit of the 2 drug. Increasing the minimum rebate will allow states to 3 4 pay less until the manufacturer has verified the clinical benefit, to help account for the risk that the product does 5 not achieve the anticipated clinical benefit. Importantly, 6 the Medicaid Drug Rebate Program coverage requirement would 7 remain, and beneficiaries would maintain access to these 8 9 products. The higher minimum rebate would also create a 10 financial incentive for manufacturers to complete 11 confirmatory trials in a timely manner.

12 An increase in the inflationary rebate would help 13 mitigate any large increases in list price that may occur 14 before the manufacturer completes the confirmatory trial. 15 This increase would not go into effect until a specified 16 numbers of years, to provide manufacturers a reasonable amount of time to complete the confirmatory trial, but it 17 18 would further penalize delays. Because this increase is 19 tied to the inflationary rebate, it would not be applied if 20 the manufacturer does not increase the price faster than 21 inflation.

22

Once the FDA grants traditional approval, the

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1 rebate amounts would revert back to the standard amount 2 calculated under the MDRP. This would effectively serve to 3 increase net price to the manufacturer once they have 4 verified the clinical benefit of the drug.

5 The Commission is not recommending specific 6 increase in the minimum or inflationary rebate nor the specified number of years after which the increased 7 inflationary rebate would be applied. That will be left to 8 9 the discretion of Congress. But the Commission notes that 10 they need to be significant enough to provide a meaningful 11 reduction in price which would also provide a strong 12 incentive to encourage completion of the confirmatory 13 trials. For example, most participants on the advisory panel suggested that the minimum rebate increase for 14 15 accelerated approval drugs should be higher than the 8 16 percent increase in the minimum rebate provided under the 17 Affordable Care Act.

18 Manufacturers have commented that they oppose 19 this policy and argue that additional Medicaid rebate may 20 discourage research and development or delay the market 21 availability of drugs for serious conditions that may 22 disproportionately affect Medicaid beneficiaries. This is

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a claim that we cannot evaluate with any type of precision. 1 It is important to note that manufacturers take several 2 factors into account, including Medicaid rebates, when 3 4 making decisions on drug development and product launch. Medicaid is not the sole payer for these drugs, so an 5 increased rebate would not necessarily have a significant 6 influence on a manufacturer's decision to pursue this 7 8 pathway. For example, the Affordable Care Act increased 9 Medicaid rebates on brand drugs from 15.1 percent of 10 average manufacturer price to 23.1 percent of average 11 manufacturer price. While we do not know whether this 12 caused any manufacturer to forego a particular drug 13 candidate, it does not appear that there was a decline in 14 drug development in the aggregate.

15 There have been a record number of drugs approved 16 in the last few years. For example, an average of 25.5 new drugs were approved per year between 2000 and 2009, 17 compared to an average of 37.8 new drugs approved per year 18 between 2010 and 2019. Manufacturers do set the price, so 19 20 it is possible that increasing Medicaid rebates would 21 create an incentive to launch a drug at a higher price or 22 attempt to shift cost to other payers. However, it is

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unclear to what extent manufacturers can raise price. Some
 economists believe that manufacturers already have the
 incentive to launch at the maximum price the market will
 bear, regardless of the level of Medicaid rebates.

Finally, manufacturers would still benefit from 5 the accelerated approval pathway as it would provide 6 earlier access to the market and allow the drug to generate 7 revenue and establish market share while the confirmatory 8 9 trial is underway. That is, manufacturers would need to 10 weigh the cost of the additional rebates and the benefit of 11 early market access, which could allow the manufacturer to 12 establish its product prior to competitors entering the 13 market.

14 For beneficiaries, coverage of accelerated approval drugs would not change. They would still be 15 16 required to cover these products once they enter the 17 market. This is in contrast to the closed formulated 18 approach that commercial payers can use and that a few 19 states have recently requested. In the past few years, 20 Massachusetts and Tennessee have requested Section 1115 21 demonstrations that would allow the states to implement a 22 closed formulary, meaning that the state could choose to

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exclude certain drugs. Both of these states specifically
 highlighted accelerated approval drugs in their requests,
 because they believe the high price of these drugs do not
 lead to prudent fiscal administration when the clinical
 benefit has yet to be verified.

6 Earlier this year, CMS approved Tennessee's request to implement a closed formulary while still 7 receiving the MDRP rebates. This is the first time it has 8 9 been allowed. Tennessee's waiver approval could open the 10 door for other states to seek a closed formulary to exclude 11 coverage of accelerated approval drugs. The 12 recommendations are a way to address price without 13 excluding coverage.

14 Beneficiary advocates have expressed concern that 15 access to innovative therapies could be decreased if 16 manufacturers reduced research and development or delayed the new therapies. However, increasing the rebate on 17 18 accelerated approval drugs could potentially increase 19 beneficiaries' access to these products once they entered 20 the market. By lowering the net price, states may be more 21 willing to implement less restrictive coverage criteria on 22 these drugs and improve access.

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1 The increased rebate would reduce spending for accelerated approval products. Because the recommendations 2 do not include a specific amount for the rebate increase, 3 4 the Congressional Budget Office provided estimates assuming a 10-percentage point increase in the minimum rebate and a 5 20 percent increase in the inflationary rebate if the 6 confirmatory trial had not been completed after five years. 7 8 Assuming these rebate changes would be implemented in 9 fiscal year 2022, the CBO estimates that these 10 recommendations would decrease federal spending between \$0 11 to \$50 million in the first year, and between \$0 to \$1 12 billion in the first five years, compared to the current law baseline. 13

To provide context for these savings, the CBO estimated gross Medicaid spending on accelerated approval drugs that would be affected by these recommendations, and by gross spending we mean before rebates. In fiscal year 2019, it was approximately \$1 billion. The \$1 billion includes both federal and state spending.

As a reminder, the Commission will take a recorded vote on the final recommendations tomorrow. I am going to go back to the actual draft recommendation

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1 language now.

2	Recommendation 1 would instruct Congress to
3	increase the minimum rebate amount above the current 23.1
4	percent of average manufacturer price for accelerated
5	approval drugs . This is the primary recommendation.
6	Recommendation 2 would increase the inflationary
7	rebate if the confirmatory trial is not completed after a
8	specified number of years.
9	The Commission should decide whether to proceed
10	with Recommendation 1 only or both Recommendations 1 and 2
11	for tomorrow's vote. And with that I will turn it back
12	over to the Commission.
13	CHAIR BELLA: Thank you, Chris. Thank you for
14	taking us through that so thoroughly and for the work
15	you've done on this.
16	Just to remind folks and to point out on the
17	agenda, we are going to take the next half hour to have
18	comments and questions from the Commissioners, and then
19	we'll take public comment on this session and the next
20	session before we break for lunch, and also to call folks
21	attention to what we recently posted on our website and

22 included with the materials for this meeting, that we're

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1 going to ask people to limit comments to three minutes, and 2 that will allow us to make sure everyone has time to 3 comment. And those of you who know me know that I will not 4 hesitate to cut off, politely, after those three minutes.

5 So with that, let's get started with Commissioner 6 comments and questions for Chris. Chuck and then Tom, and 7 then Sheldon.

8 VICE CHAIR MILLIGAN: Thanks, Melanie. I'll try 9 to keep mine to three minutes too and not get cut off.

10 So Chris, actually, do you mind going back to 11 Slide 8 for a second? Can somebody go back to Slide 8 for 12 a second?

So I want to elaborate on the second bullet, the FDA has acknowledged that surrogate endpoints creates risks. I went back and read the FDA report from 2014 about accelerated approval that was in our meeting materials, and I just want to elaborate on this a little bit, based on what the FDA wrote.

19 They wrote that accelerated approval, under 20 accelerated approval, and this is a quote, "There generally 21 will be fewer, smaller, or shorter clinical trials than is 22 typical for a drug receiving traditional approval, which

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1 may generally mean there is less information about the 2 occurrence of rare or delayed adverse events," closed 3 quote.

4 So we can go back to Slide 9. I'm going to be in support of both of these recommendations. I do want to 5 build on what Chris presented. One aspect of it, to me, is 6 we're actually supporting the FDA here rather than taking 7 over their role or undercutting the FDA. I think that by 8 9 creating an incentive to complete the confirmatory trial we 10 are addressing the fact that accelerated approval, 11 especially for rarer drugs that affect smaller populations, 12 have typically much smaller sample sizes, much shorter clinical trials. And even though they're predictive of a 13 14 likely clinical benefit in the surrogate endpoint, there 15 isn't enough data yet to demonstrate that, and that's the 16 purpose of the confirmatory trial. So I do think what we're doing here supports the FDA. 17

18 I want to make three other quick points, and then
19 I'll stop.

I think that these recommendations set the right balance between access to accelerated approval drugs and creating an incentive to complete those confirmatory

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1 trials. I don't come at this primarily from a financial 2 point of view in terms of the rebate revenue or the effect 3 on state or federal budgets. I primarily don't come at it 4 from that point of view.

5 I primarily come at it from the point of view of 6 creating an incentive to complete the work, complete the 7 confirmatory trial, build out the larger sample sizes, 8 understand better the rare and delayed consequences from a 9 clinical outcome point of view for the Medicaid

10 beneficiaries.

11 The second point I want to make is there is no 12 evidence historically in my experience that any of these 13 rebate increases have actually affected the pipeline for 14 drug research and drug approval.

15 Chris talked about how the pipeline after the 16 passage of the ACA has been more robust than prior to the ACA, in spite of the fact that the rebate went up from 15.1 17 18 to 23.1 percent, but even before that, when states about 20 19 years ago were moving toward a preferred drug list and 20 supplemental rebate programs and negotiating with 21 manufacturers around supplemental rebates, there wasn't any 22 particular impact on the development of drugs. And I think

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partly that's because Medicaid isn't the only player in this market, the only purchaser, the only customer of pharmaceuticals for their covered lives, but I think also because manufacturers do continue to receive a healthy margin, in spite of these rebates.

And then the final point I want to make is our recommendation, I think, properly really would leave to Congress the work of setting the rebate level, determining if any particular drugs for whatever reason should be carved out from this increased rebate.

We are doing something that is directionally recommending how Congress act but not specifically making determinations about rebate percentages or any of that, and so I think we're fulfilling our role as an advisory body to Congress. And I think then the heavy lifting would be with Congress around actually putting the details around this.

17 So I'm in support of these recommendations. I 18 intend to vote in support of both of them tomorrow, and 19 thank you, Melanie. That's all I had to say.

20 CHAIR BELLA: Thank you, Chuck.
21 Tom and then Sheldon and then Fred.
22 COMMISSIONER BARKER: Thanks, Melanie.

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1 And, Chris, I want to start off by saying thank you for the presentation. I really thought this was a very 2 well-done, well-thought-out presentation. I really 3 appreciate the background. So thank you very much for all 4 the work that you've put into it. 5 I just had a couple of questions and then a 6 The first question is -- and this is really a 7 comment. 8 basic question, and I'm sorry that I don't know the answer 9 to this. Just as a foundational matter, is an accelerated 10 approval drug approved under 505(b)(1) of the Social 11 Security Act? In other words, is it a covered outpatient 12 drug and subject to --13 MR. PARK: Yes. 14 COMMISSIONER BARKER: -- rebates now because base 15 rebates? 16 MR. PARK: Yes. So CMS has clarified that even though it's going through Section 506(c) initially for 17 18 approval, they do consider it to be a covered outpatient 19 drug, and so manufacturers are currently paying rebates on 20 these products. 21 COMMISSIONER BARKER: Okay. You hit on exactly the question that I had which is, is it considered -- are 22

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1 they considered covered outpatient drugs? Okay. That's 2 what I assumed the answer was, but thank you for clarifying 3 that.

And then my second question -- and I think Chuck just answered this, but I just want to clarify. We are not making a recommendation to Congress as to the amount of the increased rebate under Recommendation 1 or 2, correct? We're just saying that Congress should increase the rebate, but we're leaving to Congress the policy decision as to how much that increase should be.

11 MR. PARK: That is correct.

12 COMMISSIONER BARKER: Okay. So just for my 13 comment, I guess I'd say I'm going to come out in the opposite place that Chuck is. I feel I absolutely 14 understand the point that Chuck is making, and I appreciate 15 16 that point. I just feel that if there is a problem with the accelerated approval process with the FDA, then that's 17 18 a problem for the FDA to solve, and that that's not a 19 problem that can be solved by changing the Medicaid rebate. 20 I feel like if the Congress believes that, for 21 example, manufacturers are not doing confirmatory trials

22 when a drug gets approved under the accelerated pathway,

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1	then that's something that something should be changed in
2	the Food, Drug, and Cosmetic Act, and we shouldn't be using
3	the drug rebate program as a surrogate to solve that
4	problem. So that's where I come out.
5	I absolutely respect the position that Chuck is
6	taking and where the recommendation seems to be going, but
7	that's where I come out on.
8	Melanie, I'll stop there.
9	CHAIR BELLA: Thank you, Tom.
10	Sheldon and then Fred.
11	COMMISSIONER RETCHIN: Can you hear me okay?
12	CHAIR BELLA: Yes.
13	COMMISSIONER RETCHIN: Okay, good.
14	Yeah. I want to go back on what Chuck said. I'm
15	having a little different take on that same issue that
16	Chuck mentioned, maybe in part, and it's really regarding
17	the rare and orphan drug argument. That's really a concern
18	to me, and I just thought I'd just talk it through a little
19	bit.
20	It becomes a statistical issue. So I'm not an
21	expert in clinical trials, but it would seem to me that
22	it's especially a concern when it comes to power.

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So clinical trials may take longer when effect size will need to be substantially larger to complete clinical trials in a very rare disease, because the occurrence of those disease or -- in terms of prevention or in terms of treatment, it takes a lot longer to accumulate cases, and you might not get there.

7 And even if the clinical trials are completed and 8 the findings are negative, there could be a large type 2 9 error, and that might be occurring already. So that's the 10 probability that a positive benefit was missed because of 11 an inadequate sample size.

12 So I guess my first question is to Chris. Did 13 the technical advisory panel comment on the issue of power? 14 And I support the recommendations. It just seems to me 15 that if there's some sort of -- we could discuss this, but 16 that the Medicaid program might consider an off-ramp appeal if the benefit of the drug was so compelling that the 17 18 accelerated approval pathway was sufficient at the normal 19 rate and having an off-ramp appeal would provide 20 manufacturers ample incentive to continue to pursue drugs 21 for rare diseases, and I know that's the argument on this. 22 And maybe statistician -- or maybe it's already

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1 considered, and that's the FDA's role. That would make me
2 even feel better.

But I don't know. Chris, do you want to comment? 3 4 Also, maybe somebody -- I don't know, Peter, if you have 5 had some experience with this in terms of clinical trials. 6 Anyway, that's my comment. Thanks. 7 MR. PARK: Sure. Sheldon, I could address the comment about the panel. They did not discuss any 8 9 particular type of error that may have occurred during the 10 sample size. They did acknowledge that it might be a valid 11 reason why some of these clinical trials may take several 12 years to complete, but ultimately, I think their opinion would be it's up to the FDA to decide whether or not the 13 evidence that the manufacturer has provided is sufficient 14 15 enough to verify clinical benefit.

In terms of the off-ramp, the off-ramp for our recommendation is for the FDA to basically confirm that the manufacturer has verified a clinical benefit and granted traditional FDA approval. So I think that's in the FDA's purview as to what type of evidence they will accept and whether they find it compelling or not. So that could be a spot where a manufacturer could work with the FDA to

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1 finalize that kind of confirmation as a clinical benefit. The challenge still remains that if it does 2 appear to be compelling but it's based on surrogate 3 endpoints, then the clinical benefit has not been verified 4 yet. So I think states still have that concern that they 5 are ultimately paying for a drug and high prices for a drug 6 where, you know, the clinical benefit has yet to be 7 verified. So I think there's still a challenge there even 8 9 if surrogate endpoints maybe point to a significant 10 improvement and is reasonably likely to predict a 11 significant improvement and a clinical benefit. 12 CHAIR BELLA: Thank you, Sheldon. 13 Oh, go ahead, Peter. 14 COMMISSIONER SZILAGYI: Yeah. I'm not an expert 15 at clinical trials for rare conditions. I do want to say 16 that the confirmatory trials, I think, are really, really 17 important. As a pediatrician who is taking care of a 18 number of children with these rare diseases, including 19 spinal muscular atrophy and others, I would want to know 20 and parents would want to know not just hope or sort of 21 partial evidence about surrogate markers, but evidence from 22 confirmatory trials and not to look for rare side effects,

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because confirmatory trials of these rare diseases are not going to demonstrate -- they don't have the power to demonstrate rare side effects, but they're really looking for effectiveness and very common major side effects.

So I'm in favor of these recommendations,
personally, but I'm not an expert on these clinical trials.
CHAIR BELLA: Thank you, Peter.

8 Fred?

9 COMMISSIONER CERISE: Thanks, Melanie.

Just a couple comments. Chris, I appreciate the work that you've done on this -- and it's a great document -- and appreciate the expert panel. I know you spent a lot of time with a number of experts looking at this, and so I know that it's a set of thoughtful recommendations.

I don't think any of us want to do anything that's going to stifle innovation, and we don't want this to come across as an us-versus-them type of situation.

I was struck by one of your stats. When you mentioned that almost half of the fee-for-service spend is on just over 1 percent of the utilization of the drugs, that situation at some point has to impact the 99 percent. I think we already see that in a number of areas where the

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cost of medicine -- not just drugs, but the cost is pricing
 people out of the market, and people aren't getting access.
 So it's impossible to ignore the price issue.

4 It's more complicated than one set of recommendations, but I do think these recommendations are a 5 step towards trying to deal with a complicated situation. 6 7 Some of the comments that this is punishment, I don't see this as punishment. I think it's reasonable to 8 expect a greater discount while drugs are still under 9 10 investigation, and if that can help push people to complete 11 the investigation sooner, then I think that's a good thing. 12 So I think this is a reasonable step, certainly not a full answer, but I think it should help states, and 13 14 it's a reasonable step forward. 15 CHAIR BELLA: Thank you, Fred. 16 I'm going to go to Darin. Before I do that, I just want to give all the 17 18 Commissioners a heads-up. It would be helpful to hear 19 where you all are. You don't have to give a long

20 rationale, particularly if your points have been covered 21 already, but I am going to put all of you on the spot just 22 to get a pulse check of where everybody is.

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So we'll go Darin, then Toby, then Kisha.
 COMMISSIONER GORDON: Yeah. Thank you. I agree
 with several of the comments already made, particularly
 Fred, and I align myself with some of those comments.

5 But I also want to just, you know, bring forth 6 that perspective from the states. In reviewing, we had a 7 variety of comment letters on both sides of the issue, 8 obviously, but just from a state perspective, I thought 9 there was a couple of points that I think were worth 10 highlighting or quoting.

11 So, one, quote, "Increased rebates will ensure 12 states are able to afford coverage of the expensive therapies while actual clinical outcomes continue to be 13 14 assessed and provide incentives for manufacturers to 15 expeditiously complete postmarketing clinical trials for 16 these drugs," end quote. I think that's an important fact. And I think the point -- there's been several points 17 18 already made to that effect.

But I want to read one more quote that I as a prior state regulator thought was important. Quote, "Because of the MDRP's requirements, states must cover these products, even as their clinical benefits remain

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undetermined during the postmarketing trial period. The 1 absence of this data makes setting appropriate prior 2 authorization criteria for these therapies difficult. In 3 some cases, such as Makena, the clinical benefits fail to 4 be determined after years of state coverage and millions of 5 dollars in state and federal expenditure," end quote. I 6 think added to that, a line of thinking is also, you know, 7 8 some of the risk that's borne by the Medicaid agency, not just financial risk, but also for some of the 9 10 beneficiaries. 11 So I do believe the recommendations -- I 12 appreciate, Chris, all the work you've done on this. I 13 believe having the expert panel -- I think the way that we approached this was thoughtful and thorough, and I do align 14 15 myself with those that are in support of the two 16 recommendations. 17 CHAIR BELLA: Thank you, Darin. 18 Toby? 19 COMMISSIONER DOUGLAS: Thank you. 20 Great work, Chris, on this, and again, I do align myself with these recommendations. 21

22 From a state perspective, I go back. What I fear

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1 from state Medicaid directors -- and when I was in the role 2 is just the position when you face significant budgetary 3 pressures and we have these new drugs come out, there are 4 actions that whether it's other state officials are 5 pressuring on the Medicaid director or the Medicaid 6 director has to go through it to look at ways to control 7 cost and make arbitrary decisions.

8 What this is actually going to do, I believe, is really improve the access during this period of time 9 10 because it's increasing revenue, and that's a big issue for 11 the state Medicaid directors, and so we have to look at it 12 through that lens, as we're giving tools back to the state 13 during this time when these drugs are being reviewed. It 14 will, in fact, create an opportunity for improving access 15 rather than arbitrary utilization controls and other 16 approaches that might impede access.

So, again, I align myself with theserecommendations.

19 CHAIR BELLA: Thank you, Toby.

20 Kisha, then Tricia, then Kit.

21 COMMISSIONER DAVIS: Thanks.

I want to thank Chris for the panel, but I also

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want to call out the TAP, the technical advisory panel that 1 put this together. You have it highlighted in the 2 3 comments, but really the expertise that was part of the 4 panel that pulled this together, I really do appreciate their recommendations and the thought that went into this. 5 Really, this is a group that is experienced with dealing 6 with these types of issues. So I just want to make sure 7 8 that this -- you know, recognizing the body of work that 9 had gone into this recommendation, even beyond just the 10 MACPAC staff and Commissioners that are here today.

I want to align myself in support of the recommendations as well. I really come at it also from the provider, you know, from a physician caring for patients.

The accelerated pathway for approval, the fact that the FDA has created this and as Tom mentioned and Chris confirmed, these are covered drugs, and this is creating access for patients in a way that if they had to wait until the confirmed approval, that certainly would delay. And these recommendations go no way to -- in no way impair that.

21 But when we think about patients, especially 22 those with rare diseases, lots of desperation, we want to

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make sure that what we are offering them goes all the way 1 through with really defining those benefits and efficacy 2 and not stopping with preliminary endpoints. I think that 3 4 these recommendations strike a middle ground in terms of not restricting access, still recognizing the FDA's 5 approval process, the accelerated approval, keeping that 6 available to patients, but encouraging the completion of 7 8 clinical trials and not burdening states with higher costs 9 for drugs that haven't been completely proven.

10 And so, for those reasons, I support the 11 recommendations.

12 CHAIR BELLA: Thank you, Kisha.

13 Tricia, then Kit, then Bill.

14 COMMISSIONER BROOKS: Thank you, Melanie, and,15 Chris, thank you. This is great work.

I think most of the Commissioners know that my colleague, Edwin Park, served on the TAP and is a Medicaid prescription drug expert. We certainly are in favor of both of these recommendations for many of the same reasons you've heard from my fellow Commissioners.

21 CHAIR BELLA: Thank you, Tricia.

22 Kit?
COMMISSIONER GORTON: Thanks, Melanie.
 So I'm in favor of these recommendations. I made
 extensive comments in our previous discussion on this
 topic. I'm not going to repeat them here. They're in the

5 record if people want to see them.

I just want to make a couple quick points. One,
sometimes the confirmatory trials do not prove that the
drugs are effective, and then FDA, in its process, says the
drug should be withdrawn. And people have mentioned
Makena. That's a recent example of this.

11 So I just want to point out to people, we weren't 12 criticizing the FDA's process. Their process says we want 13 to give access early and because it's a promising drug, and 14 our recommendation, I think is fine with that. The 15 question is how you price that early access.

The second thing I wanted to point out is the commercial payers. In fact, they do take a wait-and-see approach, right? So access to Medicaid is better because of the rebate program, which sort of very quickly, automatically with approval from the FDA provides access so the drug. The commercial payers often wait and see; right? And it's because they are waiting for those confirmatory

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1 trials to be completed.

2	And then the last thing I want to say is I
3	appreciate and respect Tom's point of view about what's the
4	right way to address this, but, respectfully, I think
5	because the other payers do get to wait and see whether
6	they're going to support these early-stage drugs, the
7	playing field is not level. Medicaid is at a disadvantage
8	compared to them, and so for that reason I would believe
9	although I completely respect why you would end up in a
10	different place, for that reason I believe that it is
11	appropriate to move forward with the recommendations.
12	Thank you.
13	CHAIR BELLA: Thank you, Kit.
14	Bill, then Stacey, then Martha.
15	COMMISSIONER SCANLON: Yes, well, thank you,
16	Chris. This was an incredibly well structured and reasoned
17	piece of work. I want to say I do also support the
18	recommendations, and I've heard the concerns about sort of
19	what might be the impact on the pipeline and value of
20	drugs. And I think it's important to recognize the
21	uncertainty about those concerns. There's not strong
22	evidence that they will be realized.

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1 Similar types of concerns have been raised about almost any proposal to try and deal with sort of drug 2 3 pricing, and as Fred pointed out, the consequences of high 4 drug prices are very real and very consequential in terms of impacts on individuals with respect to the financial 5 burden, but even more important potentially is the issue of 6 sort of when those prices lead to sort of the inability to 7 access needed medicines and the consequences of 8 9 noncompliance.

10 So I think at some point we must come to grips 11 with the idea that we have to start to address sort of the 12 cost of drugs and dealing with this uncertainty about sort 13 of what's going to happen to the pipeline is a part of 14 that.

15 Having worked in the drugs area from many 16 different angles over the years, I think one simple conclusion is that the drug market is incredibly complex. 17 18 A second conclusion is there are many opportunities for 19 manufacturers to recoup revenue or to increase revenue sort 20 of under different circumstances. And so, therefore, I'm 21 not even convinced that there will not be a response to an increased rebate in terms of manufacturers' prices, launch 22

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prices, and subsequent increases over time that will recoup 1 at least a portion of the additional rebate that's being 2 3 charged. And the reality, though, the increased rebate 4 will still provide the manufacturers an incentive to complete the research, because even if they are whole from 5 day one sort of when a drug is launched, they will still 6 make more when the research is done. So I think that it's 7 8 the right type of incentive to have.

9 In terms of Tom's concern about this being an FDA 10 sort of responsibility, I'm not sure what tools the FDA 11 would be able to use short of not approving an accelerated 12 approval drug or withdrawing approval for such a drug, 13 which may have worse consequences than actually sort of 14 increasing any rebate where I think the concerns are 15 relatively minimal.

I think the accelerated approval pathway is an attempt to balance the risk of uncertainty over the lack of information or due to the lack of information about these drugs with the benefit that comes from potential earlier access to them. But with that sort of balancing, a part of that responsibility is to move as quickly as possible to get the necessary information to make a final sort of

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determination. And so I think that the recommendations are moving us in that direction, and in some respects, I think it's important that there be assistance to FDA sort of in this process, and these recommendations would be an assistance of that type.

Thank you.

6

7 CHAIR BELLA: Thank you, Bill. Stacey and then8 Martha.

9 COMMISSIONER LAMPKIN: Thanks. I also support 10 both of these recommendations, and just to add a couple of 11 things to the conversation that's been going on. To 12 emphasize Kisha's points about the Technical Advisory 13 Panel, I was privileged to get to sit in and listen to their discussion and deliberation on this and the other 14 15 areas that they considered for us, and it truly was an 16 impressive group of experts coming from a variety of backgrounds in the industry and being very thoughtful. So 17 18 we appreciate the contributions that they've made to our discussion and recommendation here. 19

And then also, as I read, you know, some of the written comments that we've gotten from various stakeholders, you know, we've discussed many of those

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points here, and I would urge us as we go back and finalize the chapter to make sure that we have addressed any areas that might just represent a misunderstanding of what the Commission is trying to do here and make sure that we've strengthened those areas.

6 But, also, I just wanted to say a couple of the 7 comment letters -- the relatively small amount of overall 8 Medicaid prescription drug spend that's associated with the 9 accelerated approval drugs almost seemed to imply that 10 because that was a relatively small and stable proportion, 11 that this recommendation is not necessary. So I just 12 wanted to say and make sure that in the chapter we're 13 emphasizing that really nice figure that Chris showed us on the early slide about different kinds of solutions that 14 15 might apply to different types of specialty drugs, and so 16 by being thoughtful about different solutions applying to different types of drugs, I mean, by definition we're not 17 18 saying there's a silver bullet solution to address high-19 cost specialty drugs, that we have to be thoughtful, break 20 it down, consider the kind of drugs and customers and craft 21 solutions that are specific to that. So any one solution 22 may not get an enormous percentage. But I do support both

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1 recommendations, Melanie.

CHAIR BELLA: Thank you, Stacey. And thank you 2 for having been our eyes on the ground for the Technical 3 4 Advisory Panel. Very helpful, I know, to all of us. 5 Martha and then, Leanna, I'll go to you next. COMMISSIONER CARTER: Thank you, Melanie. I came 6 into this meeting unsure about how I felt about these 7 recommendations. I read all the comment letters, and I 8 9 really thank people for sending those. I wanted to 10 acknowledge the work of the Technical Advisory Panel and 11 the comments from the other Commissioners. I also want to acknowledge the fear that I think 12 13 I hear from patients and their families that they might not have access to these drugs that are -- may be, you know, 14 15 their only hope at improving quality of life, even if it 16 may not extend life.

And I also acknowledge the concerns of Medicaid program directors trying to preserve access in difficult budgetary times, always, and although, as Stacey said, it's a relatively small spend in the Medicaid program for any individual state, it can be a significant expense.

22 So with balancing all of that, I think I still

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come down on preserving access, and I actually believe that 1 these recommendations do the best job that we can do at the 2 3 moment in attempting to preserve access to patients and 4 families.

CHAIR BELLA: Thank you, Martha. I'm going to go 5 to Leanna, and then I'm going to ask Brian and Kathy for 6 where they stand on this, and then we'll wrap it up and 7 head into the next session. 8

9 COMMISSIONER GEORGE: Yeah, I'm in agreement with 10 what I've heard here. The proposals continue to give 11 beneficiaries the right to choose. You don't necessarily, 12 as the beneficiary, have to accept the drug. We can always [inaudible] because that's, you know -- and it expedites 13 14 the process towards full approval, which is good, so that those people who are on the fence who want to see the full 15 16 -- can see that. But, yeah, I'm in agreement with this. CHAIR BELLA: Thank you, Leanna. Brian? 17

COMMISSIONER BURWELL: I support both these 19 recommendations. I see this primarily as a shared risk 20 situation. Accelerated approval increases risk across the board for all stakeholders, and I think it's fair that the 21 22 risk be shared between the manufacturers and the payers.

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18

And I see these recommendations as a good middle point for
 sharing that risk, and, therefore, I approve them.

3 CHAIR BELLA: Thank you, Brian. Kathy, you get
4 the last word.

5 COMMISSIONER WENO: Great. I too support both 6 the recommendations, and thank everyone who participated or 7 who wrote a letter and, Chris, who wrote a great report, as 8 well as the TAP panel, because they really educated me on 9 the issue, and I feel comfortable recommending both.

10 CHAIR BELLA: Thank you, Kathy.

11 Chris, do you have any final comments based on 12 what you've heard?

MR. PARK: No. Thank you for all your comments, and we'll certainly try to reflect those in the chapter as we move along in the process.

16 CHAIR BELLA: Okay. I just want to pile on the 17 thanks to you, Chris, as well as to the folks that 18 participated in the panels, as well as to everyone that 19 sent us letters. And we will take public comment following 20 the next session.

21 So, with that, we will end this session and move 22 into the session on improving integration through D-SNP

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contracting, and Kirstin and Ashley are going to lead us
 through that session. Just as a reminder for folks, there
 are no recommendations coming out of this body of work.
 This will be a chapter in the June report that's consistent
 with our focus on duals, but no specific recommendations
 that we're discussing at this point in time.

Welcome, and we'll turn it over to you two.

8 ### IMPROVING INTEGRATION THROUGH D-SNP CONTRACTING:

# REVIEW OF DRAFT CHAPTER

MS. SEMANSKEE: Thank you, Melanie. Good
morning, Commissioners. Kirstin and I are here to discuss
our draft chapter on strategies for state contracts with
dual-eligible special needs plans, or D-SNPs. I think
we're just waiting for the slides to come up.

15 Next slide, please.

This chapter continues our work on integrating care for dually eligible beneficiaries and increasing enrollment in integrated care models. While a number of integrated models exist, this chapter focuses on D-SNPs because they have higher enrollments than other models and are widely available. We hope to get feedback from Commissioners on the draft chapter and next steps for

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1 future work.

2 Next slide, please. D-SNPs are available in 44 states and the 3 District of Columbia, and enrollment in D-SNPs is 4 increasing. Of dually eligible beneficiaries in D-SNPs, 5 the majority are in minimally integrated D-SNPs. Highly 6 integrated dual-eligible special needs plans and fully 7 integrated dual-eligible special needs plans provide a 8 9 higher level of integration by covering Medicaid benefits 10 like behavioral health and long-term services and supports, 11 or LTSS. 12 States have authority under current law to promote integration and increase enrollment in their 13 contract with D-SNPs. This authority can be a powerful 14 15 tool, but relatively few states have exercised it fully due 16 to limited experience using managed care for dually eligible beneficiaries and a lack of Medicare expertise. 17 18 Next slide, please? 19 This map shows the most highly integrated D-SNP available in each state as of January 2021. Although D-20 21 SNPs are not always available statewide, often due to

22 difficulty contracting with D-SNPs to cover rural areas,

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overall 94 percent of dually eligible beneficiaries live in
 a county where a D-SNP is available in 2021, and 26 percent
 of dually eligible beneficiaries are enrolled in D-SNPs.
 Next slide, please.

D-SNP authority under current law to contract 5 with D-SNPs was defined in the Medicare Improvements for 6 Patients and Providers Act of 2008, or MIPPA, and refined 7 8 in the Bipartisan Budget Act of 2018. MIPPA requires all 9 D-SNPs to have contracts with the state and meet a minimum 10 set of requirements, but these requirements do not result in fully integrated coverage. States can use their 11 12 contracting authority to go beyond the minimum 13 requirements, but few have done so. Strengthening the 14 ability of states to leverage these authorities to further 15 integrate care for dually eligible beneficiaries is an 16 important step in promoting integration.

17 Next slide, please.

Earlier this year, we contracted with Mathematica to explore opportunities for states to maximize their MIPPA contracting authority with D-SNPs. We presented the results of their work in January, which focused on the 13 strategies listed in this table. These strategies are

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1 described in more detail in the chapter, and we presented 2 on them in January. Some can be implemented by all states, 3 while others can only be implemented by states with 4 Medicaid managed care for dually eligible beneficiaries.

Next slide, please.

5

States' use of MIPPA strategies depends on the 6 7 unique state contract, and their decisions to implement 8 different strategies are often complex. Some states, 9 including Arizona, Idaho, and Tennessee, have been able to 10 maximize the use of MIPPA authority to require D-SNPs to 11 attain the FIDE SNP designation. Over 20 percent of dually 12 eligible beneficiaries in these states are enrolled in 13 integrated care. Arizona and Tennessee are both Medicaid 14 managed care states, with managed long-term services and 15 supports, or MLTSS, programs, and they both use default 16 enrollment to enroll Medicaid beneficiaries into D-SNPs 17 when they first become eligible for Medicare. In contrast, 18 Idaho does not have a long history of Medicaid managed 19 care, but was able to leverage MIPPA authority to build an 20 integrated care model on its FIDE SNP that provides all 21 Medicare services and most Medicaid services, including 22 LTSS.

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Generally, states where D-SNPs are aligned with Medicaid managed care plans are well positioned to use MIPPA authority. When a D-SNP and a Medicaid managed care plan are aligned, meaning they are operated by the same parent company, the beneficiary can receive their Medicaid and Medicare services through the same organization, allowing for higher levels of coordination.

8 States with D-SNPs aligned with MLTSS plans are 9 best positioned to maximize integration because their 10 Medicaid managed care plans cover long-term services and 11 supports. Our analysis identified 27 states where at least 12 one D-SNP and Medicaid managed care plan are aligned, 13 including 15 states where D-SNPs and MLTSS plans are 14 aligned.

15 Next slide, please.

This map shows states where D-SNPs are aligned with Medicaid managed care plans as of January 2021. The dark-blue states are states where all D-SNPs are aligned with a Medicaid managed care plan. These states are best positioned to maximize their MIPPA authority. For example, it can require all D-SNPs to use exclusively aligned enrollment to enroll full benefit dually eligible

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beneficiaries who receive their Medicaid benefits from the 1 aligned Medicaid managed care plan. This ensures one 2 organization is responsible for both Medicaid and Medicare 3 4 benefits for all their members, maximizing integration.

The light-blue states on this map are states 5 where D-SNPs are aligned with a Medicaid managed care plan 6 but not all the D-SNPs in the state. And the dark-gray 7 8 states are states that do not enroll dually eligible 9 individuals in Medicaid managed care, and they cannot use 10 strategies like requiring exclusively aligned enrollment. 11

Next slide, please.

12 States without Medicaid managed care have less 13 ability to use MIPPA strategies. These states could use 14 direct contracting with D-SNPs to cover Medicaid benefits 15 for their members, but this strategy requires substantial 16 state resources and investments, especially for states that lack experience with contracting and procurement. States 17 18 with Medicaid managed care would require large up-front 19 investments to build staff capacity and Medicare expertise 20 necessary to maximize their MIPPA authority.

21 Finally, states without D-SNPs are starting from 22 scratch, but may actually be able to achieve higher levels

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of integration in their initial D-SNP contracts as they do not have to worry about reflecting current enrollee coverage.

4 Next slide, please.

We should note that several factors may limit 5 states' ability to use D-SNPs as a vehicle for integration. 6 7 For example, some states carve out certain populations or benefits from Medicaid managed care, including LTSS and 8 9 behavioral health, so cannot create fully integrated D-10 SNPs. States may also be hesitant to focus on D-SNPs if 11 they would compete with other integrated models in the 12 state, like Medicare-Medicaid plans, or MMPs. Small or 13 rural states may have trouble attracting D-SNPs if there are too few covered lives to make such plans financially 14 15 viable. States may also face a tradeoff between further 16 integration in existing products, increasing enrollment in 17 D-SNPs, at least in the short term. Finally, limited state 18 capacity and Medicare expertise prevent states from making 19 full use of MIPPA, causing the Commission to recommend in 20 June 2020 that additional federal funding be made available 21 to states to enhance expertise in Medicare and to implement 22 integrated care models. This need remains important.

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Now I will turn it over to Kirstin to discuss
 future directions on this topic.

3 \* MS. BLOM: Thanks, Ashley, and sorry. The slide
4 movement was a little clunky there. Apologies about that.

5 So after going through all of the MIPPA 6 strategies in this contract work that we did that Ashley 7 just walked through, we've decided to focus our work in the 8 next cycle on two strategies, and the first of those is 9 limiting enrollment to full-benefit dually eligible 10 beneficiaries.

11 The purpose of limiting enrollment in this way is 12 to focus state efforts to integrate care on the population 13 that stands to benefit from it the most.

Using this strategy would create uniformity within the D-SNP in terms of things like care coordination and simplifying materials for beneficiaries and around things like benefits covered.

This is a policy that others have considered. As you guys know, organizations like MedPAC have come close but not recommended it, but not all states are using this. So we want to spend some time on understanding better why that is, what the pros and the cons are.

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For example, one potential drawback that gets cited, depending on how this is implemented, beneficiaries would have to potentially disenroll from the D-SNP and enroll in an MA plan. That's partial benefit duals, and that could create some disruptions.

As an alternative to limiting enrollments to only full-benefit duals, one interviewee we talked with suggested establishing separate plan benefit packages. So that's something that we want to think about in this next cycle. That would be a separate plan benefit package, depending on the type of dual, so partial or full-benefit dual.

13 Some states are already doing this, actually, 14 like Pennsylvania using separate plan benefit packages, and 15 this could avoid the problem of having to disenroll a 16 partial bene dual from the D-SNP, instead keep them in, but just have them under a separate plan benefit package. 17 18 One way to make this even less disruptive 19 potentially is to establish a crosswalk so that when 20 someone -- when they set this up, they could just crosswalk 21 in and under a more streamlined process rather than being 22 pulled out or having to go without coverage briefly. That

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1 would involve a change in MA rules. So that's something
2 that we would have to think about.

3 So this is something we need to do additional 4 work on. So our plan is to do that over this next cycle 5 before we would be able to bring something back to you 6 guys. We're planning to let a contract with a vendor to 7 interview some states and some beneficiaries as well as 8 plans to better understand any concerns or barriers that 9 might exist to setting this up.

10 The vendor will also, hopefully, analyze the 11 movement from partial to full benefit status. This is 12 something that a number of Commissioners have raised in the 13 past and that we don't feel like we have a great handle on. 14 So we're going to try to understand better how often that 15 might be happening and how many people might be affected by 16 it and then what types of issues that might create around 17 administrative burden for plans and beneficiaries.

And then the second piece is going to be requiring that D-SNPs submit marketing materials to the state for review. We think that doing this obviously can ensure accuracy of Medicaid information for beneficiaries across the D-SNP or D-SNPs in the states, making it easier

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for them to choose coverage, and this again is something that some states are already doing. But we'd like to, again, understand better why more states aren't doing this, whether there are barriers, whether there's an administrative burden issue or delays that might result from the additional review.

7 And then, again, as sort of an alternative to 8 just requiring state review, we want to think about the 9 idea of establishing a formal joint review process like the 10 one that is currently in place for the MMPs under the 11 Financial Alignment Initiative. Under that, under the 12 MMPs, they submit materials to CMS and the state for a 13 joint review.

This is also something that the duals office, the Medicare-Medicaid Coordination Office, recommended in their FY2019 report to Congress. So we are planning to spend some time on this in the next meeting cycle, talking to that office and to others who might have information about the applicability of the joint review process under the MMPs to D-SNPs.

21 So today what we're looking for is feedback from 22 you guys on the draft chapter on the stuff that Ashley

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1 walked through but then also sort of our plans for the next 2 meeting cycle. We appreciate very much the -- a couple, a 3 few Commissioners have already sent us feedback, and that's 4 very helpful. Happy to take any additional feedback today, 5 or you can certainly contact us directly.

6 And with that, we're happy to take any questions. 7 Thank you.

8 CHAIR BELLA: Thank you, Kirstin. Thank you,9 Ashley.

10 I think I have one point of clarification, and 11 then I'll save comments for the end. While we'll be 12 focusing on two of those that you named, we're not letting go of the other work we've been doing. We'll still be 13 looking at the various levers that are uncovered in this 14 15 chapter as part of our broader efforts to look at 16 increasing integration, enrollment in integrated products, and increasing the level of integration in existing 17 18 products. Is that correct?

19 MS. BLOM: That's right.

20 CHAIR BELLA: Comments? Kit and then Chuck and 21 then Stacey.

22 COMMISSIONER GORTON: So I have a couple

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questions. The first, you talk about D-SNPs being available in 44 states, and then you cited a CMS report in the draft chapter that said 94 percent of duals live in counties where they have access to a D-SNP. I'm just having trouble understanding all the math.

6 My personal experience is in a handful of states, 7 but none of those states managed statewide-ness, because of 8 rural issues and other things.

9 My question is, are you really comfortable about 10 who has access to what? And the reason I have that 11 question is if we're going to get to a place where we're 12 going to start saying, well, this should happen, the Commission has been trending towards a point of view that 13 says duals should be in integrated programs -- and I don't 14 15 feel like -- from a foundational level, I have a good 16 enough sense about who really has access to one and who 17 doesn't. So I would like to see a little more detail on 18 that to make sure that we're not saying that some -- even 19 if it's a small percentage of people, it should be an 20 integrated program, but none exists, because the impetus 21 there then is to create programs where they don't exist. 22 So I just would like to understand that a little better.

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1 That's one of the things. Because Medicaid operates at a 2 county level and not at a state level, and I think in 3 Medicaid, because of the statewide-ness requirement, we're 4 accustomed to thinking about states as units when, in fact, 5 the Medicare program doesn't operate that way. So that's 6 one piece.

7 And then the second piece I would like us to --8 and I'm not sure how to do this, but I'll just raise the issue/question -- is if you're going to focus on aligned 9 10 plans, that by necessity, I believe, gets you to a place 11 where you're going to have fewer plans, right? And we 12 talked last time when we talked about this about the 13 multiplicity of choices that people in L.A. County have, 14 for example, and including hundreds of choices is more 15 choice than is useful. But some choice is, in fact, 16 useful, and if we get to limited plans, then sometimes the plans lose their Medicaid contracts. And then there's 17 18 turnover.

And I'd like to understand the beneficiary disruption from that because -- I think we have examples of what happens, but I think because plans' provider networks don't line up that the potential for disruption -- you

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talked about the disruption in terms of the partial 1 beneficiaries and that sort of thing, and I get that, but 2 3 I'd like to really make sure before we get to a place where 4 we're going to talk about, okay, this is how it should be, if we're going to make a recommendation that it should be 5 straight, I would like to know that when periodically a 6 7 plan falls out and a new plan comes in, that that's not 8 overly disruptive to beneficiaries' relationships to their 9 treating providers. Does that make sense?

10 MS. BLOM: Mm-hmm.

11 COMMISSIONER GORTON: Thanks.

12 CHAIR BELLA: Thank you, Kit. I think your last comment is in the bucket of let's keep these in mind as we 13 14 move forward on some of the other tools around D-SNP, not 15 necessarily looking for a response now, but, Kirstin and 16 Ashley, do you have a comment on the math? And if not right now, can we come back to make sure we all do 17 18 understand where -- actually how available these products 19 are today?

20 MS. SEMANSKEE: Yes. We can make that clear in 21 the chapter, and also, we've done some other work that is 22 not currently in the chapter to kind of look at the county-

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level availability of D-SNPs and MMPs, and we can come back 1 to the Commission with more information on that. 2 CHAIR BELLA: Okay. Does that work, Kit? We'll 3 4 bring it back? 5 [No response.] CHAIR BELLA: Okay, perfect. Thank you. 6 7 Chuck, then Stacey, then Brian. VICE CHAIR MILLIGAN: Great work. 8 I'm going to build on Kit's comments. I think 9 10 one of the things that's going to be helpful for the 11 Commission to understand is the issue of that choice. When 12 I look around the country and I look at how many D-SNPs are three-and-a-half-star plans or three-star plans that don't 13 14 offer the same supplemental benefits that a regular 15 Medicare Advantage plan, non-D-SNP, non-SNP Medicare 16 Advantage plan offers, because it's a four- or four-and-ahalf- or five-star plan in that market, dual eligibles are 17 18 going to pursue the Medicare product that's in their best 19 interest, including the best benefit packages, the best 20 supplemental benefit packages, the best quality of care. 21 And I do continue to believe that one of the big challenges to integration is the belief that integration as 22

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1 a value is so important that people will choose it, the 2 dual eligibles will choose it, in spite of the fact that 3 rationally there might be much better Medicare Advantage 4 options to them, available to them than a D-SNP that is 5 mediocre in their market.

6 So I think I would encourage, as you look into 7 this, to look at -- and before that, you know, sometimes we 8 talk pejoratively around lookalikes and loopholes in that. 9 I'm talking about something much more fundamental, which is 10 a Medicare Advantage plan that's just better than the D-SNP 11 in that market, from a star rating and supplemental benefit 12 point of view.

So I think as the Commission advances its knowledge and understanding of barriers to integration, I think it's going to be important to get a better understanding of the alternative Medicare Advantage options available.

The one other thing I'll mention about that is as CMS changes the weights of star ratings and increases the weight associated with CAHPS scores, D-SNPs often have really, really poor CAHPS scores, and so you might see three-and-a-half-star D-SNPs this year fall to three or two

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and a half, and that will lead to frozen membership on the D-SNP side. CMS won't let them enroll new members, which will create a different kind of barrier because of how the star ratings' programs and sort of the carrot and stick around star ratings play out.

And so I think, all to say, it's going to be really important to keep your acumen up around Medicare Advantage, non-D-SNP dynamics because that implicates D-SNP integration opportunities.

10 CHAIR BELLA: Thank you, Chuck.

11 Stacey and then Brian.

12 COMMISSIONER LAMPKIN: Thank you. I just have a 13 couple of questions. I think they're probably more 14 forward-looking than chapter-looking, but you can tell me 15 if we know more about this already.

First, I think the opportunities that states have to use the tools and the MIPPA toolbox and integrate are really engaging and powerful and exciting to think about. J just want to make sure that we're thinking about all the different angles of some of these options, and so both of my questions have to do with the aligned plans, where we're aligning a D-SNP with the Medicaid managed care plan.

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1 So one question that I have is how these aligned, D-SNP, Medicaid managed care organizations are managing 2 their business internally. Are they really aligned 3 4 internally, and what triggers that guestion? It's just a 5 conversation I had with an executive from a managed care organization, probably two or three years ago now, where I 6 was asking questions about their D-SNP, which was supposed 7 8 to be aligned, but he really didn't know anything about it 9 because it was a different profit center. It was a 10 different product, and so what does that look like on the 11 inside is my question, that alignment.

12 Then the other one is, do we think that any of 13 these alignment-related strategies have tendrils that 14 affect other parts of the program, unintended consequences 15 like, for example, are there any of these alignment 16 policies that a state could pursue that would be 17 disadvantageous, for example, to smaller regional plans or 18 provider-owned health plans that operate in Medicaid 19 managed care but may not be practical to operate a Medicare 20 Advantage plan or a D-SNP? Is there anything there that we 21 should be concerned about? Maybe not. It's just a question that occurs to me because I know that a lot of the 22

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1 D-SNPs are the big behemoth players.

2 So I don't know, Ashley or Kirstin, whether you 3 have anything to say that we know already on either one of 4 those topics, or we could just put it on the list for 5 looking forward.

6 MS. BLOM: I think that's probably a good one for 7 us to put on the list. I don't know, Ashley, if you have 8 anything to add.

9 MS. SEMANSKEE: I think we mentioned in the 10 chapter that small regional plans may be less likely to 11 operate both in Medicaid and Medicare. So they might not 12 have an aligned plan and if some strategies like selective 13 contracting that require plans to be aligned may affect 14 those plans.

15 CHAIR BELLA: Stacey, on your first point, I 16 think as I think about four buckets of work or four themes, one of them is promoting greater integration in the 17 18 products, which is kind of like getting under the hood and 19 seeing inside the integrated products and are they actually 20 integrated. So I think that's an important reminder for us 21 to keep pushing on that. I don't think it's where we all 22 want to be, and therefore, sometimes I think the

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1 beneficiary isn't experiencing as integrated an experience
2 as would be ideal.

Do you have any further comments, Stacey? 3 4 [No response.] CHAIR BELLA: I'm going to take that as a no. 5 Okay. Brian and then Darin. 6 7 COMMISSIONER BURWELL: So, Ashley and Kirstin, I think this is an excellent chapter. I also think it's a 8 9 very important chapter, one that we've talked about doing 10 for quite a while is the role of MIPPA and creating 11 integrated products, and I think you do a great job in 12 content. I think we are at a point in terms of the larger 13 14 policy landscape that there may be growing interest in 15 doing something about duals and promoting integration. So 16 I would really like to see this chapter be -- you know, it's a complex topic, and the dual policy wonks are going 17 to read this and understand it, but I think there are a lot 18 of people that aren't. And I would like to make this 19 20 chapter more accessible to the broader policy community. 21 I submitted a number of comments and ways I think

22 that we can do this with call-out boxes and vignettes. For

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example, I think a nice vignette would be how integration,
 D-SNP integration occurs in some of these more advanced
 states like Tennessee and Arizona, how the plans are
 linked, and how that affects consumer choice.

And going back to Kit's question, I know that 5 there have been instances in Arizona at least where the 6 Medicaid MLTSS plan has lost the contract, and a new 7 8 contractor has come in, and their people have had to be shifted out of that plan and the aligned D-SNP plan as 9 10 well. So I think a little vignette about how that was 11 managed by Arizona would be a great educational piece for 12 people to read.

I do think that in terms of future products or future directions, one obvious direction is to further strengthen the MIPPA agreement to add more requirements to what has to be in a MIPPA agreement to have it approved. So I think we should include that.

I do think we need kind of more contextual information at the beginning of the chapter about what the MIPPA agreement is, what the process is in terms of having an agreement between a state and a D-SNP, and when the D-SNP comes up for approval every year that they have to have

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1 the MIPPA agreement as part of the application, just a
2 little process-oriented about how this linkage between
3 states and D-SNPs works around the MIPPA agreement.

4 Finally, I do think we do have a lot of work that we could do around the enrollment process and choice in 5 integrated care products. In the MLTSS states that I have 6 worked in, they have all had an enrollment broker 7 8 contractor that beneficiaries can use to get information 9 around -- they're assigned to a particular Medicaid plan, 10 what their opportunities are to switch out, and what their 11 opportunities are for enrolling in a D-SNP, whether it's an 12 aligned D-SNP or a non-aligned D-SNP. I think these 13 enrollment processes and how they affect consumer choice 14 are a very important part of the future of the development 15 of integrated care models.

16 CHAIR BELLA: Thank you, Brian.

17 Darin?

18 COMMISSIONER GORDON: My comment will be brief. 19 I think on the topic that was brought up, that Stacey 20 brought up, and Melanie commented on it and Brian did, as 21 well, about what integration looks like within an 22 organization, it just makes me think when we talk about the

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different states I do think it's important maybe to 1 highlight how long they've been in that approach or that 2 model. I know where we looked at, you know, the very first 3 4 year, versus where we were five years into it, it's very different. And I do think there is a bit of an evolution 5 that occurs in that. So, you know, if we are looking at a 6 state, for example, on commenting about what that 7 8 integration was like at the plan level, I think it's just 9 important that to, I think, provide that context. How long 10 has a state been in that journey, just so that we don't 11 lead to conclusions for someone that maybe just started 12 versus someone that's been doing it for a while.

13 CHAIR BELLA: Thank you, Darin. Other folks want 14 to comment?

15 Okay. I have a couple. You guys didn't really 16 think that I would leave without commenting on duals, but I will be brief too. I very much appreciate the work and 17 18 it's feeling like we're striking a nice balance, this sort 19 of big picture, what should the future look like, and then 20 more technical. But I think if the big picture is the 21 March report, our chapter on what we would have to think 22 about to have a unified program, and then our June chapter

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will be much more sort of tactical steps and things states
 could be doing.

The only comment I would say is the key 3 ingredient for whether it's the big or the more technical 4 5 is the state's ability to actually do it. And so it does keep harkening back to our recommendation from last year 6 about needing to do what we can to support state capacity, 7 8 to develop Medicare expertise, to have dedicated resources. 9 And so I don't want to lose sight of that. If it 10 were up to me we would be reiterating that for Congress 11 every month, and just emphasizing that it's just so 12 critical for our ability to do any of the things that you guys uncover, as potential opportunities. 13 14 But that is the last comment, other than to say 15 thank you. Thank you for that work. 16 So we are going to move into -- well, actually, 17 I'm sorry. Ashley and Kirsten, do you have what you need from us to finalize the chapter and have it ready for the 18 19 June report?

20 MS. BLOM: Yes. Thank you guys, and thanks again 21 to the people who have already submitted comments to us. 22 We are working through those now.

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1 CHAIR BELLA: Okay. Wonderful. Thank you. We are going to move into public comment. We are 2 opening up public comment to the two sessions we've had, so 3 this session and then the one before this session on the 4 recommendation related to accelerated approval. I will 5 remind folks that may not have heard me at the outset that 6 7 we are asking for people to limit their comments to three 8 minutes so that we can ensure we have time to get through 9 all the comments. I will give you a polite little verbal 10 indicator when you've hit your three minutes, and then I 11 actually do have the ability to turn your sound off, so I 12 will do that if we need to, to keep things moving along. 13 And I would also ask folks to state their name 14 and the organization they're representing when they do make 15 a public comment. And lastly I would say you are always 16 welcome to submit comments electronically, and the way to 17 do that is to send them to comments@MACPAC.gov. 18 So if you are in the public, thank you for 19 joining us, and please use your little hand icon in the 20 GoToWebinar and then we will recognize you and unmute you, 21 and you will be able to make your comment. So we will open 22 that up now.

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### PUBLIC COMMENT

2 \* MS. HUGHES: Kari, you are self-muted. You can
3 unmute yourself and make your comment.

4 MS. ROSBECK: Hi. Yes, thank you. My name is Kari Rosbeck. I'm the President and CEO of the Tuberous 5 Sclerosis Alliance, a nonprofit dedicated to find a cure 6 for tuberous sclerosis complex, or TSC, while improving the 7 lives of those affected. TSC is a rare genetic disorder 8 9 that causes tumor growth in all the body's vital organs. 10 Symptoms can include seizures, kidney failure, brain and lung tumors, autism spectrum disorder, and severe learning 11 12 disabilities. TSC is also the leading genetic cause of both epilepsy and autism. 13

14 TSC is a good example of how the accelerated approval pathway can work to get treatments to patients who 15 16 do not have other safe, effective options. Subependymal giant cell astrocytomas, or SEGA, is a slow-growing tumor 17 18 that can cause life-threatening complications by blocking 19 cerebral spinal fluid, and remains a major clinical feature 20 of TSC. Not all individuals are surgical candidates, 21 leaving them with fatal complications.

22 Novartis' Afinitor, a cancer medicine, was

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originally introduced in 2009, and granted accelerated access approval for TSC indications in 2010 for SEGA, 2012 for renal angiomyolipomas, and 2018 as adjunctive therapy for partial-onset seizures. Novartis completed the FDArequired studies, submitted data to FDA, and received regular approval.

7 If the proposed additional rebate had been in 8 place, I believe it is unlikely that they would have used 9 the accelerated approval pathway and maybe even declined to 10 study Afinitor for TSC. The outcome would be individuals 11 would remain without treatment options. Applying the 12 additional rebate to accelerated approval indications and rare diseases would be complex to administer and would 13 14 penalize manufacturers who are doing everything right. 15 Ultimately, it is the patients who would pay the price. 16 As the TSC community can attest, this FDA program

17 is vital to providing treatments where previously there was 18 a serious unmet medical need. We encourage you not to 19 place disincentives on manufacturer use of this program and 20 to keep the ultimate beneficiary in mind, the patients who 21 desperately need these medications.

22 Thank you so much.

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1 CHAIR BELLA: Thank you, Kari. MS. HUGHES: Kristin, you have been unmuted. You 2 can unmute your line and make your comment. 3 4 MS. WHEEDEN: Thank you. Please confirm that you 5 can hear me. 6 CHAIR BELLA: We can. 7 MS. WHEEDEN: Thank you. Hi. My name is Kristin 8 Wheeden and I serve as Executive Director of the American 9 Porphyria Foundation, and I'm also a mom to a 15-year-old 10 son named Brady, who lives with a type of porphyria called 11 erythropoietic protoporphyria, or EPP for short. 12 Porphyria is not a single disease but a group of 13 eight inherited genetic disorders that result in an 14 accumulation of porphyrins and porphyrin precursors in the 15 body. Now I'll not give you an entire lesson or the 16 porphyrias today, because Melanie will be sure to cut me off quickly, but I will share that EPP presents with 17 18 intolerance to sunlight. Sun and other artificial light 19 causes extreme phototoxicity and burning pain, akin to 20 putting your hand in boiling water. It's something that no 21 one in their lives should feel. And if treatments all are 22 in place, all should have access.

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1 Patients with extremely rare diseases like the porphyrias may never see a treatment developed without 2 working drugs as incentives, and pragmatic approaches to 3 4 FDA approvals greatly accelerated approval pathway. In fact, the first treatment under the Orphan Drug Act was the 5 1983 approval for a porphyria treatment called hematin, 6 that is -- you can hear the doorbell ringing -- that is 7 8 still part of the standard of care to this day.

9 We are very unfortunate to have three approved 10 therapies and one drug approved -- excuse me -- that is 11 currently in a Phase III clinical trial addressing 12 porphyria subtypes. Each of these treatments received one 13 or more FDA designations designed to provide incentives to 14 encourage and aid the development of drugs for debilitating 15 rare diseases, like the porphyrias.

As a parent, I can assure you that we want robust evidence on whether a new treatment is effective, as well as the risks that are associated with it. Accelerated approval is not a shortcut around safety and efficacy. It is essential in its pragmatism for both patients and manufacturers. We agree that manufacturers securing accelerated approval must follow through with FDA-required

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studies, but disagree that failure to do so in ultra-rare conditions is a problem, much less one justifying a penalty on use of the accelerated pathway.

4 It is a struggle -- and I will put on my professional hat as well as my mom hat -- it is a struggle 5 to find companies interested in and willing to invest in 6 developed treatment for low-prevalence conditions. Please 7 8 do not follow through with recommendations that can 9 disincentivize and create another barrier to therapy 10 development for people with rare and ultra-rare disease 11 like the porphyrias.

12 Thank you for listening.

13 CHAIR BELLA: Thank you, Kristin.

MS. HUGHES: Diane, you've been unmuted. You can unmute yourself and make your comment.

MS. BERRY: Thank you. Can you confirm you can hear me?

18 CHAIR BELLA: We can.

MS. BERRY: Thanks so much. I'm Diane Berry with Sarepta Therapeutics. Sarepta submitted written comments on this proposed recommendation, which I hope you've had a chance to review. Sarepta is a leader in precision genetic

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1 medicine for rare diseases, including EXONDYS51, which has 2 been raised in MACPAC meetings as an example of what, 3 quote, "may be wrong with accelerated approval."

However, facts and a growing body of evidence
tell a different story of how Duchenne and EXONDYS51 in
fact exemplify the success of the accelerated approval
pathway and that it works as it was intended by Congress
and FDA.

9 Duchenne is a universally fatal, rare, pediatric 10 disease caused by the absence of dystrophin, a protein vital for muscle structure, function, and preservation. 11 12 With 100 percent certainty, without dystrophin, patients with Duchenne experience progressive muscle deterioration, 13 irreversibly losing the ability to walk, feed, and dress 14 15 themselves, and breathe unassisted over time, ultimately 16 succumbing to their disease in their mid to late 20s. Time 17 is not on their side.

In utilizing the accelerated approval pathway for Duchenne, FDA recognized the life-threatening and debilitating nature of this disease, the lack of available therapy, and that dystrophin production is a justifiable surrogate endpoint reasonably likely to predict a clinical

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benefit, a point recently reinforced by a team of
 independent clinical researchers.

MACPAC has referenced that manufacturers take too 3 4 long to complete postmarketing confirmatory studies. It doesn't get any easier to conduct clinical endpoint-driven 5 trials post-approval than it was pre-approval. We cannot 6 will these trials to go faster. Timelines for such trials 7 8 are necessarily driven by the same disease-specific 9 considerations as well as additional operational factors 10 and regulatory engagement. It is reasonable to expect 11 verification of clinical benefit to take years, 12 particularly for slowly progressing, highly variable diseases like Duchenne, and new therapeutic classes with 13 novel mechanisms of action like EXONDYS51. 14

15 Notably, subsequent applications of accelerated 16 approval in Duchenne have gained efficiencies due to learnings applied from the EXONDYS51 experience. Post-17 18 approval data generation is far from static. Beyond our 19 commitment to executing postmarketing requirements, we are 20 actively creating opportunities to collect real-world 21 evidence. While not yet reviewed or validated by FDA, the 22 analyses demonstrate that EXONDYS51-treated patients may

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1 experience a delay in loss of ambulation by as much as 3.4 2 years, and a significant clinically meaningful attenuation 3 of pulmonary function decline.

EXONDYS51's approval enabled Sarepta to reinvest all of its revenue and more back into developing additional and improved innovations for Duchenne patients, and it signaled to the broader industry that a viable regulatory pathway exists for this complex, rare disease. Five years ago, there were no FDA-approved treatments for Duchenne.

10 CHAIR BELLA: Your time has expired. If you
11 could wrap it up, please.

12 MS. BERRY: Okay. I would just like to emphasize three points. First, a differential rebate will undermine 13 FDA's accelerated approval pathway, because it will 14 15 discourage drug developers from utilizing it to pursue 16 development of therapies in otherwise intractable disease areas and will harm patients if treatments are never 17 18 developed. Second, assessing a higher rebate on 19 accelerated approval drugs could impact slow completion of 20 postmarketing studies. Many rare diseases, including 21 Duchenne --

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CHAIR BELLA: I am going to ask you to wrap it

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up. If you want to go ahead and get your third point in
 and then we're going to have to move on. Sorry.

MS. BERRY: The last point is what was recognized during discussion, that targeted accelerated approval drugs is, we feel, misdirected, as it will not yield significant budget savings. They account for less than 1 percent of annual Medicaid spending year after year and is not a key driver of growth in health care spending. Thank you.

9 CHAIR BELLA: Thank you very much.

MS. HUGHES: Marc has been unmuted. Marc, you
can make your comment.

MR. YALE: Thank you so much for allowing me to make a comment today. My name is Mark Yale and I'm the Advocacy and Research Coordinator for the International Pemphigus & Pemphigoid foundation, and I also serve on the board of directors for Haystack Project.

Through my own experience as a rare disease patient living with pemphigoid, as well as my involvement in advocacy for pemphigus and pemphigoid patients, and others living with extremely rare conditions, through Haystack Project, I can tell you that accessing treatment can be an immense undertaking. Pemphigus and pemphigoid

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have been treated off-label with a variety of different
 therapies that have varying degrees of success in helping
 control our disease, and payers can make getting access to
 off-label treatments extremely challenging.

5 We are now one of the handful of ultra-rare 6 conditions with an FDA-approved treatment, Rituxan, now considered first-line therapy for pemphigus vulgaris. 7 8 There is no question that manufacturer incentives, like the 9 FDA priority review breakthrough therapy designation and 10 orphan drug designation were really vital to getting this therapy as quickly as possible for patients with pemphigus 11 12 who struggle every day to control their symptoms.

We were fortunate that Rituxan has been on the market since its approval in 1997, and that due to the nature of our condition, clinical trials could be completed without surrogate endpoints. The proposal to create an additional rebate for accelerated approval, though, could be a significant deterrent to developing a new product for pemphigus.

The proposal also raises questions that do not have good answers from a policy perspective. For example, if Rituxan's pemphigus indication were achieved through

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accelerated approval, would an additional rebate apply, and 1 would it only apply to that indication? It would seem that 2 the proposal would decrease research rather than encourage 3 postmarket studies, especially when medically accepted off-4 5 label uses would be covered without the additional rebate. Placing a disincentive on the pathway that is 6 7 designed to encourage early access to promising treatments 8 could have the greatest impact on ultra-rare disease 9 patients like myself, and your proposal today is basically 10 a vote against investment in patients like me. 11 Thank you again for your time, and I hope you 12 consider my comments. CHAIR BELLA: Thank you, Marc, and thank you for 13 14 sharing your personal story. 15 MS. HUGHES: And Jack has been unmuted. Jack, 16 you can make your comment. 17 MR. ROLLINS: Good afternoon. Confirming that 18 you are all able to hear me? 19 CHAIR BELLA: It's a little faint but we can hear 20 you. 21 MR. ROLLINS: Okay. Hopefully this is better. 22 I'm Jack Rollins, Director of Federal Policy at

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the Association of Medicaid Directors, and I would like to 1 offer some comments in support of the Commission's 2 consideration of the enhanced rebate for drugs approved on 3 4 the accelerated approval pathway. I'd like to 5 contextualize this support by calling to attention the longstanding challenges of the sustainability of the 6 Medicaid pharmacy benefit imposed by high-cost care and 7 8 specialized therapies.

9 While we fully support the development of such 10 therapies and the promise that they represent for 11 particularly vulnerable patients with rare diseases and 12 conditions, we want to recognize that the Medicaid Drug 13 Rebate Program, as currently structured, was not really 14 designed to address the very high entry point costs 15 associated with these products.

Across a number of states, we have seen the pharmacy benefit be a key driver of increased costs of the program, and those costs do come with tradeoffs, as every state is required to operate a balanced budget in every fiscal year in their Medicaid programs and throughout the state budget writ large. So we strongly encourage the Commission to gives states additional tools to manage those

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1 costs in an appropriate manner, and we view this proposal 2 as a step towards that direction.

We also want to call to attention the challenges with focusing on value-based purchasing as the sole path forward for managing these types of drugs. Value-based arrangements often will require some specific negotiations on a per-product or even per-indication basis, that many states do not currently have the clinical and administrative capacity to execute on.

10 There is also no guarantee that value-based 11 purchasing arrangements would successfully contain costs 12 for these products for the states. We also support value-13 based purchasing, in principle, but we do not recommend 14 that it be the primary vehicle for managing these types of 15 products.

16 We have submitted some written comments to this 17 effect as well, which we hope you will all have the 18 opportunity to review, and I appreciate the consideration 19 of perspectives from the state Medicaid agencies on this 20 important topic. Thank you.

21 CHAIR BELLA: Thank you, Jack.

I see no other hands at the moment. Any last

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1 comments from Commissioners? Oh, it looks like we do have
2 another commenter.

3 MS. HUGHES: Kara, we have unmuted your line, so
4 you can make your comment.

5 MS. BERASI: Yes, can you just confirm you can 6 hear me?

7 CHAIR BELLA: We can.

8 MS. BERASI: Excellent. Thank you. My name is 9 Kara Berasi. I am a board member of CDG Care, a 10 pharmacist, and also the mother of a child with CDG, or 11 congenital disorder of glycosylation. Glycosylation is a 12 process of adding sugar building blocks called "glycans" to proteins, and all body systems require glycosylation to 13 work normally. Over 400 genes play a role in 14 glycosylation, and over 130 of those genes are known to 15 16 cause CDG.

There are currently 149 known CDG types with additional types being discovered each year, and to give an idea of how rare these disorders are, the most common form, which is PMM2-CDG, has only about 250 diagnosed patients in the United States.

22 CDG is usually apparent from infancy. It can be

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associated with a broad variety of symptoms and can vary in
 severity from mild to severe and also can be disabling and
 even life-threatening. In fact, 20 percent of patients die
 within their first year of life.

5 There are currently no FDA-approved treatments, 6 so supportive therapies like physical, occupational, and 7 speech are the only options for the majority of CDG types. 8 There's only one of 149 types that can be treated with oral 9 mannose, but that has not been effective in the other 10 types.

11 It can be very difficult to get researchers and 12 manufacturers interested in pioneering innovation for 13 extremely rare disorders like this one, especially when 14 there are so many types with similar mechanisms but 15 different body system impacts. So accelerated approval for 16 us is not a shortcut or a pathway with sub-par evidence. It may be the only way a treatment for CDG could become a 17 18 reality.

So we do not view the additional rebate as a way to help patients by making treatments more affordable; rather, it's a threat to ever getting treatments developed or tested through to approval.

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1 So we want to stand with you and find another way to get the postmarket studies done that seems to be the 2 3 apparent reason for considering this proposal. The company 4 has done nothing wrong by using this pathway, and yet 5 they're being punished before they defaulted on 6 commitments. So I'm sure it's more administratively 7 burdensome to apply these penalties and rebates after 8 they've defaulted, but what isn't burdensome in the world 9 of health care or even more so in the world of ultra-rare 10 that my son and so many others live in every day as we 11 fight for the attention of these big drug companies and a 12 chance for a more typical life? Thank you all so much for your time and kind 13 14 consideration today and giving me the opportunity to speak. CHAIR BELLA: Thank you, Kara. 15

MS. HUGHES: Michelle, you have been unmuted to make your comment.

MS. DAVIS: Hello. My name is Michelle Davis. I joined the International Fibrodysplasia Ossificans Progressiva Association, also known as the IFOPA, in 2016 as its executive director. I'm also the mom to a son with an ultra-rare cancer, synovial sarcoma.

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1 I'm here today to talk to you mainly about FOP and the impact on the drugs that are being developed that 2 this policy potentially has. FOP is an extremely rare 3 4 condition affecting only one in two million people. It is one of the rarest, most disabling genetic conditions known 5 to medicine. An FOP bone forms in muscles, tendons, 6 ligaments, and other connective tissues, and ridges of 7 extra bone develop across joints, progressively restricting 8 9 movement and forming a second skeleton that imprisons the 10 body in bone.

11 Babies with this condition will show malformation 12 of the great toes at birth, and the progression rate is 13 unpredictable but appears in a pattern of upper body in childhood and lower body in adolescence. Flareups can 14 15 occur spontaneously or follow physical trauma such as 16 childhood immunizations, falls, surgery, biopsy, or viral illness. No treatment exists for FOP, but parents do have 17 18 hope that one of the products in clinical trials will 19 receive approval.

20 Given the seriousness and rarity of FOP,
21 investigational treatments are eligible for FDA fast-track
22 designation as well as FDA breakthrough therapy and rare

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pediatric disease designations. Fast-track designation allows companies to have more engagement opportunities with the FDA and allows them to be eligible for accelerated approval and priority review, all of which will help treatments reach patients faster, especially those with ultra-rare, life-limiting, disabling, life-shortening diseases like FOP.

8 Please do not disincentivize the development of 9 therapies for rare and ultra-rare disorders like FOP by 10 penalizing an approval pathway that could be the tipping 11 point between companies pursuing and not pursuing research.

12 We appreciate the need for ensuring Phase 4 postmarketing studies are completed. Our patients will 13 benefit from the information on that more than anyone. We 14 15 are also on the front line as really rare patients and can 16 tell you how difficult it is to do those studies, how to keep those patients engaged, which is something not always 17 18 in a company's control. Maybe we should incentivize 19 patients rather than penalize the company.

20 We need to have more creative than the proposal 21 you are considering today. We need all the incentives we 22 have to date and more in getting companies to study

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1 conditions like FOP.

2 Thank you.

3 CHAIR BELLA: Thank you. I think we have one
4 last comment.

5 MS. HUGHES: Yes, Georgia, you have been unmuted. 6 You may make your comment.

MS. BURKE: Thank you. My name is Georgia Burke. I'm a directing attorney with Justice in Aging, which is a national advocacy organization seeking to improve the lives of older adults, and I guess I'm the only commenter who's talking about the D-SNP chapter.

12 I wanted to support the value of encouraging and supporting more state expertise in Medicare. Having a 13 state office of Medicare or some other way within the state 14 15 of having sufficient dedicated staff with responsibility 16 for working specifically on duals issue is really a 17 critical element to the success of integration efforts. As has been noted, MIPPA does offer an 18 19 opportunity for very specific requirements in state 20 contracts, but state oversight of the implementation of 21 those contractual requirements and state coordination both 22 with CMS and with the plans and with affected stakeholders

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1 throughout the life of the contract is just as important.
2 And I think one of the real values that we saw with MMPs
3 was the coordination that developed and the relationships
4 that were developed between CMS and the states, and they
5 were so important as ways of being able to address the
6 issues that arose during the introduction of the Financial
7 Alignment Initiative.

8 There is no doubt about it: Medicare and 9 Medicaid are both extremely complicated programs, and 10 setting up very intentional pathways for exchange of 11 expertise and coordination at the agency level between both 12 CMS and the state is just as important to integration as 13 integration within the plan structure itself.

14 Thank you.

15 CHAIR BELLA: Thank you, Georgia.

MS. HUGHES: Okay. Camille, you have been unmuted to make your comment.

MS. DOBSON: Hi, good afternoon. Camille Dobson, deputy executive director of ADvancing States. We represent the aging and disability directors that deliver LTSS to Medicaid and non-Medicaid clients. I also wanted to speak in support of the Commission's work on dual-

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eligible integration. It continues to be a large focus for 1 our members. I'm particularly interested in the work 2 around different benefit packages for partial- and full-3 benefit dual eligibles. I think that would be an 4 5 interesting research approach as we find a lot of states do not include dual eligibles, partial duals in particular, 6 because they don't really see any value in capitating that 7 8 benefit to the health plans and the hassle of doing 9 crossover claims and those kinds of things are not 10 sometimes worth the squeeze, so perhaps there's something 11 there.

12 I also wanted to echo Chuck's note about the 13 value of integration as -- integration as a value in itself 14 and the fact that there may be, in fact, better MA plans 15 Star rated in the service area. We've heard that 16 repeatedly from the SHIP counselors who are on the front 17 lines of helping individuals take their Medicare coverage, 18 and they almost exclusively have told us that they look at the Star ratings. And so without better information about 19 20 why integration is a good thing for dual eligibles, they're 21 very likely to encourage individuals to pick the highest 22 rated plan and ones that have more robust supplemental

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benefits. So I think that's not a small issue to consider.
Again, I know it's a little bit in the weeds, but
I think it was a really interesting point and echoes what
we've heard.

5 So I'll just conclude, again, with my gratitude 6 for your ongoing work on this subject and really helping 7 the states focus and provide resources to help them do a 8 better job.

9 CHAIR BELLA: Thank you, Camille.

10 All right. I appreciate everyone who has made 11 public comment today, especially those with your personal 12 stories. Thank you very much for taking the time to do 13 that and for those of you who have commented. Additional 14 comments, again, can always be submitted to comments at 15 MACPAC.gov.

16 With that, we are going to wrap up the morning. 17 Thank you to the Commissioners. We will resume at 1:15, 18 and we will have a session on improving access to 19 behavioral health services for adults. So we'll see you 20 all at 1:15. Thank you.

21 \* [Whereupon, at 12:21 p.m., the meeting was 22 recessed, to reconvene at 1:15 p.m. this same day.]

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1 AFTERNOON SESSION 2 [1:15 p.m.] CHAIR BELLA: All right. Why don't we go ahead 3 4 and get started. Welcome back, everyone. This afternoon, we're going to focus a lot on behavioral health, starting 5 with a session on access for adults. 6 7 I'm going to turn that over to Chuck who is going 8 to lead us through this part of the meeting and say welcome 9 to Erin. 10 VICE CHAIR MILLIGAN: Thank you, Melanie. 11 Erin, we look forward to learning about the continuation of this body of work. So it's all yours. 12 13 ### IMPROVING ACCESS TO MENTAL HEALTH SERVICES FOR ADULTS: REVIEW OF DRAFT CHAPTER AND 14 15 RECOMMENDATIONS 16 MS. McMULLEN: Thanks, Chuck. So, over the past several months, the Commission 17 has discussed access to mental health services for adults 18 on several occasions. While Medicaid beneficiaries with 19 20 mental illness have multiple needs that could be addressed 21 through changes in public policy, in this chapter, we focus 22 in on the role of Medicaid and improving access to care for

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1 individuals in crisis.

Last month, we discussed three policy options 2 aimed at more clearly defining Medicaid's role in 3 4 supporting state crisis systems. This included offering additional guidance and technical assistance to states; in 5 part, the need for additional guidance for the 6 implementation of 988, a new nationwide three-digit dialing 7 quote for the National Suicide Prevention Lifeline, which 8 9 takes effect in July 2022.

10 States and communities are now grappling with how 11 this will affect existing local crisis hotlines and systems 12 needed to engage with individuals who are in crisis or 13 immanent risk of suicide.

Based on your feedback last month, only two of the policy options we discussed were incorporated into draft recommendations for your consideration today. We decided not to move ahead with recommendations focused on improving collaboration between the Substance Abuse and Mental Health Services Administration, or SAMHSA, and the Centers for Medicare and Medicaid Services, or CMS.

21 Rather, a discussion regarding collaboration between these22 two agencies has been incorporated into the draft chapter.

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During the March meeting, Commissioners also raised concerns about the role of other payers, including Medicare and commercial insurance in the provision of crisis services. Given the Commission's statutory authority, the draft chapter does focus on how CMS and SAMHSA can be more effective in supporting Medicaid efforts to improve access to crisis care.

8 So today we will review a draft chapter for the June report to Congress and discuss the two draft 9 10 recommendations I mentioned earlier. The draft chapter 11 does cover a number of different areas, many of which we 12 have presented on previously. As such, a lot of my comments today are intended to capture the key findings of 13 the sections listed here rather than the detailed analyses 14 15 laid out in the chapter.

So, to set the context for the two recommendations and future work on improving access to care for beneficiaries with mental illness, the chapter begins by discussing the prevalence of mental health conditions of the Medicaid beneficiaries and the rates at which they receive treatment, comparing the experience of beneficiaries to those with private coverage.

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In this section of the report, several
 observations are made, and a few key findings are listed
 here.

Some of you have reached out regarding the
prevalence and treatment rates among beneficiaries of color
for both this chapter and the chapter on children and youth
that Melinda will present after this session.

8 Generally, we found that beneficiaries of color 9 experience mental health at lower rates than their white 10 counterparts. We also found that beneficiaries with mental 11 illness who are Black, Hispanic, or multiracial were less 12 likely to receive treatment when compared to their White 13 peers.

There is no single answer that can explain these differences, and there likely are different explanations for various ethnic groups. However, we still try to incorporate additional studies into the draft chapter to further examine variations in the prevalence of mental illness among minorities.

20 While the findings in the previous slide are the 21 result of a number of factors, coverage of mental health 22 services heavily impacts access to care. Last month, we

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heard that the Commission wanted to frame recommendations on improving access to crisis services within the broad mental health continuum. As such, the chapter lays out the continuum of care as established by the American Association for Community Psychiatry.

We then go on to summarize state coverage 6 7 policies for 15 discrete mental health services. We found that many states do not cover a full continuum of mental 8 9 health care, covering on average 12 out of 15 mental health 10 services. The largest gaps in the continuum are for 11 residential services and supportive services, including 12 supportive employment and skills training and development. 13 In addition to gaps in service coverage, there are a number of reasons why Medicaid beneficiaries with 14 15 mental health conditions receive treatment at low rates. 16 The chapter includes analyses of several data sources which point to a provider shortage as well as a severe 17 18 maldistribution of mental health providers at the state 19 level. Access to mental health services is further 20 affected by the unwillingness of some providers to 21 participate in Medicaid.

I should caution that none of the findings we

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present on this slide or in the draft chapter are new.
 Concerns about access to mental health services have been
 well documented for over a decade.

The consequences of limited access to mental health treatment are significant. The chapter examines the intersection of mental health, mortality, and rising rates of suicide. We highlight various studies that demonstrate that individuals with mental health conditions often die prematurely, which we'll discuss as well in the chapter on clinical integration.

11 Suicide is one of the most widely acknowledged 12 contributors to premature mortality among individuals with 13 mental illness. It's the 10th leading cause of death in 14 the United States.

15 Limited access to treatment has also contributed 16 to the criminalization of mental illness. Law enforcement is often the first to respond when individuals experience 17 18 mental health crises. As a result, a disproportionate 19 share of individuals with mental illness wind up in jail or 20 prison. Most people with a history of mental illness do 21 not receive treatment while they're incarcerated in prison. 22 Beneficiaries are also more likely to experience

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involvement with the criminal justice system than their privately insured peers. We found that beneficiaries with any mental illness were more than three times as likely to report that they were on parole or probation in the past year compared to those with private coverage.

6 The chapter then turns to how crisis services can 7 be used to facilitate real-time access to behavioral health 8 care for beneficiaries of all ages. In order to ensure 9 that beneficiaries are receiving appropriate care at the 10 right time, some states have developed crisis systems that 11 provide early intervention when an individual is 12 experiencing a behavioral health crisis.

13 Crisis systems also triage and assess individuals and connect them with the appropriate level of care. 14 15 Ultimately, the goal of crisis services is not just to 16 determine the level of care needed for an individual, but 17 to resolve their behavioral health crisis so more intensive 18 services are not needed. Offering such care is a key 19 strategy to reduce inappropriate use of psychiatric 20 hospital beds, decrease boarding in emergency departments, 21 and reduce the need for law enforcement to respond to 22 behavioral health crises.

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1	We discussed two national efforts in the chapter
2	to address rising rates of suicide and to facilitate access
3	to behavioral health care for individuals in crisis, the
4	first of which relates to the implementation of 988, as I
5	mentioned earlier. This takes effect in July of 2022.
6	The National Lifeline isn't just one call center.
7	It's made up of a network of over 170 state and local
8	crisis hotlines that are linked by a toll-free number
9	that's available 24 hours a day, 7 days a week. Many
10	stakeholders have expressed concern that there will not be
11	sufficient capacity to meet the increased demand when 988
12	goes live. In part, this is because funding for crisis
13	hotlines is often a state and local responsibility, and
14	that will continue to be the case after 988 is implemented.
15	There are multiple ways states can finance
16	hotline services, and how Medicaid can support these
17	hotlines will be discussed shortly.
18	Until recently, the core components of the
19	behavioral health crisis continuum had not been fully
20	defined. In February 2020, SAMHSA did issue national
21	guidelines for crisis care, establishing the three-part
22	elements of a crisis system that are listed on the slide.

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We discussed each of these components in detail last month, and the chapter further describes each of these components and how technology, including caller ID and GPS-enabled technology, can be used to coordinate and respond to behavioral health crises in real time.

While most states are using Medicaid to pay for 6 7 some form of crisis services, many state crisis systems are 8 not fully aligned with SAMHSA's national guidelines. 9 States including Arizona and Georgia are highlighted in the 10 chapter, as Medicaid is playing a growing role in 11 implementing comprehensive crisis care in those states. 12 Even in these states that are considered innovators in the 13 delivery of crisis care, services might not be provided in 14 accordance with SAMHSA's guidelines.

15 Congress has taken several actions to increase 16 funding for crisis services. Last month, we reported that 17 the Mental Health Services Block Grant included a 5 percent 18 set-aside for crisis services, and Congress has also 19 appropriated an additional \$1.5 billion to the Mental 20 Health Services Block Grant.

Finally, the American Rescue Plan offers anenhanced FMAP for certain community mobile-based crisis

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intervention services. It also made available additional
 funding for state planning grants.

Current federal quidance does identify some ways 3 4 Medicaid can pay for crisis services, but it often falls 5 short of providing enough detail to states or to offer a roadmap to support the three components of a crisis 6 7 continuum. We reviewed each of these authorities last 8 month. So I'm not going to go into detail describing each 9 one, but I do want to reiterate that throughout the chapter 10 for each of these authorities, we note that states do not 11 have sufficient guidance that addresses how Medicaid can 12 complement other funding sources, including state and local funds or block grant funding to support components of the 13 crisis continuum. This type of guidance is needed, as 14 15 Medicaid cannot be the sole supporter of state crisis 16 systems.

17 Improving access to crisis services does require 18 effective communication between CMS and SAMHSA. However, 19 federal programs targeting individuals with mental illness 20 are spread across multiple agencies, and prior studies have 21 documented a lack of coordination at the federal level. 22 The chapter describes findings from a 2014 report

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issued by the U.S. Government Accountability Office, or
 GAO, that highlighted a lack of coordination among federal
 programs that serve those with serious mental illness.
 Ultimately, these GAO fundings promoted congressional
 action.

The 21st Century Cures Act authorized 6 Interdepartmental Serious Mental Illness Coordinating 7 8 Committee to enhance coordination across federal agencies, 9 to improve service access as well as care delivery for 10 people with serious mental illness. This committee 11 includes a number of members from various federal agencies 12 and departments, including CMS, and in December of 2017, the committee issued a report to Congress that included 13 various recommendations. Among other things, the committee 14 15 did recommend that a definition should be established for 16 crisis services, and there should be an implementation of a national standard for crisis care. 17

18 The national guidelines that SAMHSA issues, which 19 I discussed on previous slides, were largely informed by 20 this report.

21 So that brings us to next steps. In the course 22 of our work on this chapter, there are several areas for

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1 further inquiry that have emerged, and our work on crisis
2 services is really just a first step at addressing access
3 to mental health care.

We do expect further work to examine the health care needs of justice-involved beneficiaries. That includes access to behavioral health treatment upon release from correctional settings as well as strategies to ensure Medicaid or CHIP enrollment upon release for eligible individuals.

10 Given the limited availability of many home- and 11 community-based services, we also plan to further examine 12 how HCBS services for beneficiaries with significant 13 behavioral health conditions are being delivered.

Finally, we also plan on examining access to behavioral health care for beneficiaries that are part of the lesbian, gay, bisexual, and transgender communities.

17 That brings us to our two draft recommendations.18 As a reminder, Commissioners will vote on these

19 recommendations tomorrow.

The first recommendation is aimed at providing additional guidance to states. It reads: "The Secretary of the U.S. Department of Health and Human Services should

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direct the Centers for Medicare and Medicaid Services and the Substance Abuse and Mental Health Services Administration to issue joint sub-regulatory guidance that addresses how Medicaid and the state Children's Health Insurance Program can be used to fund a crisis continuum for beneficiaries experiencing behavioral health crises."

7 The rationale for that recommendation is listed 8 here, and your chapter goes into greater detail. Sub-9 regulatory guidance could be used to further clarify how 10 Medicaid and CHIP can be used to pay for the three 11 components of the behavioral health crisis continuum. 12 Specifically, it could further describe how states can use the authorities highlighted on previous slides as well as 13 how to bring funding to pay for different components of the 14 15 crisis continuum. In developing new guidance, we do know 16 that the Secretary should invite participation of all 17 relevant agencies with a role in implementing the National 18 Lifeline and agencies affecting children and families.

19 The implications for that recommendation are 20 listed here. We do not foresee that the act of developing 21 this guidance would affect federal spending, but we do 22 think it would assist states in overcoming barriers to

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designing and implementing crisis services as envisioned by
SAMHSA's national guidelines. It could also enhance access
to community-based care for those experiencing behavioral
health crises. These gains could be particularly important
for beneficiaries of color who are generally less likely to
receive mental health treatment than their White
counterparts.

8 Finally, we do not expect this to have a direct 9 effect on plans and providers, but we do note that guidance 10 could assist states in setting clear expectations for 11 providers to facilitate access to crisis care.

12 The second draft recommendation really builds off the first. It would provide technical assistance and 13 14 planning support for state crisis continuum. That option 15 reads: "The Secretary of the U.S. Department of Health and 16 Human Services should direct a coordinated effort by the 17 Centers for Medicare and Medicaid Services and the Substance Abuse and Mental Health Services Administration 18 19 to provide education and technical assistance on the 20 implementation of a behavioral health crisis continuum that 21 coordinates and responds to people in crisis in real-time. 22 Additionally, the Secretary should examine options to use

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existing federal funding to support state-level activities
 to improve the availability of crisis services.

The rationale for that option is listed here. In addition to guidance, states really need technical assistance and dedicated planning to coordinate the multiple state agencies and delivery systems that are involved in the provision of behavioral health services.

8 As I mentioned earlier, we believe existing 9 funding could be used to support planning and technical 10 assistance efforts. Congress has increased funding for the 11 Mental Health Services Block Grant, and the Secretary could 12 use existing planning requirements under the block grant to support this work. Moreover, Congress has appropriated an 13 additional \$15 million to CMS to administer grant funds to 14 15 plan for mobile crisis provision. As with the first 16 recommendation, we note that the Secretary should work with 17 other relevant agencies as needed.

18 The implications for Recommendation 2.2 are 19 listed here. I'm not going to go through them, as they are 20 similar as the implications for Recommendation 2.1.

21 So that concludes my presentation. I'm happy to 22 take any questions in addition to any feedback you have

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regarding the contents of the chapter as well as the draft
 recommendations. Thank you.

VICE CHAIR MILLIGAN: Thank you, Erin.
Let me start by mentioning to members of the
public, we have this session and then we have the next
session on mental health services for children and
adolescents. We will then take comment after that second
session.

9 So, Commissioners interested, if you have 10 questions or comments you'd like to make and if you're able 11 to, at this point, signal your support or concerns about 12 either of the two recommendations that Erin presented. So 13 I see Peter and then Kit and the Kisha.

14 COMMISSIONER SZILAGYI: Thank you, Chuck.

Erin, thank you for a very clear presentation, as always. I think it is an excellent chapter. I think focusing on major mental health problems in crises is a really good place to start, and as you mentioned, future work needs to sort of go down the continuum or actually go upstream in the continuum.

I do have a generic question, and this relates to both this chapter and the pediatric chapter. This has to

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do with the implications for both the recommendations. 1 2 If there is better guidance and better -- so one of the problems here is lack of access for appropriate 3 mental health services. If there's better guidance and 4 better technical assistance, wouldn't that increase 5 utilization of mental health services? I don't know 6 whether the implications for cost would be increased or 7 8 decreased long term, because better utilization at one 9 point might lead to reduced utilization down the road. But 10 wouldn't we expect more use of mental health services, and 11 would that have any financial implications? 12 MS. McMULLEN: So --13 COMMISSIONER SZILAGYI: And are there any 14 modeling studies? And maybe one other question. Sorry to 15 interrupt. Could we estimate what -- if the guidance was 16 followed perfectly across the United States about best use of even existing services, is there any estimate for what 17 18 might the impact be on improved access to care or use of 19 care? And by increased utilization, that's not a bad 20 thing. I think that's actually often and usually a good 21 thing.

22

MS. McMULLEN: Yeah. So I'll start with the kind

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1 of first question around utilization.

2 I do think that one of the kind of goals of a crisis system is to connect people with ongoing community-3 4 based and try to avoid higher cost like inpatient or 5 emergency department services if that's appropriate. 6 I do think SAMHSA's guidance does recognize that some people are going to need inpatient treatment, and that 7 8 might be appropriate. 9 Whether or not there's been studies, it is hard 10 to get studies that are specific to Medicaid. There's only 11 a few states that are really close to kind of offering 12 SAMHSA's full kind of -- like the perfect model of what's being offered. There's only a few states we can look at. 13 14 The chapter does highlight the experience of one

15 county in Arizona, and it talks about up-front costs and 16 what they saw in terms of savings. We can look and see if 17 there's other studies. I know some other Commissioners 18 emailed me about this as well. So we can look and see.

19 The experience in Pima County did show that there 20 was substantial savings from implementing these programs, 21 but again, trying to find Medicaid-specific costs related 22 to this is hard. It's especially challenging since we know

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that there is a role for SAMHSA block grants and other
 types of state funding when it comes to the continuum.

And then your question on the modeling, I haven't seen anything that kind of 100 percent estimates like what this would cost and look like, but we can see if we can find some additional information to incorporate into the chapter.

8 COMMISSIONER SZILAGYI: Great. Thanks.9 Excellent chapter. Really well done.

10 VICE CHAIR MILLIGAN: Thanks, Peter. So I have 11 now added Martha, Fred, and Sheldon to the list. But, Kit, 12 you're up next.

COMMISSIONER GORTON: So thanks, Erin, for this 13 14 ongoing, very important work. I agree with Peter. I'm 15 also pleased that we're focusing on the crisis end of 16 things because I think we often focus on the back end, and I think it's nice to make sure we have the full picture. 17 18 So two comments. One to the issue that you 19 mentioned earlier, that some of us raised, in terms of the 20 data suggesting different prevalences by race and 21 ethnicity. It occurred to me, as I have continued to think

22 about that, one hypothesis is at least the data that I saw,

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I think I saw in the chapter, were survey data, which means that they're self-reported data. So one of the things we may be seeing is cultural differences in self-reporting, or, similarly, we may be seeing cultural differences in self-identification, so one group more likely to identify themselves as having suffered something than another group.

7 I think I've seen data, but I may be imagining 8 this, that suggests that in young people, young people of 9 color are less likely to take the same set of symptoms and 10 attach a label of a behavioral health problem to it than 11 young people who are white. So we may be seeing a 12 cultural/reporting difference, and it may be worth poking at that a little bit, just to be able to present a clearer 13 14 picture to people. So that was one thing.

The second is a very technical thing, and that is some of the data that you presented in the chapter, you're talking about differences in utilization patterns for people who are identified as having a mental health problem. And included there are distinctions in terms of how people of color get more inpatient care and white people get more ambulatory care.

22 I want to point out where I think you looked at -

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- in one part of it, though, you distinguished between 1 clinic care and private therapy care, and I think we need 2 to be careful there, because how providers are enrolled in 3 4 Medicaid billing systems has nothing to do with do you walk into a building and get escorted to a private room where 5 you sit down with a licensed professional to work? 6 Sometimes that gets billed as a clinic visit and sometimes 7 8 that gets billed as a private visit, and the service is 9 identical. And so I think we need to be careful about 10 that. Sometimes in hospital-based clinics the motivation 11 for doing that is to get the clinic fee in addition to the 12 professional fee.

13 So I just think what we want to be looking at 14 there, if we can, and the data may not support this, is 15 actual units of a type of service. Who received 16 counseling, regardless of place of service, and that may be 17 important when we get more into telemedicine as well. 18 Because if talk therapy is, as we believe, at least 19 somewhat efficacious, and may be the most available if 20 you're in rural somewhere, then the fact that you got it, 21 that doesn't mean you had no access to that service. It 22 just means you had access to that service delivered in a

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different modality than in a public clinic or in a hospital clinic or in a private therapist's office or whatever. So it's all the same service, rendered by equivalently qualified professionals, just in different settings.

5 So it seems to me, and maybe that's overly 6 technical, but it seems to me we need to be careful that we 7 don't draw conclusions from place of service codes -- you 8 get my point.

9 MS. McMULLEN: I will just say that the treatment 10 data in the chapter is also derived from the National 11 Survey on Drug Use and Health, so we're beholden to the 12 different categories of how they map out treatment. I do not want to steal the thunder of Chris Park and Aaron 13 14 Pervin, because I know they are talking about T-MSIS 15 tomorrow. But I think these are important things that you 16 raise, that we can think about as we start to explore how 17 we can use T-MSIS to look at behavioral health issues. So 18 we will keep that in mind as we kind of move forward and 19 start thinking into this more.

20 COMMISSIONER GORTON: Yeah, and then we just need 21 to be circumspect in how we characterize it. So if the 22 data don't inform it then we may not be able to draw as

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1 sharp and crisp a conclusion as we would like.

VICE CHAIR MILLIGAN: Thank you, Kit. Kisha.
COMMISSIONER DAVIS: Hi. Thanks, Erin. It was a
really good chapter and I really appreciated how much you
really brought in the kind of racial perspective and the
differences that we see there.

7 As Kit mentioned earlier, just being really 8 careful about how we talk about experience versus reporting 9 of mental illness in minority communities. We know that 10 black patients are less likely to report, and that doesn't 11 mean that they experience it less. So several times we say 12 they experience, you know, mental illness less, and I would 13 counter that. We can't say that, for sure. We can just 14 say that it's reported less.

15 And also, you know, I agree with the 16 recommendations. When we're giving the rationale, though, you do such a good job in the chapter of really laying out 17 18 how this is affecting different communities of color and 19 kind of the detriment that they experience, but we don't 20 talk about that really in the rationale. And we don't give 21 any guidance, you know, creating this continuum to really 22 specifically help address some of these racial differences.

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And so saying something in the rationale about encouraging cultural competency and the education of those crisis service providers, and, you know, benefits of outreach to minority communities. That's all throughout the chapter but it's not mentioned at all in the recommendation or rationale, so bringing that in a little bit more.

7 VICE CHAIR MILLIGAN: Thank you, Kisha. Martha.
8 COMMISSIONER CARTER: I want to echo the other
9 Commissioners. This is a great chapter and I really
10 appreciate the work you've done on it.

11 Thinking about the recommendations and which 12 agencies need to play a part, and at the risk of like 13 bringing in the kitchen sink here, I think we want to consider the role of HRSA in behavioral health services. 14 15 In the adult world, of course, the community health centers 16 are often front line for suicide attempt. You know, I've 17 been there when somebody walks in and says, "I'm going to 18 kill myself and I need help." And when we get to the 19 second chapter, the next chapter on pediatric mental 20 health, the same thing for the school-based health centers. 21 So funding for those programs in the community as a first 22 step to address crises I think is really important.

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1 And the second part that goes along with that is addressing, through HRSA and wherever else the funding 2 comes from, the workforce needs, National Health Service 3 4 Corps, to make sure that we have the appropriate number of providers in the right places, in the communities that have 5 the highest need. You know, I know that's a congressional 6 funding issue often, but still that these agencies work 7 8 together to assess the need and to try to direct the 9 resources in the best way possible. So I'd like to 10 consider adding HRSA to that mix. 11 VICE CHAIR MILLIGAN: We'll come back to that,

12 Martha, before we wrap up this session. Fred, you're up. 13 COMMISSIONER CERISE: Thanks, Chuck. Erin, I 14 have a quick question and then some thoughts. In this 15 section, and in the other ones too, it stands out that 16 there's an increased prevalence among some of these 17 conditions -- you know, the severe mental illness, co-18 occurring disorders -- among Medicaid beneficiaries. It's 19 striking when it's worse than the uninsured. And I just 20 wonder, how much of that effect do we see as they get sick 21 and then they become eligible for Medicaid and that's what 22 we're counting? I mean, is there a good way to track, you

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know, the fact that it may be weighted towards Medicaid 1 because they become eligible as a result of that condition? 2 3 MS. McMULLEN: So unfortunately the survey data 4 we used to do these analyses doesn't include kind of the basis of an individual's Medicaid eligibility. We just 5 know that the individual self-reports that they are on 6 In 2015, we did do, in our report to Congress, a 7 Medicaid. 8 chapter on behavioral health that was based on 2011 MSIS 9 analysis. And in that chapter, throughout it, we looked at 10 people who are eligible for Medicaid on the basis of a 11 disability, to those who were eligible for Medicaid through other pathways. And we did see that most -- I think it was 12 close to half -- of people who were eligible on the basis 13 14 of a disability had some sort of behavioral health 15 condition.

16 That data, you know, is ten years old at this 17 point, and we haven't done new analyses. But that's the 18 best data that I have seen on this topic. So I do think 19 that the issue of, you know, if you qualify for SSI on the 20 basis of your disability and you receive Medicaid, it could 21 be possible that there are people with higher acuity when 22 it comes to their mental illness that are in the Medicaid

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1 program. I can't say that with -- you know, I don't have 2 the data to like 100 percent back that up, but I would 3 venture to guess that it's a factor.

4 COMMISSIONER CERISE: I just wonder how much you 5 see a shift from the uninsured and even the commercial side 6 to Medicaid as a result of the disease, you know.

7 MS. McMULLEN: We can pull in a little bit more. 8 COMMISSIONER CERISE: So my comment is, I know we're focused on Medicaid, and that's what we look at. The 9 10 problem with this is it just crosses all payers, right, and 11 you make a mention of that in some of the rationale there, 12 that it really is impossible to separate this, so who is 13 responsible for setting up the infrastructure? I think the 14 recommendations are right on target, because somebody's got to take the lead to provide the guidance there. 15

And if you look at, right now my experience is the places that have more complete continuums, it tends to be those big, publicly supported, the local mental health authority or the other districts, that, you know, the state is working with to do everything from the housing to the acute response, the EDs, and that sort of thing. And while Medicaid may be the biggest payer, there are others that

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are benefitting from that system, and so how do you pull in the other payers that really have a responsibility. They own a portion. That ED is sitting there for everybody. And so as you set up that infrastructure, how can we pull everyone into that conversation. All the other payers rightfully have some obligation or some responsibility because it is supporting their members as well.

8 So, anyhow, it's an observation that you can 9 break the federal strains of Medicaid, but there are other 10 payers that are benefitting from that structure, because if 11 you look at the places that tend to have those continuums 12 it's the places that are drawing on public support to set 13 that up, because it's impossible for most places to just independently braid those different funding streams 14 15 together and put that continuum out there and make it work. 16 So my bid for multi-payer involvement.

VICE CHAIR MILLIGAN: Thanks, Fred. Sheldon?
 COMMISSIONER RETCHIN: Yeah, thanks. Can you
 hear me okay?

20 VICE CHAIR MILLIGAN: Yes.

21 COMMISSIONER RETCHIN: Thanks. Thanks, Chuck.
22 Well, first, Erin, I think this is an outstanding

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chapter, but not only that, I think that everything we do 1 at the Commission is important, so I don't want to 2 overshadow everything else that we're doing. But for the 3 4 mental health crisis that we're facing in the country, this the largest unmet need that I know of, and before the 5 pandemic I felt a sense of momentum, so I'm glad we're 6 getting back to that sense of momentum, and I think it's 7 8 just in the nick of time.

9 I'm delighted over the recommendation. I'm 10 delighted with the implementation of the 988 national 11 lifeline. In fact, I predict that the lifeline is going to 12 uncover an even larger unmet need for mental health.

13 Let me just point out one thing that's sort of an 14 observation. If we were talking about creating a crisis 15 continuum, a national crisis service, for diabetics, 16 because too many diabetics were going into ketoacidosis, I 17 think we would conclude -- and I know this is not exactly a 18 metaphorical, but I think we'd conclude that there's 19 something wrong with access to care for diabetics. So we 20 have something wrong with access to care in mental health, 21 and the crisis continuum is going to unearth that even 22 more.

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I do want to add that I appreciated the statement regarding the implication there were communities of color in the impact statements. That wasn't lost on me and I appreciate that add.

5 I especially applaud the next steps, which is 6 going to include the examination of the intersection of 7 unmet needs of mental health and the criminal justice 8 system, especially for communities of color who are treated 9 differently in our justice system to begin with. This is 10 even more tragic.

And then let me just finally, as you all know, where I would probably end up, and that's on workforce. The participation rates are embarrassing for adult psychiatrists, and they're only moderately better in the commercial, so I understand we've got a real workforce problem. I think we've talked about that a lot.

But I have one question. With all of the variations in pricing and reimbursement, there must be variations in reimbursement we see across states for psychiatrists. Do we know if there is an elasticity there? Is this a payment problem or is it another issue with psychiatrist participation? Erin, do you know?

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MS. McMULLEN: No, I think I was able to include one study in the chapter that looked at payment rates across, but it was comparing what Medicaid pays for psychiatrists when compared to primary care physicians for similar services.

6

COMMISSIONER RETCHIN: For parity.

7 MS. McMULLEN: Yeah, for parity. And that data 8 is also a few years old. So I haven't seen something that, you know, is specific to Medicaid payment and elasticity 9 10 for psychiatrists. I do think that through work of some of 11 my colleagues we have shown that if you pay more, providers 12 are more likely to participate. We certainly have seen 13 that happen in Virginia with their substance use waiver. 14 But I haven't seen anything that gets at the exact issue 15 that you're raising.

16 VICE CHAIR MILLIGAN: And, Fred, were you coming 17 in on this point?

18 COMMISSIONER CERISE: I'd just comment or just 19 ask you; how much do you think that has to do with --20 without a good continuum of care, you're sort of on an 21 island a lot of times. I mean, it's a hard field, because 22 you lack so much system support. Imagine being an

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oncologist and I can't get somebody radiated or I can't get surgery or I can't get a line put in to do my chemo, because the rest of the system is not in place. I just wonder how much of it is, it's just hard to work in such a system where you lack a lot of the support to provide the full range of care that people need.

7 COMMISSIONER RETCHIN: Are you talking, Fred,
8 about just psychiatrist participation rates in Medicaid or
9 across the board?

10 COMMISSIONER CERISE: Across the board, because 11 we know it's an issue in commercial as well, right, but 12 particularly in Medicaid.

13 COMMISSIONER RETCHIN: Yeah. I just want to say, 14 though, you know, participation rates do go up from 15 Medicaid to commercial, so money makes a difference. And 16 it's not small. I mean, there's like a 25 percent spread. I don't want to diminish the lack of infrastructure, but 17 18 with this crisis, when you have 30 percent participation rates in Medicaid, that's a national embarrassment. That's 19 20 the field. And I don't understand why plans aren't looking 21 at this elasticity to see how much will it take to get some 22 parity.

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EXECUTIVE DIRECTOR SCHWARTZ: Sheldon, I just want to add here that I think there's been a lot of focus on low Medicaid payment for physician services for a long time, but I don't think anybody's calculated elasticity in demand for any of those services, and so there's obviously a lot of room for improvement, but I don't think there's anything empirical here that will --

8 COMMISSIONER RETCHIN: Yeah, I agree.

9 VICE CHAIR MILLIGAN: Okay. Peter, and then I 10 want to kind of bring us in to close this session.

11 COMMISSIONER SZILAGYI: Just because it's 12 related, this isn't about mental health services, but there 13 was a very nice study in the pediatric world regarding the 14 primary care bump and increased participation by primary 15 care physicians due to the primary care bump. So that's 16 not exactly a test of the elasticity, you know, like a 17 number of different levels of increase of payment, but it 18 certainly is a test of one level of increase of payment, 19 and it did shoe increased primary care participation with 20 Medicaid patients. COMMISSIONER RETCHIN: Exactly.

21 VICE CHAIR MILLIGAN: Okay. Thank you all. So I22 want to take two polls among us before we conclude this

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session. The first one -- and, Martha, the issue you 1 flagged I'm going to hold for the second poll question, so 2 for awareness. I did not hear anybody opposed or concerned 3 4 with these recommendations. I heard some support from a few folks, but no opposition or concerns. I just want to -5 - if you have a concern, could you raise your hand so I can 6 just see if there's anybody who's concerned about these 7 recommendations? Okay, seeing none. 8

9 The second poll question is, and, Anne, I invite 10 your participation in this, and Erin as well: Are there 11 any concerns around including HRSA as a carve-out entity 12 for inclusion in these recommendations because of the issues Martha raised around community health centers and 13 14 National Health Service Corps benefitting from getting some 15 guidance along with SAMHSA and CMS? Are there any concerns 16 about inclusion of HRSA in the recommendation? And if you have concerns, if you could raise your hand or signal it 17 18 now. Anne?

19 EXECUTIVE DIRECTOR SCHWARTZ: So I appreciate 20 what Martha is saying about the importance of community 21 health centers and the importance of National Health 22 Service Corps around workforce issues. Fred had also

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raised issues around public hospitals. We brought in
 issues regarding other payers. And all these are important
 for ultimate solution to this problem.

What I'm concerned about is that the 4 recommendation is meant to be focused and targeted on the 5 actors that are needed right now to help Medicaid programs 6 be more effective in this space. And I think it would be 7 8 more appropriate to talk about HRSA and others in the text, but keep the recommendation focused on its purpose right 9 10 here rather than making the recommendation a catch-all for 11 all of the actors that are involved in the system. So I'll 12 just turn it to Erin.

13 COMMISSIONER CERISE: And since you referenced my 14 comment, Anne, I would agree with that. I agree.

VICE CHAIR MILLIGAN: And so before, Erin, going to you on that, if instead we leave the recommendations as is, but we in the chapter call out HRSA's role in informing the delivery of mental health services, that's, I think, where, Anne, you're directing us. Martha, are you comfortable with that as an approach you could support in the recommendations?

22 COMMISSIONER CARTER: I can live with it.

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VICE CHAIR MILLIGAN: Okay. I'll take it,
 Martha. Thank you.

Erin, any other comments about any of this? Do you have what you need from us coming out of this session? MS. McMULLEN: Yeah, I definitely have what I need, and I will definitely take all the feedback you've given today to incorporate some changes into the draft chapter, including the rationale.

9 VICE CHAIR MILLIGAN: Great. Well, thank you for 10 your excellent work and your ongoing excellent work on this 11 subject matter for us.

12 So that concludes this session, and we can move 13 into the next session on children and adolescents. And I 14 think Melinda has joined us. Melinda, welcome. We look 15 forward to kind of the continuation of the work that you've 16 been doing on our behalf. It's all yours.

17 ### ACCESS TO BEHAVIORAL HEALTH SERVICES FOR CHILDREN
 18 AND ADOLESCENTS COVERED BY MEDICAID AND CHIP:
 19 REVIEW OF DRAFT CHAPTER AND RECOMMENDATIONS
 20 \* MS. ROACH: Great. Thanks, Chuck and good
 21 afternoon. In this session, we'll review the draft chapter
 22 on access to behavioral health services for children and

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adolescents with draft recommendations that we presented
 last month. The recommendations themselves have not
 changed, though we've updated the rationale and
 implications based on your feedback.

This slide lists the main components of the draft 5 chapter preceding the recommendations. The first section 6 brings together the analyses we previously presented to the 7 8 Commission on prevalence and treatment rates, as well as 9 the availability of behavioral health providers. Where 10 possible, we also examined access among Medicare 11 beneficiaries by race and ethnicity. The chapter then 12 discusses the availability of behavioral health providers serving children and adolescents before turning to the 13 needs of those with significant mental health conditions to 14 15 further frame the draft recommendations.

The next two slides review highlights from MACPAC's analysis in the 2018 National Survey on Drug Use and Health, which is discussed in more detail in the draft chapter. Most of this data was presented in December with the exception of more recent work we did to look at variations by race and ethnicity.

In 2018, nearly 20 percent of adolescents, age 12

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1 to 17, enrolled in Medicaid reported experiencing a major 2 depressive episode in their lifetime. About 12 percent had 3 suicidal thoughts, and nearly 4 percent had attempted 4 suicide in the past year.

5 These prevalence rates were similar when 6 comparing Medicaid beneficiaries to youth with private 7 coverage and those who were uninsured. However, there were 8 some differences across racial and ethnic groups enrolled 9 in Medicaid.

Among Medicaid beneficiaries, mental health conditions were more common among white youth when compared to their Black and Hispanic counterparts. Black and Hispanic youth enrolled in Medicaid were also less likely to report having attempted or thought about suicide compared to white beneficiaries.

In 2018, about 4 percent of adolescent Medicaid beneficiaries had experienced a substance use disorder in the past year. The prevalence of past-year SUD was similar when comparing Medicaid beneficiaries to those with private coverage and the uninsured, though the use of alcohol and certain drugs varied by coverage status. Among youth enrolled in Medicaid, non-white beneficiaries were

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1 generally less likely than their white counterparts to 2 report using drugs and alcohol.

This slide revisits data that was previously 3 4 presented on access to behavioral health treatment, which 5 is discussed in more detail in the draft chapter. The Commission may recall that in 2018, many youth with 6 behavioral health conditions needed but did not receive 7 8 treatment. This was true for Medicaid beneficiaries as well as youth with private insurance and those who were 9 10 uninsured. For example, only 54 percent of youth with MDE 11 and 56 percent of youth with MDE with severe role 12 impairment reported receiving any form of mental health treatment in the past year. While youth covered by 13 Medicaid received treatment at similar rates as their peers 14 15 with private coverage, they were more likely to have 16 received non-specialty services, for instance, from a 17 pediatrician or school counselor, and to have stayed overnight in a hospital or residential facility. Medicaid 18 19 beneficiaries were also more likely than youth with private coverage and those without insurance to have received 20 21 services from education sources.

22 This is one of the newer tables included in the

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draft chapter which has mental health treatment rates among 1 youth enrolled in Medicaid by race and ethnicity. As you 2 can see, among all youth in Medicaid, certain racial and 3 4 ethnic groups were less likely to have received any form of mental health treatment in the past year. Specifically, 5 lower rates of treatment were reported by beneficiaries who 6 are Black, Hispanic, and American Indian or Alaska Native 7 and Hawaiian Native or other Pacific Islander. 8

9 Among Medicaid beneficiaries with MDE, youth 10 received treatment at similar rates, regardless of their 11 race or ethnicity. However, there were variations when 12 looking at Medicaid beneficiaries with MDE with severe role 13 impairment. Among Black youth who experienced this 14 condition, only 48 percent received some form of treatment 15 compared to 68 percent of their white peers.

16 The next section in the chapter uses different 17 data sources to examine the availability of behavioral 18 health providers serving youth in office-based settings, 19 school-based health centers, and behavioral health 20 treatment facilities and finds that the supply of these 21 providers was limited across the country, with particularly 22 acute workforce challenges in rural communities.

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One opportunity to expand the behavioral health workforce is through child psychiatry access programs like the one pioneered in Massachusetts. These programs now exist in many states to help pediatric primary care providers manage the mental health needs of their patients through telephone, video, and in-person consultation with behavioral health specialists.

8 The next part of the chapter focuses on the needs of children and youth with significant mental health 9 10 conditions who are greatest risk for out-of-home placement 11 and poor outcomes. We discuss factors affecting access to 12 care, including the role of various state and federal 13 agencies, Medicaid and CHIP coverage requirements, and barriers to designing benefits for this people. Access to 14 15 home and community-based behavioral health services, 16 including intensive care coordination and peer supports, 17 can prevent these children and adolescents from being removed from their homes and communities. Such services 18 19 have been shown to improve clinical and functional 20 outcomes, school attendance, and other measures. It can 21 also reduce rates of attempted suicide and contacts with 22 law enforcement, yet they're often unavailable or difficult

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to access. In numerous class action lawsuits, courts have ruled that states are not meeting their obligations to ensure access to these services under Medicaid's early and periodic screening, diagnostic, and treatment benefit. And as previously noted, adolescents with Medicaid coverage are more likely to be treated in inpatient residential settings when compared to their privately insured peers.

8 This slide revisits information we presented last 9 month on the multiple federal, state, and local agencies 10 that play a role in serving this population and the need 11 for coordination across these entities.

12 At the Federal level, this includes CMS and 13 SAMHSA as well as ACF, which administers federal funding for child welfare. Of note, ACF is responsible for 14 overseeing implementation of the Family First Prevention 15 16 Services Act, which, among other things, expanded the use of federal child welfare funds to include certain 17 18 behavioral health services that prevent out-of-home foster 19 care placements.

At the state and local level, key partners beyond the Medicaid agency include behavioral health, child welfare, and criminal justice agencies.

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1 While many factors affect access to services, experts have highlighted state capacity as an immediate 2 3 Specifically, the Commission expressed concern concern. that states face challenges figuring out how to use 4 available Medicaid authorities to structure benefits for 5 children and adolescents with significant mental health 6 conditions. While there are a number of options states can 7 8 pursue such as 1915(c) waivers and 1915(I) state plan 9 authority, the process can be difficult to navigate, and 10 states have received minimal federal support for their 11 efforts in recent years.

12 It can also be challenging to engage the multiple 13 federal, state, and local agencies to play a role in 14 expanding services for this population. Stakeholders have 15 noted that while states generally have the federal 16 authority needed to improve access, they often lack the 17 awareness and capacity to use them and can benefit from 18 additional federal guidance and support.

19 The draft chapter notes that the analytic work 20 just discussed and the recommendations we'll cover shortly 21 are just a first step in addressing access to behavioral 22 health services for children and adolescents. We expect

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the Commission's future work to examine access for those in 1 foster care, including concerns about how implementation of 2 the Family First Prevention Services Act may affect access 3 to Medicaid-covered services in certain residential 4 5 treatment settings. MACPAC is also planning to examine the experience of children and adolescents through future work 6 on access to behavioral health services for justice-7 8 involved populations and individuals who identify as 9 lesbian, gay, bisexual, or transgender.

10 Moving on to the two draft recommendations, as 11 previously noted the recommendation language has not 12 changed since last month, though some of the rationale 13 language and implications have been updated to reflect 14 Commissioner feedback.

The first draft recommendation is focused on additional federal guidance. It reads: "The Secretary of Health and Human Services should direct CMS, SAMHSA, and ACF to issue joint subregulatory guidance that addresses the design and implementation of benefits for children and adolescents with significant mental health conditions covered by Medicaid and CHIP.

22 This slide outlines the rationale. New guidance

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is needed to facilitate state adoption of home and 1 community-based behavioral health services that permit 2 children and adolescents with significant mental health 3 4 conditions to avoid institutional placements. Previous quidance issued by CMS and SAMHSA in 2013 was useful, but 5 is now out of date. Among other things, new guidance 6 should describe additional evidence-based services and 7 8 state examples, strategies for addressing racial and ethnic 9 disparities, opportunities to reimburse for technology-10 enabled services, and authorities states can use to pay for 11 home and community-based behavioral health services in 12 Medicaid and CHIP. In developing such guidance, coordination between CMS, SAMHSA, and ACF is needed to 13 address the roles of state Medicaid behavioral health and 14 15 child welfare agencies.

16 Similar to the draft recommendations that Erin 17 discussed in the previous section, we don't anticipate that 18 issuing new guidance would have a direct effect on federal 19 spending. Among states, new guidance could spotlight the 20 need for home and community-based behavioral health 21 services and ultimately expand access to such services. We 22 anticipate that the draft recommendation could improve

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access to beneficiaries, could be particularly important
 for those of color given the lower observed rates of
 behavioral health treatment among certain racial and ethnic
 minorities. For plans and providers, there would be no
 direct effect.

The second draft recommendation addresses 6 7 technical assistance and planning support. It reads: The 8 Secretary of Health and Human Services should direct a 9 coordinated effort by CMS, SAMHSA, and ACF to provide 10 education and technical assistance to states on improving 11 access to home and community-based behavioral health 12 services for children and adolescents with significant mental health conditions covered by Medicaid and CHIP. 13 14 Additionally, the Secretary should examine options to use 15 existing federal funding to support state-level activities 16 to improve the availability of these services.

In addition to subregulatory guidance, technical assistance and planning opportunities are needed to enhance state capacity and jump-start efforts to expand and continue services. Such technical assistance coupled with planning support could help states establish cross-agency partnerships, engage stakeholders, design new Medicaid and

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1 CHIP benefits, and overcome other barriers such as limited 2 state resources and capacity. Existing funding, including 3 recent increases in the Mental Health Services Block Grant, 4 could be used to support planning efforts that bring 5 together state behavioral health authorities with Medicaid 6 agencies and other key stakeholders.

7 The implications here are largely the same as 8 those associated with the first draft recommendation, 9 though we anticipate more of an effect on state capacity to 10 implement new benefits. We look forward to your discussion 11 and feedback on the draft chapter and the recommendations. 12 Thanks.

13 VICE CHAIR MILLIGAN: Thank you very much,14 Melinda.

15 Commissioners, who would like to start? I see 16 Peter.

17 COMMISSIONER SZILAGYI: Thank you, Melinda. A 18 very nice presentation. I actually think this is a really 19 outstanding, very comprehensive chapter, and I think it 20 will be used widely, including the graphs and tables, you 21 know, like all MACPAC publications.

22 First let me say I definitely agree with both

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recommendations about guidance and technical assistance. I 1 do have to say that if you look at some of the data like 2 3 half of youth with a major depression episode received 4 care, 6 percent of youth with substance use disorder received care, adding guidance and technical assistance is 5 not going to -- it's an initial step, obviously, and it's 6 not going to solve the fundamental problems. But it is an 7 8 initial and a really important step. And we all know 9 that's the way health care gets better, is by steps, not 10 necessarily, you know, major transformations. But I did 11 want to make the point that given the extent of the 12 problems, it's only an initial step.

13 If you ask pediatricians what's the number one 14 problem they face, it's mental health problems among their 15 patients. If you ask parents what's the number one problem 16 that they face, it's behavioral and mental health concerns. 17 So we're really -- as Sheldon said, we're in a very, very 18 important area.

I do want to make the point that some of the chapter, I think, appropriately focuses on serious mental health problems in children, and we may want to consider another chapter that's more earlier in the continuum

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because what pediatricians are seeing is an entire continuum of mental health and behavioral problems in children, and this really addresses more the major depressive episodes, substance use, and more the serious ones.

Just a couple final points. As Sheldon 6 mentioned, workforce is a major problem. We as 7 8 pediatricians, we can refer children on Medicaid to good 9 mental health services, but they may have to wait four to 10 six months. We can refer them to behavioral health 11 services, but they may have to wait three months, and they 12 can't see a psychologist if they're on Medicaid; they can if they're not on Medicaid. I've had this experience just 13 14 in the last month. And so workforce and payment, you know, 15 infrastructure is really, really important.

My final point, I think there's new modalities that are really worth highlighting in the future, not for this chapter, tele-behavioral health, which we have covered a little bit. Integrated care -- I'm not talking about EHR integration. I'm talking about collocated integrated care where there's good models in the pediatric world. Mobile health units for children, specifically for children, for

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1 accompanying police, and trauma-focused care.

And, finally, I'm really happy that we're going to -- that future work is going to focus on foster care and families and justice-involved population. So thank you very much.

6 VICE CHAIR MILLIGAN: Thank you, Peter.
7 I see Kit and then Fred and then Sheldon and then
8 Tricia.

9 COMMISSIONER GORTON: Okay. Melinda, thanks for 10 great work and, as Peter said, important work. He said it 11 way more articulately than I do, so what he said.

I was going to suggest that the recommendations might include reference to state and federal and local education agencies, but I will take Anne's feedback about HRSA and apply it to the specific case. But I do think that the chapter is not intentional enough about talking about the role of schools in the lives of children and youth.

And I even think in our summary -- if you look at your slides where you have the -- well, you have a laundrylist slide that says here's everybody who's involved, right? The word "school" doesn't appear on that slide, and

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I think that's just a huge oversight. I'm not just talking about school-based clinics who do wonderful, important work, and I don't want to diminish that at all. But the schools themselves provide huge volumes of Medicaid-funded services, and some of them are associated with IEPs. So you have paraprofessionals in schoolrooms.

Some of you know I've started substitute teaching high school science, and half of my classes have paraeducators in them, helping kids with mental health and behavioral health issues online. It's an interesting experience, so -- and Medicaid is paying for an awful lot of that.

So it's important to understand how the schools do get integrated or don't get integrated, and I think that might be something, Melinda, to explore in the future is how successful have we been in integrated the health care silo with the education silo. And I would posit that we've been relatively unsuccessful in integrating it.

19 So I think we need to expand and be more 20 intentional about talking about education. The federal 21 educational authorities don't necessarily contribute all 22 that much, but the state and local departments of

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education, local school boards, they contribute a huge amount about whether the schools are open to providing services for kids or not. In some of the more rural communities, the lone school counselor is doing all of this single-handedly and trying to make the referrals that Peter was talking about.

7 So I think important to amplify a little bit and 8 focus a little bit, the text of this chapter on that, and 9 then I think in the future, I would like to see some more 10 attention -- we've talked about integration of Medicaid and Medicare. I think for children, as important, is 11 integration of education-based health-focused services and 12 health-based, health-focused services, all of which are 13 paid for by Medicaid. So, actually, we own the whole 14 15 thing.

16 Thank you.

17 VICE CHAIR MILLIGAN: Thank you, Kit.

Sheldon -- or excuse me. Fred and then Sheldon.
COMMISSIONER CERISE: Well, a little bit related
to Kit's point and to my earlier question as well, Table
3.7 in the chapter, it's striking that the percentage of
services among the uninsured compared to Medicaid there,

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even in a school setting where you wouldn't necessarily 1 expect to see that, you know, people that have seen a 2 school counselor or a social worker, and so I know it would 3 be helpful to understand that a little bit better if we're 4 going to rely on the schools, as I think it's appropriate, 5 that setting to reach kids. I'd hate to think that that's 6 being filtered by insurance status, whether that's Medicaid 7 or anything else, but, you know, if you look at the chart, 8 9 that's what it looks like.

10 VICE CHAIR MILLIGAN: Melinda, did you want to 11 respond to that?

MS. ROACH: I guess I'll just state the points on the role of schools are very well taken, and it's something that we can highlight a bit better in the chapter.

15 VICE CHAIR MILLIGAN: Okay, great. Thank you.16 Sheldon and then Tricia.

17 COMMISSIONER RETCHIN: Yeah. First of all, 18 Melinda, I think this is just an incredibly important 19 contribution, like Peter said. This extends beyond just 20 with MACPAC. I think it's comprehensive and will be used 21 by policymaker in lots of different areas. So I 22 congratulate you for this, and I'm really delighted that

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you and Erin have this continuum, child to adult, because
 I'm just wondering a little bit about the differences.
 Maybe you came across -- and I sort of direct some of this,
 also the question to Peter.

5 This is just my impression, that with adult SMI, 6 serious mental illness, that a large part of the 7 psychopharmaceutic interventions are delivered by primary 8 care physicians, not necessarily by an adult psychiatrist. 9 So the shortfall there maybe is not as, I guess,

10 catastrophic or influential.

11 But, on the other hand, on the pediatricians, 12 Peter, I'm venturing that with the same level, very serious 13 mental illness, that child psychiatry is used a bit more than with adults, and that said, maybe you agree with that 14 15 or not, but I'm really just sort of puzzled by, in this 16 case, the workforce. And you're right. I have a perception that child psychiatrists are still in great 17 18 demand, and they have a large unmet need. Supply is less 19 than the demand, but then there is this projection that's 20 sitting out there that not only is it meeting demand, but we will have an oversupply of child psychiatrists within a 21 22 decade. How is that possible?

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I mean, Peter, maybe Melinda, what's your reaction to that?

3 COMMISSIONER SZILAGYI: Melinda, do you want -- I 4 saw that sentence in the chapter, and I was shocked that 5 there might be an oversupply. And I don't know whether 6 that has to do with --

7 COMMISSIONER RETCHIN: It's out there.
8 COMMISSIONER SZILAGYI: You know, an oversupply
9 in total numbers but not an oversupply where it's really
10 needed among vulnerable communities, rural areas, and
11 others.

But I think you're right that in the pediatric world, there may be a little bit more dependence on mental health, at least to initiate treatment. Some of the models that Melinda put into the chapter, like the Massachusetts model, is kind of a co-management with perhaps an initial visit with a psychiatrist and then the pediatricians can take over.

Also, in the pediatric world, there is concern that mental health, so even children who present with depression, it may not be depression. It may be trauma, and then they would need a different kind of care, or it

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1 may not even be ADHD. It may be trauma because trauma is 2 so common among children or children who are traumatized, 3 and so there is often, I think, a need for initial mental 4 health care and then co-management.

5 So I really like the examples that Melinda put 6 into the chapter, but I don't really -- I didn't get under 7 the -- I don't know about the data about the psychiatrists 8 and whether it's a maldistribution.

9 COMMISSIONER RETCHIN: Melinda, do you know? 10 MS. ROACH: I think that's a really good point 11 that Peter raises about a maldistribution, but it's 12 certainly something that's not addressed by these HRSA 13 projections. And we can look more closely at the model and 14 sort of other projections out there to sort of understand 15 how they compare.

I think the other thing that the HRSA model doesn't take into account because it was done pre-COVID is the impact on demand that we are already seeing and expect to see into the future for these services. So I think that's another factor that could impact that calculation. COMMISSIONER RETCHIN: Can I just add, though, Melinda, when you're finishing this off, because you have

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the benefit of the adult-child continuum here, to maybe 1 contrast. Readers may not realize the sort of difference 2 3 in practice where child psychiatry may be playing a very 4 different role commonly, more commonly than with adult psychiatrists, so it exacerbates the workforce need. 5 6 MS. ROACH: We can incorporate that. Thanks. 7 VICE CHAIR MILLIGAN: Thank you, Sheldon. Tricia? 8 9 COMMISSIONER BROOKS: Yes. Thanks, Chuck. 10 Melinda, great chapter. Overall, I'm really 11 happy to see a focus on children's behavioral health. 12 But I think we've got to move it upstream. I think we have to talk about very early childhood. I'm glad 13 Peter mentioned trauma because a lot of mental health 14 15 issues along with other problems start with trauma, and in 16 fact, the Health Policy Institute of Ohio just did some interesting analysis of the cost of trauma for children. 17 18 And we know that if early on, kids have behavioral issues, 19 they enter school not ready to work. It's just -- you 20 know, it continues on into adulthood.

21 I would like to see something a little more
22 specific about there being a barrier to behavioral health

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for young kids where the pediatrician or other provider is 1 not -- doesn't want to peg the child with a diagnosis. 2 In 3 some states, that interferes with the child being able to 4 get treatment without a diagnosis, and I think that's another piece of the puzzle here that could be clarified in 5 guidance, that it may be early to name a diagnosis for a 2-6 year-old, but that doesn't mean that that 2-year-old can't 7 benefit from services. 8

9 MS. ROACH: That's definitely something that we 10 can work on incorporating. We're familiar with, for 11 example, the example out in California where family 12 services are being provided without a diagnosis. So that's 13 something we can highlight.

14 COMMISSIONER BROOKS: Thank you.

15 VICE CHAIR MILLIGAN: Thank you, Melinda.

16 Martha. And I don't see anybody else after

17 Martha. So if you want to jump on the line, please do so.

18 Martha?

19 COMMISSIONER CARTER: Yeah. Thanks.

20 One thing we've sort of talked around but haven't 21 clarified is the difference between school-based behavioral 22 health services and school-based health center services,

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and I don't know if there is a way for you to pull that out, but they do provide different types of services. So any clarification you can see that, I think, would be helpful.

5 VICE CHAIR MILLIGAN: Anybody else? 6 [No response.]

7 VICE CHAIR MILLIGAN: I actually did want to8 follow up on that point too, Melinda.

9 In terms of the school-based side, I've heard a 10 few different comments. Part of it, I think, is the 11 delivery of school-based health care through -- school-12 based health centers often FQHC related.

But there's separately this issue of IDEA and individualized education plans and sort of the special ed role, that I don't know the byplay between those programs in terms of delivering behavioral health to children through the school system, either through IDEA or kind of more kind of traditional school-based health center services.

20 So to the extent that can be integrated into 21 future steps along with some of the other bullets that you 22 have on the slide right before the slide on the screen

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1 right now where you were going to sort of signaling to
2 everybody where you're planning to go, it seems like -- and
3 thank you for pulling it back a little, if we can do that.
4 I think it was the -- yeah, wherever the next steps are.
5 Yeah, thank you.

I think including in this list the relationship
of schools and school-based health care and IDEA would
probably be an important contribution for children and
adolescents.

10 The other thing I wanted to flag, just based on 11 some of the comments, is about the supply of child 12 psychiatrists. My perception -- anecdotally, but my 13 perception is it tends to be often -- those psychiatrists 14 tend to often be primarily more academic medical center-15 based, more limited hours, more kind of medication 16 management, less available for crisis, less available after 17 hours, and so I think as we tease out the supply and 18 workforce issues, to whatever extent we can start filling 19 in the details around crisis and the scope of services that 20 are delivered, is it broader than medication management, I 21 think some of those elements really will illuminate where 22 there might be access challenges and where there might not

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1 in terms of services.

Toby, did you want to jump in on this? 2 COMMISSIONER DOUGLAS: Yeah, just one quick --3 and it's what Peter had said earlier. I do want to add on 4 the next steps around technology-enabled solutions as we 5 think about supply or just the limited supply, how is 6 Medicaid facilitating and paying for -- or allowing for 7 benefits of technology approaches. I think that's where a 8 9 lot of other payers are going, and we need to -- how 10 Medicaid can support our children through approaches that 11 might not be with providers.

VICE CHAIR MILLIGAN: And including tele-12 behavioral health, presumably, Toby. Is that right? 13 14 COMMISSIONER DOUGLAS: Absolutely. I think it's more -- it's clearer, but then I'm getting more even just 15 16 there are apps and there are other ways that might not be the provider that could support when they can't get an 17 18 actual visit, whether it's virtually or in person with a 19 provider.

20 VICE CHAIR MILLIGAN: Okay. Thank you.

21 Okay. I want to go to the poll question I asked 22 during Erin's session. I haven't heard any concerns raised

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by Commissioners regarding the recommendations for this 1 particular topic in this chapter. If you have any 2 concerns, if you could signal by raising your hand. 3 4 Okay. Seeing none, I just did want to close that out in terms of preparing for tomorrow and voting. 5 Melinda, do you have what you need from us from 6 7 the discussion and otherwise? 8 MS. ROACH: I do. Thanks for all the comments. We'll take them back and incorporate into the chapter and 9 10 recommendations. 11 VICE CHAIR MILLIGAN: Okay, great. Thank you. 12 So I think we're a little ahead of schedule, and 13 we can go to public comment at this point. And then we'll take a break after that. 14 15 Operator, are there any individuals who have 16 raised their hand? Again, we're going to follow the same ground rules that Melanie laid out in the morning session 17 in terms of three-minute time frames for public comment. 18 19 Do we have any individuals who have signaled an interest in 20 offering a comment for this? 21 ### PUBLIC COMMENT

22 \* MS. HUGHES: Yes. Nataki, you've been unmuted.

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1 So you may unmute yourself and make your comment.

2 MS. MacMURRAY: Good afternoon. Thank you so 3 much.

4 I really wasn't intrigued about the discussion of -- it really points to issues of capacity. I hear you 5 talking about it in terms of supply, but I think it's also 6 capacity to provide adequate services to young people, 7 8 especially, and if you could talk a little bit more about 9 how the recommendations of the Commission may help to shape 10 and inform the need to build a capacity, to be able to have 11 not just more routes of access, but more capacity.

12 You mentioned the Boston and Massachusetts and 13 the work that it's been doing, and I just was on a 14 conference call the other day listening to the fact that 15 Massachusetts incorporated expert into a lot of their 16 school-based services, and they're identifying more youth who have a need for treatment. But, unfortunately, less 17 18 than 50 percent of them are actually being able to get 19 services, and even when those 50 percent get services, it's 20 three to four months after a diagnosis. And so part of 21 that is access. Part of that is capacity, et cetera. 22 So I would love to hear the Commission talk a

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little bit more about it and include a little bit more 1 information in the chapters to really talk about how your 2 3 recommendations can push and promote and increasing the 4 capacity to be able to provide services. 5 Thank you. VICE CHAIR MILLIGAN: Thank you. 6 7 Nataki, I might have missed it. Did you identify 8 \_ \_ 9 MS. MacMURRAY: I did not. I'm sorry. I was 10 trying to beat the three-minute clock. 11 This is Nataki MacMurray from the Office of 12 National Drug Control Policy, your friends at ONDCP. Thank 13 you. 14 VICE CHAIR MILLIGAN: Thank you. So thank you for that comment, and, Melinda, I will defer to you about 15 16 how to incorporate that comment into the chapter as we prepare to finalize and release it in June. 17 18 Our next individual? 19 MS. HUGHES: We have Kirsten. Kirsten, you've 20 been unmuted. Please unmute your line. 21 MS. BERONIO: Hi. This is Kirsten Beronio with the National Association for Behavioral Healthcare. 22

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1 I just wanted to point out something that may be helpful in thinking about the challenges around workforce 2 and capacity and access to psychiatric services for 3 4 children, adolescents, and hopefully, you could highlight 5 in your report, programs like the Massachusetts Child Psychiatry Access Project and the HRSA program that kind of 6 builds that out and provides grants to support broader 7 8 availability of that kind of consultative psychiatric 9 service for pediatricians as a way to just supplement and 10 try to help fill the gap.

11 There are complications in Medicaid, I think, in 12 paying for some of those consultation services that happen outside of the presence of the beneficiary, but I know of 13 at least one state that has addressed some of those 14 15 challenges, Rhode Island in a recent 1115 demonstration 16 where they were about to get approval to pay the 17 psychiatric providers directly for those consultation services that can help address some of the challenges 18 19 there.

20 So I just wanted to point that out in case it's 21 of interest as a strategy for addressing some of the issues 22 you've been talking about.

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VICE CHAIR MILLIGAN: Thank you for that comment.
Operator, I don't see anybody else. Do we have
anybody else lined up?

4 MS. HUGHES: No other hands.

5 VICE CHAIR MILLIGAN: Okay. Thank you.

6 So, Melanie, I was going to hand it off to you to 7 kind of wrap us up and take us to break.

8 CHAIR BELLA: Well, Chuck, that's like the 9 easiest thing I've done all day.

10 If there are no other comments and we are set on 11 these two sets of recommendations, we are ready to take a 12 break. So we are scheduled to come back at 3:15, and we 13 will talk a little bit more about behavioral health, this 14 time looking at electronic health records, and then 15 following that session, we'll talk about the NEMT reports. 16 And then we'll conclude for the day.

17 Thank you all, and if you could all be back at18 3:15, we will get started again. Thank you.

19 \* [Recess.]

20 CHAIR BELLA: Okay. Thank you, everyone, for 21 being back on time. I hope you got a little bit of a 22 break. It is still the Chuck show so I'm going to hand it

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1 over to check guide us out on this body of work.

VICE CHAIR MILLIGAN: Thanks, Melanie, and I
think it's also the final installment of the Aaron and Erin
show for this particular reporting cycle. So welcome both.
We look forward to this topic, and I will turn it over to
you, whichever one of you will be leading us from the
beginning.

8 ### ELECTRONIC HEALTH RECORDS AS A TOOL FOR

# 9 INTEGRATION OF BEHAVIORAL HEALTH SERVICES: REVIEW 10 OF DRAFT CHAPTER

11 MS. McMULLEN: Thanks, Chuck. So since the 12 publication of the Commission's 2016 chapter on behavioral health integration, MACPAC has repeatedly commented on the 13 need to improve the integration of clinical care for 14 15 patients with both behavioral and physical health 16 conditions. We discussed behavioral health integration within the context of the opioid epidemic and as it relates 17 18 to privacy and confidentiality standards for substance use 19 disorder, commonly known as 42 CFR Part 2. We've also 20 examined how fragmentation between physical and behavioral 21 health systems affect pregnant women with behavioral health 22 needs.

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1 At the December meeting, we continued the Commission's discussion on behavioral health integration, 2 but we focused more narrowly on how increased use of 3 4 certified electronic health record technology, or CEHRT, can improve integration. We presented the results of an 5 internal analysis that showed behavioral health providers 6 use EHR at lower rates compared to physical health 7 8 providers. We also provided background information on how 9 states leveraged the Health Information Technology for 10 Economic and Clinical Health Act, or HITECH Act, to make 11 EHR incentive payments to physical health providers. 12 Next slide please. Aaron and I totally planned that out. 13 14 So today's presentation will include some 15 background information before summarizing the components of 16 the draft chapter. We'll discuss components of clinical integration and rates at which beneficiaries with mental 17 18 health conditions experience co-occurring disorders. We'll 19 also offer some observations on beneficiary use of the 20 specialty behavioral health system. 21 Then I'll hand it over to Aaron to discuss health

22 information technology and how it can promote clinical

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integration. The material he will present is new and is 1 meant to address questions raised by Commissioners at our 2 December meeting. He will also summarize findings 3 4 presented at December's meeting and outline barriers to EHR adoption among behavioral health providers. We'll conclude 5 by discussing mechanisms to promote EHR adoption among 6 behavioral health providers. These mechanisms will be 7 8 examined further in the 2021-2022 meeting cycle.

9

Next slide.

10 This chapter is really meant to set the stage for 11 a discussion of policy options to address low rates of EHR 12 adoption among behavioral health providers. It was structured this way based on the Commission's extensive 13 14 commentary on fragmentation between physical and behavioral 15 health delivery system. Through this work, the Commission 16 has recognized that Medicaid should play a role in 17 promoting integration, and CEHRT adoption could help achieve greater integration, but many behavioral health 18 providers were left out of large-scale efforts to digitize 19 health care records under HITECH. 20

21 Next slide.

22 The chapter opens by describing a framework for

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1 clinical integration that was first used by the Commission 2 in its June 2016 Report to Congress. As you can see on 3 this slide, clinical integration is a term that's used to 4 describe a wide range of activities, designed to provide 5 care to the whole person rather than focusing on specific 6 body systems, diagnoses, or conditions.

7 The chapter defines each of the components listed 8 on this slide. I'd like to draw your attention to just a 9 few of them, as EHRs can be used to address several of the 10 components listed here.

Obviously, EHRs can facilitate data-sharing. Sharing patient information can help care managers and providers from different disciplines communicate and coordinate care. EHRs can give authorized individuals immediate access to patient data and support knowledge transfer and informed decision-making among providers.

Data-sharing allows providers and systems to exchange information on demographics, type of insurance coverage, hospital admissions, medications, as well as other clinical documentation. This data-sharing could help support other components of clinical integration, including care coordination and screening and referral to treatment.

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1 Next slide.

The chapter then examines the prevalence of co-2 occurring conditions among adults with mental illness. 3 4 Here we show some high-level findings that were presented at the September Commission meeting. This chart details 5 lifetime rates of co-occurring conditions among adults with 6 past year mental illness. The draft chapter includes 7 prevalence estimates for specific illnesses as well as 8 9 rates of co-occurring substance use disorder.

10 As you can see, in 2018, non-institutionalized 11 adults with any mental illness who were enrolled in 12 Medicaid reported having a higher rate of co-occurring conditions over the course of their lifetime when compared 13 to their peers with private coverage. Beneficiaries also 14 15 had higher rates of co-occurring conditions when compared 16 to adults who were uninsured. Across all coverage categories, rates of comorbid conditions were higher for 17 18 adults with serious mental illness when compared to adults with mild to moderate conditions. Generally, beneficiaries 19 20 with serious mental illness reported higher rates of co-21 occurring conditions than Medicaid beneficiaries with mild 22 to moderate illness.

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1 Next slide. So this morning I presented some findings related 2 to the rates at which beneficiaries with mental health 3 conditions receive treatment. Specifically, we found that 4 Medicaid beneficiaries often receive treatment in different 5 settings than those with private coverage. Beneficiaries 6 are more likely to receive treatment in specialty mental 7 health care facilities which tend to specialize in the 8 9 treatment of serious mental illness. Despite high rates of 10 co-occurring conditions among beneficiaries with mental 11 illness, these settings often fail to provide integrated 12 care. In this chapter, we reinforce various points on 13

14 beneficiary use of the specialty behavioral health system. 15 We draw upon prior reports to Congress, where the 16 Commission has commented on the fragmentation between behavioral and physical health providers and their systems. 17 18 Historically, these systems have been financed separately. 19 This means that Medicaid enrollees with co-occurring 20 conditions often find themselves interacting with multiple 21 public and private agencies, and receive physical and behavioral health care from different sources. 22

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1	When providers are unable to share information
2	about their patients, this knowledge might lead to
3	conflicting treatment, such as prescribing medications with
4	potentially dangerous or even deadly interactions. Given
5	the high rates of co-occurring disorders among
6	beneficiaries with mental illness, limited data-sharing
7	represents a barrier to clinical integration.
8	With that I'll hand it over to Aaron.
9	VICE CHAIR MILLIGAN: Aaron, we can't hear you,
10	if you're having issues on your end.
11	MR. PERVIN: Can you hear me now?
12	VICE CHAIR MILLIGAN: Yes.
13	* MR. PERVIN: Okay, great. Thanks.
14	Thanks, Erin. A few months ago you heard from
15	Medicaid officials in D.C. and Missouri discuss how
16	integral health IT was to their care coordination efforts.
17	MACPAC has also talked to states, federal health IT
18	officials, and behavioral health provider associations,
19	where we heard from stakeholders that EHR adoption, and
20	specifically certified EHR adoption, is a necessary step to
21	improving clinical integration of behavioral and physical
22	health services. While EHR adoption does not guarantee

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1 effective integration, it is a necessary step for improved 2 clinical information-sharing.

The way that certified EHRs can strengthen 3 integration is multifaceted. Certified EHRs guarantee that 4 behavioral health providers can access state information 5 exchanges. These information exchanges allow for 6 behavioral health providers to have access to critical, 7 real-time patient information, such as when they have been 8 9 admitted into the emergency room for mental health reasons. 10 Health information exchanges have been shown to 11 improve health outcomes such as lowering the probability of 12 a hospital readmission, lowering the risk of medication discrepancies, and reducing redundant imaging and lab 13 testing. Certified EHRs also guarantee that behavioral 14 15 health providers can participate in value-based payment 16 arrangements. In certain value-based contracts, behavioral 17 health providers can be on the hook for quality measures 18 such as following up with a patient after an ED visit for 19 mental illness, alcohol, and other dependence within seven 20 days.

21 Furthermore, certified EHRs can be built to
22 automatically calculate and submit these scores to state

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agencies, whereas manually calculating these scores can often be cost-prohibitive to participation in these valuebased contracts.

4 Furthermore, certified EHR adoption among behavioral health providers can also help states improve 5 their quality reporting. For example, our MACPAC 2020 6 Report to Congress highlighted the challenges that states 7 8 face in pulling data from providers for the child and adult 9 core set measures. Oftentimes, these data are stored by 10 the providers in unstructured formats, making data 11 extraction highly difficult. Certified EHRs guarantee that 12 data structure and data transmissions adhere to federal standards. However, specialty behavioral health providers 13 are missing out on much of this value because adoption 14 15 remains low.

We presented this slide last time in our December presentation, but wanted to highlight it again because it shows the low rates of data-sharing among non-federally owned specialty behavioral health facilities, specifically mental health centers and substance use treatment centers. Among the non-federally owned facilities, only 8.6 percent of mental health centers and 2.7 percent of substance use

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1 treatment centers electronically share patient records with 2 other providers.

This chart also shows the value of federal involvement in health IT adoption. Facilities owned by the Department of Defense have benefitted from federal investments in health IT, and these facilities share data at much higher rates compared to their non-federal counterpart.

9 In addition to stakeholder interviews, we also 10 spent the last six months reviewing public comment letters 11 on various roles that address behavioral health adoption of 12 EHRs, the most recent one of which was released in January. 13 We found that there are many barriers to certified EHR 14 adoption for the behavioral health community.

15 However, the principal barrier is cost. 16 Investing in EHRs is expensive. For context, for those eligible under Medicaid's meaningful use program, 17 18 individual providers are paid as much as \$64,000 over five 19 years, and acute care hospitals could be paid up to \$12 20 million over four years for an EHR. Behavioral health 21 providers often have low margins. As such, they lack the 22 capital to invest in the expensive hardware, software, and

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1 staff training that comes with adopting an EHR.

Furthermore, federal standards on certification were designed to comply with the Health Insurance Portability and Accountability Act, or HIPAA. They were not designed to comply with state privacy laws, nor were they designed to comply with 42 CFR Part 2, which governs the disclosure of substance use treatment.

8 As discussed in many previous presentations, 9 state privacy laws and Part 2 regulations require EHRs to 10 have data privacy requirements that go above federal 11 certification standards.

12 Finally, there's a large amount of choice of EHRs on the market. However, a small amount of these EHRs are 13 suitable to the needs of behavioral health providers. As 14 such, providers need extensive guidance from health IT 15 16 experts on what kind of EHRs to purchase. Purchasing an EHR that both meets certification requirements and meets 17 18 the needs of the practice can be challenging. Federal and 19 state efforts to promote EHR adoption usually have some 20 funding set aside to advise providers on what kind of EHRs 21 are suitable for their practice.

22 Next steps for this project include evaluating

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different mechanisms that can be used to promoted certified 1 EHR adoption among specialty behavioral health providers. 2 These include incentive payments for certified EHR 3 4 adoption, similar to what occurred under the meaningful use program. We also plan on reviewing Section 1115 behavioral 5 health demonstrations, including those expanding the 6 continuum of care for substance use disorder. These 7 8 demonstrations require states to develop a behavioral 9 health IT plan.

10 We will also review 75 and 90 percent federal 11 match that is used by state agencies to upgrade their 12 health IT infrastructure. We want to determine whether 13 this match can be used to promote behavioral health data-14 sharing.

Finally, the Substance Use Disorder Prevention that Promotes Opioid Recover and Treatment for Patients and Community Act, or SUPPORT Act, authorizes the Center for Medicare and Medicaid Innovation to test behavioral health incentive payments for EHRs in Medicaid. We will investigate CMMI's plan to incorporate this into their models.

22

Thank you, and we look forward to your comments

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1 and questions.

VICE CHAIR MILLIGAN: Thank you very much, both
of you. So any Commissioner who wants to go first. Tricia
and then Brian.

5 COMMISSIONER BROOKS: Sorry. I lost my unmute6 button.

7 Thank you for this work. I really appreciate the 8 fact that electronic health records not only need to be 9 integrated between behavioral health but also to make sure 10 that there are those loop-back mechanisms so that there is the exchange of information both ways. And I think that 11 12 this also sets up potentially functionality that would remove barriers that we find now in early intervention 13 services, or developmental referrals for young children. 14 15 And I wouldn't want to lose sight of the fact that as 16 changes might be recommended to electronic health records for that coordination, that it be considered more broadly 17 than just for behavioral health. 18

19 The other comment I wanted to raise is not 20 necessarily specific to behavioral health but in terms of 21 pediatric-specific electronic health records. I think 22 there are a number of shortcomings in some of the health

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records that have not had specific pediatric functionality built into them, and I think those are barriers for providers and others to report on quality metrics. And I would hope that in the future we could spend a little time looking further into that as well.

6 But thank you for this work on the chapter. I 7 was happy to see it.

8 VICE CHAIR MILLIGAN: Thank you, Tricia. I have9 Brian and then Sheldon.

10 COMMISSIONER BURWELL: So my questions are kind 11 of more around the landscape of this issue. For one, I'd 12 like to kind of have a better context for what kinds of 13 behavioral health providers are adopting electronic health records, or have a high probability. A lot of behavioral 14 15 health providers are solo practitioners. I can't imagine 16 those, or small group practices, I can't imagine them adopting electronic health records. So I assume we're 17 18 talking about larger organizations of some kind or another 19 that are behavioral health providers that may have 20 electronic health records and interact with physical health 21 providers around their patient populations. So some 22 context around the market would be of interest to me.

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1 And also, I don't know how much we plan to get into the actual kind of IT nitty-gritty about this, around 2 interoperability and do all certified EHRs have the ability 3 4 to push and pull data with outside systems, and to what extent is it a two-way process. Because I can see 5 behavioral health providers pulling data off of physical 6 health providers around medical issues, but I could see 7 8 them not being, because of all the privacy issues, not 9 pushing data out very much, and how those roles of 10 interoperability are operationalized in agreements between 11 different types of providers.

12 That's kind of a complicated question, but I think it's important to our understanding of this issue. 13 VICE CHAIR MILLIGAN: Thanks, Brian. Erin or 14 15 Aaron, did you have anything you wanted to respond to? 16 MR. PERVIN: Sure, I can answer a couple of those, and then I can kick it back to Erin if she has any 17 18 additions. So we did look at -- the surveys that we used 19 did also have a piece where you could look at whether or 20 not providers that are affiliated with larger hospital 21 systems adopted EHRs at greater rates, and so that kind of 22 gets to your question about some of the landscape. And

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while we did notice that adoption rates are higher if a
center was affiliated with a larger organization, the rates
of adoption still weren't comparable to providers that were
eligible for HITECH incentive payments. But we can
definitely do more work on kind of the landscape and market
of who is adopting what kind of EHRs, and we can definitely
look into that as we continue this work.

8 On your second question on interoperability and 9 certified EHR technology, so EHRs are quite varied. 10 There's high-quality ones; there's low-quality ones. For 11 the purposes of this presentation, we're focusing very 12 specifically on certified EHRs because they guarantee some of that interoperability. Functions are built into the 13 14 system. Certified EHRs are supposed to adhere to the 15 interoperability rule that came out recently, and so that's 16 one of the reasons that we're trying to focus on CEHRT 17 because CEHRT offers kind of the bar of where quality -- of 18 EHRs that are equipped to be interoperable with the rest of 19 the system.

20 VICE CHAIR MILLIGAN: Erin McMullen, did you have
21 anything you wanted to add? Okay. Thank you.

22 So I did see Kisha and Martha also raise their

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1 hands, but, Sheldon, you're up next.

COMMISSIONER RETCHIN: Thanks, Chuck. Thanks for 2 the piece on electronic health records and how they may be 3 4 leveraged to improve the integration of physical and mental health with providers who use them. I'm going to just sort 5 of build a little bit on Brian's comment with a little more 6 specificity, and that is, you know, it's not just the large 7 8 health systems out there that have adopted electronic 9 health records after the Meaningful Use money from the 10 stimulus after the Great Recession, but really just looking at the vendors out there, there are two, maybe three -- but 11 12 really two very large vendors, Epic and Cerner. And as far as I know, they both have extensive behavioral health 13 14 modules that are included.

15 I guess my question is, there is -- and we've now 16 been at this in Meaningful Use for going on 12 years. Is there -- there must be a fair amount of studies, health 17 18 services research studies that show whether they actually 19 work. And, you know, I don't -- I have to say I've been an 20 advocate of electronic health records my whole career, but I do think we overhype them a bit in terms of actually 21 22 whether it makes a difference with patient care. But do

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you know or do you have any literature review on those two vendors and whether it has actually made a difference in the care of patients who have behavioral health illnesses on physical services and physical illnesses on behavioral health services?

MR. PERVIN: I can take a stab at that. So what 6 we've heard -- in terms of your first question about 7 8 vendors, so there's a lot of EHRs on the market, but what 9 we've heard from states and also providers is that EHRs 10 that are focused on behavioral health tend not to have a 11 lot of those functionalities built in and also adhere with 12 some of those other interoperability requirements that 13 Brian brought up. That also kind of goes to another point 14 that we brought up, which is that behavioral health 15 providers do need a lot of guidance because of the amount 16 of EHRs that are on the market with the relatively small amount of behavioral health modules that kind of meet their 17 18 practice needs. But, again, this is something that we can 19 continue to look at in the fall, but that's our 20 understanding of kind of what the market looks like.

21 Erin, I don't know if you want to speak to some
22 of the integration evidence.

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1 MS. McMULLEN: Sure. I did want to mention that I think one of the challenges when we're talking about EHR 2 adoption with behavioral health providers when comparing 3 4 them to hospitals or other providers really does -- Part 2 5 does play a really big role. You know, Aaron in his comments earlier mentioned that EHRs were built to comply 6 with HIPAA. There is no requirement that they comply with 7 Part 2. Even if like a Cerner or other behavioral health 8 module doesn't necessarily mean that Part 2-protected 9 10 information is being put into the electronic health record. 11 So we've spent some time over the past six months, and with 12 other work we've done on integration, talking to different 13 providers, hospital systems, kind of separate substance use treatment programs, and a lot of the times they have to 14 15 keep that information out of the electronic health record 16 because it can't be -- there's not appropriate protection systemwide to make sure that people's information isn't 17 18 disclosed.

So I think part of the struggle when looking at the behavioral health market for EHR vendors -- and it goes back to what Aaron was talking about earlier -- is that the costs are pretty prohibitive. The fact that most

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behavioral health providers cannot afford to buy an EHR 1 means that there's not a ton of demand to come up with a 2 3 solution to share data. We can, you know, certainly look 4 back at our Part 2 chapter and think about how we can integrate some information around some of the benefits of 5 being able to share this information clinically and how 6 that affects patient care. So Aaron and I can look at 7 8 doing that as we move forward.

9 COMMISSIONER RETCHIN: Thanks.

VICE CHAIR MILLIGAN: Thank you. Kisha, Martha,
 and then I saw Brian coming back into line. Kisha?
 COMMISSIONER DAVIS: Sure. Thanks, Erin and
 Aaron, another really good chapter. Two comments.

14 One, I've had the benefit throughout my career, all of my primary care practice settings have had the 15 16 benefit of having integrated behavioral health and the benefit of being able to, you know, have access and have 17 that cross-communication with the behavioral health 18 19 provider is really just essential in trying to provide 20 whole-person health. And so as much as we can facilitate 21 that and encourage that, that's really helpful.

22 The behavioral health providers have the benefit

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of working in a medicalized setting and so have access to 1 that EHR and access to the medical information. But I will 2 3 say that it was always harder on their end because those 4 EHRs were built to help with more physical medicine, and so trying to adapt what they need and to be able to put that 5 into an EHR format was always difficult when their notes 6 were always clunky and choppy because it just wasn't built 7 8 for them.

9 The other comment -- and this goes, Erin, to what 10 you were just saying -- you know, when we have these next 11 steps, the clash that we continue to have between HIPAA and 12 Part 2, until there's better alignment there or we get to a better solution or, you know, really figure out how to be 13 able to share and have that interoperability, then it's 14 15 really hard to get to the next steps, you know, in 16 promoting further adoption and further integration. I think there's definitely a benefit there. I've seen that. 17 18 It's beneficial to my patients. But, you know, we keep 19 coming up against this Part 2 barrier and getting to a 20 better solution on that.

21 So, you know, I would include that in the next 22 steps. It's going to be something that we're going to need

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1 to continue to revisit.

VICE CHAIR MILLIGAN: Thank you, Kisha. Martha? 2 COMMISSIONER CARTER: I think I'm on the same 3 4 train about Part 2. I was always confused -- and I suspect many other people are -- about the rules regarding data 5 sharing there a health information exchange when you're 6 looking at HIPAA and Part 2 data. And I think we -- you 7 all referenced HIEs but not specifically any challenges 8 9 related to whether it's allowed. I mean, I think there was 10 just a lot of confusion there.

11 And another point about EHRs and behavioral 12 health is that there's a special protection for what's 13 called "psychotherapy notes," and if the behavioral health 14 provider uses psychotherapy notes, those are the notes --15 I'm not a behavioral health person, but what they told me 16 was those are the notes they make to themselves, interpretation of what has happened in their session. So 17 18 they're very private notes, and they have to be -- they 19 have an extra level of protection. They can't be shared. 20 And so an EHR has to be built to sequester those, 21 absolutely not share those. And so there's a lot of 22 mistrust and concern because the behavioral health people

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1 are on this, and they know they can't share this stuff
2 without patient permission. And I think their own
3 psychotherapy notes -- I don't want to speak for them, but
4 I don't think they share them anyhow.

5 So I think it's -- I can't understate the concern 6 about Part 2 and HIPAA and the whole role of integrating 7 behavioral health and clinical and dental, all the whole-8 person care kind of notes that we want to do.

9 MR. PERVIN: Can I just add one thing?
10 VICE CHAIR MILLIGAN: Yes.

11 MR. PERVIN: Yeah, so both very good points 12 around Part 2, and I think I just want to -- I think Kisha 13 brought up a very important point, which is that the EHRs 14 were built for physical health providers. They weren't 15 built for behavioral health providers. And until there's a 16 demand from behavioral health providers, until they have, you know, finances that they're able to use to purchase 17 18 these EHRs, that demand might not really be there. And so 19 I think our belief is that, you know, the EHRs could be 20 built to serve the behavioral health provider's needs, but 21 so far right now they are only being built to -- or they're 22 primarily being built to serve the physical health provider

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space, which is why you get -- which is why you get these challenges around data segmentation and EHRs not built to kind of keep that information private.

4 VICE CHAIR MILLIGAN: Thank you, Aaron. Brian?5 You're on mute, Brian.

6 COMMISSIONER BURWELL: Okay. Sorry. I have to 7 believe the trend is for greater adoption of EHRs among 8 behavioral health providers, both just for their own 9 business purposes and also managed care will require more 10 reporting, et cetera.

11 So if I'm a psychiatrist, I have a group practice 12 in an urban area where I see a lot of Medicaid patients, et 13 cetera, will Epic sell me a module, a behavioral health 14 module? I can't afford the full hospital -- you know, they have 70 percent of the hospital market. So I want to 15 16 integrate with hospitals and share information. Is there such a thing as a mini-module? I would think that Epic 17 18 would find that profitable.

MR. PERVIN: Sure, this is something we could look more -- sorry, we could look more into over the summer and the fall. Again, our understanding is that Epic can -so we haven't done a lot of research on what specific

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products are offered by specific vendors, but we can look into that more in the summer and the fall, and then in addition to that, we can determine -- we can investigate whether or not the modules that are being offered by Epic, by Cerner, are really meeting the needs of the behavioral health community.

7 COMMISSIONER BURWELL: Okay. Thanks.

VICE CHAIR MILLIGAN: Fred?

COMMISSIONER CERISE: There's an issue of scale, 9 10 too. You know, one fairly large behavioral health provider 11 we've spoken to about this, they're too small for Epic to 12 do a deal with. So they end up not being in that game 13 because, you know, they're not a big system, and so to do these small deals I think is a challenge right now for the 14 -- certainly for Epic. And small practices, they don't 15 16 have that same access. Even medium size or, you know, behavioral health, moderately sized behavioral health 17 18 practices that are not associated with a larger system are 19 going to have difficulty there.

20 VICE CHAIR MILLIGAN: Thanks. Was there anybody21 I missed who wanted to contribute? Kit.

22 COMMISSIONER GORTON: So just to follow upon

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Fred's last point, I wonder -- again, is this future work, 1 but I wonder if it would be worthwhile to invite the 2 3 vendors, some of them, to come and talk about what they see 4 as the challenges. You know, are they even thinking about this? Have they tried to solve it in ways that we don't 5 know that they've tried to solve it? Have they run into 6 brick walls somewhere? Are there insurmountable government 7 8 hurdles? You know, it might be that you guys would talk to them on the phone, and you would hear -- you know, you 9 10 would hear that they don't have anything to say that's 11 worth taking the Commission's time -- in which case, okay, 12 cool. But it might be that they have some insights into 13 what the barriers are that we're not recognizing because 14 we're Nation technology people, and so I just wonder, just posing a question, whether it might be useful at some point 15 16 to talk to them and maybe have them talk to us.

17 VICE CHAIR MILLIGAN: Thanks, Kit. And it 18 looked, Darin, like you wanted to jump in on -- oh, Erin 19 McMullen, did you have something you wanted to mention? 20 Oh. Darin?

21 COMMISSIONER GORDON: Yeah, just along all these 22 lines that we're talking about, you know, what we heard

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when we had moved to integrate the services, we had heard 1 from behavioral health providers, you know, it seems like 2 lot of discussions about some of the more dominant physical 3 4 health EHRs and then morphing to the behavioral health organizations, I mean, because there are some EHRs out 5 there that are particularly geared toward the behavioral 6 health community. And I heard from those providers; they 7 8 said they had a great EHR for the behavioral health side, 9 and they talked to their -- you know, the company that 10 provided that, and they wanted to build out some of the 11 functionality for the physical health side, but that wasn't 12 their core competency. And I heard the same argument on the physical health side building on the behavioral. So it 13 was like -- it's not that some of the -- you know, that 14 15 there aren't some really good tools that are focused on the 16 behavioral health side that are already out there, maybe not -- obviously not broadly, but I just think, you know, 17 18 if we go down the road Kit's talking about, which I don't 19 think it's a bad road to go down, if we just invite the 20 dominant player on the physical health side to have that 21 conversation, I think we're going to be missing some of the 22 issues that you have expertise in silos on both sides.

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1 The only other thing I want to raise, when we talk about integration -- and I think this is great work, 2 3 Aaron and Erin, and I think you all should work on more 4 projects together because it's just cool having Aaron and Erin on a project together. It's really around also like 5 edits that may be in place or other processes in place that 6 inhibit from the payers, whether it's the state or the 7 8 health plans, that inhibit some of this integration as well. We saw that, and, quite frankly, it wasn't 9 10 intentional. But when you start integrating these 11 services, how you submit claims and, you know, like having 12 two visits in a single day, one on the physical health side 13 and one on the behavioral health side, systems started rejecting them because it looked like it was duplicate 14 15 services on the same day. I do think there's that whole 16 other component on the integration side that has to be 17 worked through. It's not impossible to work through, but, 18 you know, we didn't hit it head on when we went down that 19 path, but we engaged providers and health plans to have 20 some kind of feedback as we went down that road to try to 21 help our regulations and our edits fall in line with our 22 objective of integration at the clinical level.

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VICE CHAIR MILLIGAN: Thanks, Darin. Kit, and then I'm going to -- Kit and then 2 3 Martha, your second bites, and then I'm going to have a 4 couple questions, and then I think we need to wrap up this session. Kit? 5

COMMISSIONER GORTON: So I just want to follow up 6 7 on what Darin was saying, which I agree with a lot. I also 8 want to point out that many states at the payer level 9 haven't integrated it, right? So Pennsylvania has a 10 behavioral health carve-out. There are different 11 behavioral health plans, right? So it's probably worth 12 looking at the state Medicaid agency, whether or not at the 13 payer level behavioral health and physical health is 14 integrated.

15 VICE CHAIR MILLIGAN: Thanks, Kit. Martha? 16 COMMISSIONER CARTER: You would probably do this, but back to our previous comment, if we're going to -- I 17 18 think it's a great idea to talk to vendors. It's not just 19 Epic and Cerner, though. We would need to look at EHR 20 systems that are used in primary care, in primary behavioral and primary medical care, but the health centers 21 22 at the CCHPBCs, folks that are already trying to do this

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and what systems are they using, probably talk to some providers in those places to, to see what they're challenging.

VICE CHAIR MILLIGAN: Thank you, Martha.

I had a couple of things. One is I did want to 5 go back to the financing piece. I do think it's going to 6 be good to track the innovation center pilots and continue 7 8 to track where the federal budget discussion goes and some 9 of the rescue plan discussion. I do think there seems to 10 be a groundswell around trying to give behavioral health providers meaningful use-type incentives, and I would just 11 12 flag that I expect you guys to track that. But I think 13 it's important to keep tracking that as an element of this. 14 And then the second thing I wanted to mention --15 and I wanted to get on the Part 2 train as well -- the 16 CARES Act did make some changes. We're waiting on regulations to come out of those changes. It will move it 17

18 more in the direction of HIPAA, although not all the way to 19 HIPAA for physical health.

I think it's going to be important to monitor how the regulatory change that is coming out of the CARES Act influence technology and functionality design. So, in

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terms of next steps, I would want to make sure that we're tracking how the regulatory framework coming out of the CARES Act gets pulled through the technology roadmaps and functionality work for some of these vendors and some of the providers.

The other thing, I wanted Aaron Pervin - I wanted to just flag. You made a couple of comments in this session that I thought gave me some insights I didn't have coming in.

10 One is it seems like the vendors and some of the 11 technology have permission to do more than what they do in 12 terms of how they create decision rules, authority, access standards, to comply with a lot of the privacy standards. 13 So it seems like we often talk about the legal and 14 regulatory framework as the barrier, but it seems like the 15 16 technology companies could go further than they go if they built in various permission rules, access standards about 17 18 who could see what. And I think it's going to be helpful 19 to track their roadmaps around the permissiveness element 20 compared to the prohibited access issues.

21 And you mentioned data segmentation. I would put 22 it in the same place, because my sense is more is possible

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while still being compliant than is happening, and it may 1 go back to where Fred was talking about scale. It may be 2 that for some of these companies, as they build out their 3 4 technology roadmaps and their release schedules and all of that, this isn't as high a priority in terms of a customer 5 base or revenue or a business plan. There are rules that 6 could be established that would be compliant that would 7 8 allow for better data sharing is my sense.

9 Did anything I just say strike you as incorrect? 10 MR. PERVIN: No. Everything you said struck me 11 as correct, and I think you put it more articulately than I 12 did, so thank you.

13 VICE CHAIR MILLIGAN: I would disagree, but thank14 you.

15 Erin McMullen, anything you wanted to add to 16 that?

17 MS. McMULLEN: I don't think so.

I think that the observations that this could be -- that this is possible, segmentation is possible is something that we've been hearing as well. So we will definitely keep our ear to the ground for the NPRM that will come out as a result of the CARES Act and Part 2 and

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HIPAA. So we will definitely continue to monitor 1 everything that's going on and how that flows in the EHR 2 3 work. 4 VICE CHAIR MILLIGAN: Thank you. So is there anything else you need from us, Erin 5 6 or Aaron? 7 MS. McMULLEN: Not this Erin. 8 VICE CHAIR MILLIGAN: Okay. 9 MR. PERVIN: I think we're okay, yeah. 10 VICE CHAIR MILLIGAN: All right. Well, thank you 11 all very much. We really appreciate the work that you've 12 done this cycle for us. I'm going to hand it over to Melanie for the next 13 14 session. 15 CHAIR BELLA: Thank you, Chuck. Thank you to 16 both Aaron/Erin(s). One Aaron is staying, and Kacey is coming. And we're going to have our final session on NEMT. 17 18 Just to remind everybody, this started as a 19 Senate Appropriations request. You've heard about the 20 analysis a few different times, and over the course of 21 that, Congress also took some action. Consider this your 22 last bite at the apple with the chapter that's going in on

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this issue, and so this is an opportunity for us just to
 give any additional feedback to Kacey -- and maybe not,

Always lovely, Kacey, to have you lead us through this. I'm going to turn it over to you.

Aaron. I'm sorry. I thought you were both on the agenda.

6 ### MANDATED REPORT: NON-EMERGENCY MEDICAL

7 **TRANSPORTATION BENEFIT: REVIEW OF DRAFT CHAPTER** 8 \* MS. BUDERI: Thank you, Melanie.

9 So today I'll be reviewing our draft chapter on 10 non-emergency medical transportation, or NEMT, and NEMT is 11 a mandatory Medicaid benefit that provides transportation 12 to and from medical appointments for Medicaid

13 beneficiaries.

3

Before I start, I'll just note that this work has been ongoing over the last year or so, and the material included in the chapter has already been presented at prior meetings. So I won't be sharing any new information today, but rather, we'll just share how we folded the findings from our study together into the chapter. Sorry. I'm just having a little difficulty

21 advancing slides.

22 [Pause.]

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MS. BUDERI: There we go. Okay.

2 So I'll start by reviewing the congressional 3 request. I'll present the key findings from our study, 4 and, Commissioners, you have the draft chapter in front of 5 you, but for the benefit of the public, I'll go over the 6 topics covered in the chapter.

So, in this slide, you see the language of the congressional request. It has no due date and does not require recommendations, and our chapter will serve as our response to the committee, and it does not include any recommendations.

12 I'll note that since the request was made, 13 Congress acted to include the requirement to provide NEMT 14 into the Social Security Act, which means that the benefit 15 cannot be made optional through regulation alone, as the 16 Trump administration had proposed. So this action changes 17 the context for our study.

18 So the chapter starts by providing an 19 introduction and listing key findings, which include the 20 following. Although the portion of Medicaid beneficiaries 21 who use NEMT is relatively small, NEMT plays a vital role 22 in facilitating access to care for those who do use NEMT.

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1 The extent to which NEMT programs meet the needs 2 of beneficiaries varies widely across states and within 3 states, with differences based on geographic location, the 4 entity responsible for delivering NEMT, NEMT providers, and 5 other factors.

6 States and other entities that administer NEMT 7 benefits are currently engaged in a number of efforts to 8 improve program administration, program integrity, and 9 beneficiary experience. These include, for example, 10 adopting new technologies, such as GPS tracking and 11 introducing new transportation network companies, or TNCs, 12 such as Uber and Lyft.

The need for and the way beneficiaries use NEMT 13 14 may be affected by changes in how beneficiaries are 15 accessing services, including expanding use of telehealth 16 services. However, the long-term effects of such changes on NEMT are unclear and will require additional data than 17 18 we currently have available. Even so, NEMT is likely to 19 continue to play a central role in helping beneficiaries 20 access care, especially medical care that must be provided 21 in person, including many types of medical care that 22 beneficiaries are using NEMT most often to access, such as

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1 dialysis.

The chapter then provides background information 2 on the origin and evolution of federal NEMT requirements, 3 an over view of current federal requirements and where 4 states have flexibility, and a discussion of past efforts 5 to exclude NEMT from benefit packages, including the Trump 6 administration's proposal to make the benefit optional and 7 states with Section 1115 demonstration authority to waive 8 9 NEMT.

10 So, on this slide, I've listed the primary 11 components of MACPAC study, which the chapter draws heavily 12 from, and I won't say much about these, because we talked 13 about them at prior meetings, but they're listed here just 14 for your reference.

15 We then talk about transportation as an access 16 enabler, including examples of transportation-related barriers reported by our focus group participants, and then 17 18 from survey data on beneficiaries who delayed care due to transportation barriers, we provide rates of reported 19 20 barriers among Medicaid beneficiaries by age, income, race 21 and ethnicity, and certain health conditions, and 22 information on the characteristics of beneficiaries who

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1 reported transportation barriers.

The chapter then turns to focus on how beneficiaries use NEMT. We include data on NEMT utilization by eligibility group, geographic area, and dually eligible status, and on the health conditions of beneficiaries using NEMT.

7 To examine medical services beneficiaries access 8 using NEMT, we include data on NEMT utilization by service 9 destination as well as examples of the types of services 10 focus group participants are accessing using NEMT.

11 Turning to matters of administration, the chapter 12 provides an overview of the different NEMT delivery models states can use, which include in-house management where 13 states manage the benefit directly, a third-party broker 14 15 model, or Medicaid managed care carve-in. We discuss the 16 advantages and drawbacks of each approach and the factors states consider when choosing which model to use or 17 18 planning a change in model.

We discuss NEMT services and providers, including data on NEMT utilization by mode of transportation, for example, shared van, taxi, public transportation, et cetera, and the factors that determine the mode of

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transportation used for each ride. We then discuss the 1 trend towards incorporation TNCs such as Uber and Lyft into 2 3 the NEMT provider networks, and some of the opportunities 4 they provide for improved program administration and beneficiary experience as well as some of the 5 considerations for using them. We also discuss provider 6 network challenges, which are widely cited by stakeholders 7 8 as one of the most significant challenges in administering 9 NEMT.

10 Next, we discuss NEMT program quality, including 11 performance issues, some of which are listed on this slide. 12 We also talk about NEMT policies at the state health plan or broker level that create difficulties or access barriers 13 for beneficiaries, which include the requirements to book a 14 15 ride 48 to 72 hours ahead of a medical appointment, 16 policies that prevent beneficiaries from bringing their children in rides with them, and a general sense among 17 beneficiaries that they have no recourse when problems 18 19 arise.

Then we discuss some strategies states and brokers are using to improve performance and better meet the beneficiary needs and list opportunities for states and

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1 the federal government to help improve NEMT programs that 2 were identified by stakeholders and focus group 3 participants.

4 We then discuss other issue of program administration, including the extent to which NEMT is 5 coordinated with other federally funded transportation 6 services and barriers to coordination, expanding use of 7 8 technology in NEMT, and program integrity issues, including 9 new program integrity requirements enacted in Public Law 10 116-260, which is the same law that added the requirement 11 to provide NEMT into the Social Security Act.

12 Finally, we discussed the role of NEMT in Medicaid, including its role in promoting beneficiary 13 physical and mental health, the value of NEMT including 14 15 potential for cost savings and return on investment and the 16 increasing provision of transportation by health plans that are not required to provide it, including Medicare 17 18 Advantage Plans. And then we discussed the implications of the COVID-19 pandemic on NEMT's role. While we don't have 19 20 data on this yet, we include anecdotal information about 21 changes in utilization and future outlook.

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22 So the chapter concludes by reiterating that NEMT
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continues to be a vital service for beneficiaries and is 1 likely to continue to play an important role in 2 facilitating access to care. We also note that as states 3 consider how to address issues such as racial disparities 4 5 and COVID-19 vaccine distribution, they may wish to leverage NEMT by more widely promoting these services. 6 7 So that's the outline of the draft chapter. I'm 8 here and Aaron is here to answer any questions that you may 9 have, and we look forward to hearing your feedback. 10 CHAIR BELLA: Thank you, Kacey, for taking us 11 through that so efficiently. 12 All right. Who would like to start? Comments or questions for Kacey and Aaron. 13 14 Anne, are you raising your hand? 15 EXECUTIVE DIRECTOR SCHWARTZ: No. I'm saying 16 it's perfect. 17 CHAIR BELLA: Oh, okay. Yeah. 18 Martha? 19 COMMISSIONER CARTER: Basically the same thing. 20 I thought it was a really good chapter. I could see that you all have incorporated our previous comments, and I 21

22 think it's a great foundational chapter. I think we need

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to keep track of this benefit to see how evaluation of the beneficiaries is utilized. Are people really getting to give feedback? Is there really quality improvement in this area? I think that's an area we want to track, but I think tit's a great chapter.

6 CHAIR BELLA: Tricia? Thank you, Martha.
7 COMMISSIONER BROOKS: Thanks, Kacey and Aaron,
8 great work here, as usual.

9 I just found it a little interesting to use the 10 positive language that industry uses talking about a return 11 on investment. I guess I don't necessarily see providing 12 services that are mandatory as being something that you're 13 necessarily investing in.

I think perhaps alternative language, because we know this is true, that increasing access to primary care drives more effective health care spending, and I guess I just don't see it being necessarily a return on investment.

18 CHAIR BELLA: Thank you, Tricia.

19 Chuck?

20 VICE CHAIR MILLIGAN: Thank you for the great
21 work on this chapter.

22

I had a couple of comments, and I think this gets

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1 more to future work to the extent that MACPAC continues to
2 look at NEMT, and my comments, I think, are less about the
3 current chapter and delivery per the requirement.

The first comment is I think it's going to be interesting to look at the extent to which utilization of NEMT might be affected by some of the telehealth expansions and some of the alternative home-based primary care models that we've seen emerge because of the pandemic.

9 I do anticipate that there is likely to be a 10 little bit of a substitution effect if individuals can 11 access primary care from home more readily and in fact 12 other forms of care from home more readily and perhaps have 13 less demand on transportation to get to their providers.

14 So I think coming out of the pandemic, we've 15 talked in the past about what changes might become more 16 permanent and what was more temporary as a necessary 17 accommodation, and I think the relationship between 18 telehealth and transportation is going to be something 19 where it will be interesting to see how that goes.

The second element I wanted to mention -- and I think I mentioned this before about NEMT -- relates to dual eligibles and touches back on the integration work that we

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1 talked about in the morning today.

2 Within Medicare Advantage and D-SNPs, network 3 adequacy can often be a constraint because of how MA 4 evaluates network adequacy requirements, and the Medicare 5 Advantage program does not typically look at the 6 availability of transportation to address network shortages 7 in certain rural and frontier areas.

8 I think the duals office is better able to think 9 about transportation when they look at MMP models because 10 the duals office tends to look at the comprehensive benefit 11 package, including all Medicaid and Medicare services, so 12 they can look at network adequacy inclusive of an individual's ability to get a ride to a specialist, whereas 13 14 a D-SNP as a stand-alone has to typically meet the other MA 15 network adequacy standards, not mindful of transportation 16 as a benefit to get to specialty care and to get to a lot 17 of medical services.

And so I do think over time, it's going to be important to keep an eye on the policy discussion around using transportation benefits to access Medicare services and how and whether Medicaid's NEMT benefit is accommodated or incorporated in the analysis of network adequacy from a

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D-SNP perspective, because I do think people in rural communities can get to a specialist through a Medicaid benefit in a way that the Medicare Advantage program doesn't typically recognize.

5 So I just want to put those out there as kind of 6 things to keep an eye on in the future, to the extent this 7 work continues, but for now, for this report, a great job 8 and my compliments.

9 CHAIR BELLA: Thank you, Chuck. Other 10 Commissioners?

11 [No response.]

12 CHAIR BELLA: I want to echo the great job on the 13 work and note that I didn't even bring up the duals, so 14 that's -- even though that was an important finding.

Okay. Do we have any comments, any last questions for these guys? Any last feedback on the chapter? Kacey or Aaron, anything you need from us? And then we'll go to public comment.

19 MS. BUDERI: I think on our end we're good.

20 CHAIR BELLA: Okay. Wonderful

21 MS. BUDERI: So thank you.

22 CHAIR BELLA: All right. We are going to invite

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members of the public to comment on any of our sessions 1 this afternoon, so that would be the sessions on adult and 2 children and adolescent behavioral health, the EHR 3 4 discussion, or the NEMT chapter and report that we just 5 finished discussing. So if you would like to make a comment, please use your little hand icon, and we'll just 6 give it a minute to see if anyone is interested in doing 7 8 so.

9 [Pause.]

10 CHAIR BELLA: I think we peaked this morning in 11 terms of public comment. All right. There don't appear to 12 be any hands. We'll do a little bit of housekeeping and 13 double check one more time.

14 So thank you, everyone, for your engagement 15 today. We made it through obviously all the sessions. We 16 made it through the recommendations. Tomorrow we will take 17 formal votes on the recommendations and ask you all --

18 VICE CHAIR MILLIGAN: Melanie, we did have
19 somebody just raise their hand, by the way.

- 20 MS. HUGHES: Yes.
- 21 CHAIR BELLA: Okay.
- 22 **### PUBLIC COMMENT**

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1 MS. MacMURRAY: Yes, good afternoon. \* This is Nataki MacMurray from the Office of National Drug Control 2 Policy. Nothing controversial to add to the conversation, 3 4 but I just wanted to say that I am looking forward to reading the chapters and thank the Commission for 5 discussing the non-emergency medical transportation 6 benefits. We have been looking at and thinking about the 7 8 benefit that seems to be underutilized, especially in our 9 rural and underserved communities. We certainly want to 10 know what states are doing and providers are doing to 11 increase the awareness of the benefit and to be creative 12 about using the benefit for the sake of clients that have mental health and/or substance use disorders who we know 13 14 are also typically going to be using a number of physical health services. And so I'm anxious to see what the 15 16 Commission is going to recommend about that.

And the same thing for the electronic health records piece for behavioral health. We have certainly been battling for a while to try and negotiate and balance the best of all worlds when it comes to electronic health records and the interoperability questions that providers and beneficiaries have, et cetera.

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So I'm looking forward to seeing what the chapters will say and give to provide some insight as we at the federal level struggle, really struggle with trying to find the right balance. So, again, thank you for the discussion and the thought.

6

CHAIR BELLA: Thank you, Nataki.

All right. Just to reiterate, we will start 7 8 tomorrow morning at 10:45. We'll start with a discussion 9 on rebalancing. We'll then go into a session on quality. 10 We will then take a break for lunch and come back and vote 11 on our recommendations, the recommendations on accelerated 12 approval and around adult and children's access to behavioral health services. And then we'll have a couple 13 additional sessions in the afternoon, and then that will be 14 15 a wrap. But let me see, Anne, is there anything else you 16 want to say before we break?

EXECUTIVE DIRECTOR SCHWARTZ: No. Sounds good.
CHAIR BELLA: Okay. Any other comments or
questions from Commissioners?

20 [No response.]

21 CHAIR BELLA: All right. So thank you all as 22 usual for your engagement today, and we will see you

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1	tomorrow at 10:45. Have a great evening.	
2	* [Whereupon, at 4:18 p.m., the meeting was	
3	recessed, to reconvene at 10:45 a.m. on Friday, April 9,	
4	2021.]	
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PUBLIC MEETING

Via GoToWebinar

Friday, April 9, 2021 10:45 a.m.

COMMISSIONERS PRESENT:

MELANIE BELLA, MBA, Chair CHARLES MILLIGAN, JD, MPH, Vice Chair THOMAS BARKER, JD TRICIA BROOKS, MBA 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 SHELDON RETCHIN, MD, MSPH WILLIAM SCANLON, PhD PETER SZILAGYI, MD, MPH KATHY WENO, DDS, JD

ANNE L. SCHWARTZ, PhD, Executive Director

AGENDA				
Session 7: Progress on Rebalancing: Lessons from the				
States				
Kristal Vardaman, Principal Analyst				
Tamara Huson, Analyst220				
Session 8: Ensuring Quality in Medicaid and CHIP				
Joanne Jee, Principal Analyst				
Naomi Shin, Research Assistant				
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Session 9: Votes on recommendations for June 2021				
Report to Congress				
Session 10: Update on Work with T-MSIS				
Aaron Pervin, Senior Analyst				
Chris Park, Principal Analyst and Data Analytics				
Advisor				

Session 11: Panel Discussion: What States are Learning

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from Expanded Use of Telehealth
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Introduction:
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Panelists:

Chethan Bachireddy, MD, MSc, Chief Medical
Officer, Virginia Department of Medical
Assistance Services
Tracy Johnson, PhD, Medicaid Director, Colorado
Department of Health Care Policy and Financing333
Sara Salek, MD, Chief Medical Officer, Arizona
Health Care Cost Containment System

Adjourn Day	7 2	386
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1 PROCEEDINGS 2 [10:45 a.m.] 3 CHAIR BELLA: Good morning, everyone. Welcome to 4 the second day of MACPAC's meeting. We're going to wait 5 just a few seconds for everybody to gather. 6 [Pause.] 7 CHAIR BELLA: All right. I think we'll go ahead and get started. Welcome, everybody. We're really excited 8 9 to kick off today's meeting with a session on rebalancing, 10 always helpful to hear what we learn from the states and 11 what they're experiencing. So, with that, I am going to 12 turn it over to Kristal and Tamara to get us started. 13 PROGRESS ON REBALANCING: LESSONS FROM THE STATES ###

14 \* DR. VARDAMAN: Great. Good morning,
15 Commissioners. As Melanie mentioned, today Tamara and I
16 are here to talk to you all about insights on rebalancing.

We'll start with a brief bit of background before moving into the results of some contractor research, and then we'll end with some policy considerations and a discussion of future work.

21 Shifting the reliance of the long-term services 22 and supports system, or LTSS, from institutions to home-

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and community-based services, or HCBS, has been a federal 1 and state policy goal for several decades. This effort, 2 known as "rebalancing," is often framed in terms of the 3 4 proportion of LTSS spending that is for HCBS. Although we 5 acknowledge that this is only one way of defining rebalancing and access to HCBS is more nuanced than 6 spending alone, it's a convenient method for measuring 7 8 progress and making comparisons across states.

9 At the national level, Medicaid spending on HCBS 10 has exceeded that on institutions since fiscal year 2013. 11 As of fiscal year 2018, about 56 percent of all LTSS 12 spending was for HCBS.

However, national figures can obscure variation 13 14 across states and populations. As you can see here, as of 15 fiscal year 2018, HCBS spending as a percentage of LTSS 16 spending remained under 50 percent in 18 states and the 17 District of Columbia. I'll note that there are a few 18 states here where data are missing due to a lack of managed 19 care data, which the authors cited as being due to COVID-20 related reporting delays.

21 In terms of groups of people who use LTSS, HCBS 22 accounts for nearly 80 percent of national spending for

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people with intellectual or developmental disabilities, but less than 50 percent of all LTSS spending for other populations using LTSS, such as individuals aged 65 and older or individuals with mental health or substance use disorders.

6 The federal government has supported state 7 efforts to rebalance in several ways. I won't go over 8 these in detail today, but there are descriptions in your 9 materials. Federal support has included enhanced funding, 10 most recently in the American Rescue Plan Act, as well as 11 guidance and technical assistance, including a recently 12 published toolkit for states.

In order to understand why some states have made less progress in rebalancing than others, we contracted with RTI International and the Center for Health Care Strategies. I'd like to take a moment to thank Molly Knowles, Amarilys Bernacet, and the rest of the team for their work on this project. Specifically, their work focused on the following questions:

First, what factors have limited rebalancing in the states where HCBS spending remains under 50 percent of total LTSS spending?

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Next, how can the federal government promote
 further rebalancing in these states?

And then, finally, do any of the flexibilities introduced by states to respond to the COVID-19 pandemic help expand access to HCBS in states with less developed HCBS systems?

7 The project team identified five study states 8 that varied in use of HCBS state plan and waiver options, 9 population density, participation in rebalancing programs 10 like the Balancing Incentive Program, and adoption of 11 managed long-term services and supports, or MLTSS. The 12 states included were Mississippi, Louisiana, New Jersey, 13 North Dakota, and West Virginia.

The case study states were selected using fiscal year 2016 data, but during the course of the study, fiscal year 2018 data became available, and the spending for these five states remained under 50 percent for HCBS.

18 The research team conducted a total of 28 19 stakeholder interviews, both in the states in the study, as 20 well as a number of experts that gave a national 21 perspective. So that included provider organizations, 22 beneficiary advocates, researchers, and other experts.

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1 The RTI and CHCS work culminated in a final 2 report that we plan to publish on MACPAC's website in the 3 coming weeks. Over the next few slides, I'll be 4 highlighting some themes from that work.

5 First, in terms of investments in rebalancing, 6 each of the case study states reported engaging in some 7 rebalancing efforts. For example, two states reported 8 increasing their Section 1915(c) waiver capacity. State 9 officials expressed reservations about being judged 10 primarily on HCBS spending, suggesting that there's more 11 nuance to their stories.

12 States also noted that the Money Follows the 13 Person program and the Balancing Incentive Program have 14 provided valuable support for their rebalancing efforts. In particular, Money Follows the Person was cited as 15 16 funding infrastructure that was used for rebalancing. 17 Finally, national-level interviewees noted 18 incentives that MLTSS plans have to support rebalancing by 19 transitioning beneficiaries out of or diverting them from 20 institutions, but it's important to note that advocates

voiced some concern about MLTSS and incentives that may be

22 in place for them to authorize fewer services than

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21
1 beneficiaries may need.

In general, many of the challenges that the team 2 identified in states with relatively low levels of 3 4 rebalancing are challenges that are common to all states in providing HCBS. For example, Medicaid's mandatory coverage 5 6 of institutional care and structure bias towards institutions was a common theme. State capacity was also 7 cited as an issue frequently. One stakeholder noted that 8 9 the depletion of state staff in recent years has led to a 10 lack of staff knowledge and community connections, which 11 hinders their ability to administer complex HCBS programs. 12 A lack of affordable and accessible housing and LTSS workforce shortages were also frequently cited issues, 13 which we hear consistently in discussions about the 14 15 difficulty of serving more people with LTSS needs in the 16 community.

17 In some cases, these issues may be particularly 18 acute for areas like rural areas where direct care workers 19 must travel long distances between clients.

In addition, some barriers may have particularly significance in the states with lower levels of rebalancing. For example, stakeholders in the study states

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sometimes cited a lack of executive and legislative 1 champions as a barrier to increasing access to community-2 3 based services. In several states, stakeholders also said 4 that the nursing home industry has a great deal of political clout. For example, in one state, legislation 5 guarantees annual rate increases for nursing homes, but not 6 HCBS providers. Stakeholders view the industry as being 7 8 resistant to rebalancing and viewed HCBS provider advocates 9 as having less influence on policymakers.

10 In terms of opportunities for supporting 11 rebalancing, we heard a variety of options, including those listed here on the slide. Tamara in a few minutes will go 12 13 over some of the areas that we plan to explore in our 14 future work. But to highlight a few here, interviewees 15 suggested, for example, presumptive eligibility for HCBS as 16 one option to improve access and discussed the potential of 17 making federal programs like Money Follows the Person and 18 the Balancing Incentive Program permanent. They also 19 thought that there were opportunities to help nursing 20 facilities diversify their services, which could help 21 overcome resistance to rebalancing, although there were 22 some barriers to this cited such as certain requirements

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1 under the HCBS settings rule.

Housing supports that leverage other state resources, such as one example of a county-based homesharing program in one state were also mentioned. And there were a variety of examples of potential ways to address workforce challenges, including pass-through payments to HCBS providers that would support increased wages for direct care workers.

9 And the last thing I'll discuss are comments 10 related to how the COVID-19 pandemic has affected access to 11 HCBS. Stakeholders said that it has exacerbated workforce 12 challenges in some areas and also noted where it has led to social isolation for some beneficiaries. States have found 13 value in the federal flexibilities that have been provided 14 15 to them under the public health emergency, and also many 16 stakeholders noted that the pandemic has highlighted potential HCBS innovations such as assistive technologies 17 18 that can help keep people in their homes. However, one 19 provider stressed that some services are best done in 20 person where you can see, you know, someone's living 21 environment.

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Again, we look forward to publishing the

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contractor report, which will have some additional details
 on the results of the work, and with that I'll turn it over
 to Tamara.

4 \* MS. HUSON: Thanks, Kristal. If we could go to
5 the next slide, please.

6 So we proposed the following four policy7 questions for your consideration:

8 First, how can state efforts to rebalance be 9 further encouraged and supported? The work with RTI that 10 Kristal just summarized brought up a number of barriers to 11 HCBS in states with relatively low levels of rebalancing. 12 In particular, this work raised barriers related to the 13 direct care workforce and housing.

14 Second, should there be fundamental changes in 15 Medicaid LTSS policies? Discussions of the limitations of 16 Medicaid LTSS frequently turned to the program's institutional bias. Changing the institutional bias would 17 18 require a change in the Medicaid statute, and it would 19 likely come at a significant cost. The cost of this change 20 would depend on a variety of factors such as the 21 eligibility criteria, the service package, and whether or 22 not nursing facility services remain mandatory.

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1 Third, how can nursing facility diversification be supported? Nursing facility industry stakeholders 2 discussed the opportunities for nursing facilities to 3 diversify their services to offer HCBS, but also identified 4 5 barriers. For example, discussions with industry stakeholders highlighted the HCBS settings rule as 6 deterring interested nursing facilities from offering HCBS, 7 8 such as adult day services, at their facilities. 9 And, finally, what have been the effects of COVID 10 on rebalancing LTSS efforts thus far? COVID has heightened 11 state and beneficiary interest in the use of HCBS over 12 institutional services, as well as highlighted several 13 inefficiencies and challenges associated with providing care in institutional settings. In addition, temporary 14 flexibilities have expanded access to HCBS, and 15 16 stakeholders largely advocated for making these

17 flexibilities permanent.

18 Next slide, please.

So as you respond to the policy questions proposed on the previous slide, we identify the following areas for particular consideration: What changes to Medicaid policy might address the areas listed on this

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slide? For example, interviewees discussed how persistent 1 and growing LTSS workforce shortages across settings and 2 provider types are a primary barrier to increasing HCBS. 3 4 Direct care workers providing HCBS typically receive low wages, inadequate training, and often have difficulty 5 getting to clients in the community. As such, wage 6 increases and added benefits, strengthened training 7 8 supports, and non-wage incentives such as transportation 9 benefits could help with recruiting and retaining staff.

10 Next slide, please.

11 The next two slides summarize work that staff has 12 proposed over the course of the next year. The 13 Consolidated Appropriations Act of 2021 directs MACPAC to 14 write a report on MFP alignment with the HCBS settings 15 rule. Specifically, MACPAC is to identify the types of 16 home and community-based settings and associated services 17 that are available to eligible individuals in both the MFP 18 demonstration program and states in compliance with the 19 HCBS final rule, and if determined appropriate by the 20 Commission, recommend policies to align criteria for 21 qualified residents with the criteria in the HCBS final 22 rule.

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1 Staff anticipate completing the necessary work to 2 fulfill this mandate over the course of the 2021-22 cycle 3 with presentations this fall and winter and a goal to 4 publish a report as a chapter in one of our 2022 reports to 5 Congress. As a note, the mandate due date is tied to the 6 final implementation date of the HCBS settings rule, which 7 is currently March 17, 2023.

8 Staff also plan to let a contract on the topic of 9 how Medicaid policy can be used to support development of 10 the HCBS direct care workforce. We anticipate a contractor will be able to review the literature and conduct 11 12 interviews to identify issues and document what states are doing to support the direct care workforce. We welcome 13 14 Commissioner feedback on this topic as we think through 15 this scope of work.

Another project, as noted in the June 2021 draft chapter on access to behavioral health services for adults, is work that will examine barriers to designing HCBS benefits for enrollees with behavioral health care needs. This will include looking at the behavioral health care needs of beneficiaries who experience limitations in their activities of daily living, barriers that states encounter

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when designing HCBS for this population, and whether
 existing federal authorities are suited to serving
 beneficiaries with significant impairment resulting from
 their behavioral health conditions.

5 Next slide, please.

In response to the question of if there should be 6 fundamental changes in Medicaid LTSS policies, staff are 7 8 considering the design issues and costs of making HCBS 9 benefits more readily available. This work will likely 10 include multiple stages, including external research 11 contracts. The first stage may be to host a roundtable 12 which will facilitate a discussion among LTSS policymakers and stakeholders on what to consider in the design of a 13 benefits package as well as eligibility and administrative 14 15 issues.

As a follow-on to the chapter and recent work on Medicaid estate recovery, Commissioners expressed interest in doing further work on LTSS eligibility policies. As such, staff are planning to do a deeper dive into this and consider the extent to which allowing presumptive eligibility for HCBS could expand access and whether LTSS financial eligibility criteria are a barrier to a

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1 beneficiary's ability to remain in the community.

And, finally, staff will monitor guidance on the HCBS settings rule, as well as the results of CMS and state compliance assessments to understand any effects on access.

5 We welcome your thoughts on the policy questions 6 and considerations we have posed as well as direction on 7 the next steps for future LTSS work over the next year.

8 With that, I will turn it back over to the Chair.9 Thank you.

CHAIR BELLA: Thank you, Tamara. Thank you,
 Kristal.

12 I'll start by just saying I'm really appreciative and really excited about this work. I think we can make a 13 real contribution here. Personally, I would love to see us 14 tackle more of the benefit redesign, particularly for 15 16 certain subpopulations, as well as workforce issues. It feels like there's a lot of other folks that are already 17 18 kind of on the bandwagon for things like MFP and for BIP, 19 but really tackling the hard issues around benefit redesign 20 in particular feels like a unique contribution we might be 21 able to make. And so I would love to turn it over to 22 Commissioners for comments or questions. Sheldon and then

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1 Brian and then Kit.

2 COMMISSIONER RETCHIN: Yeah, Kristal, Tamara, 3 this is a great piece of work, and like Melanie just said, 4 I think it's a very important contribution that we move to 5 more of the balanced approach to long-term care.

6 So you know I'm going to probably say something 7 about workforce, and that's what I want to focus on for a 8 second.

9 So I've mentioned this before, but for direct 10 care workers in the U.S., in particular in the HCBS and 11 long-term care settings, we rely heavily on immigrants, on 12 the immigrant population, and I think solving the workforce problem is never going to be done organically. I don't 13 want to be morose about it, but I do think it's going to be 14 15 a very heavy lift because we have more and more entries 16 into long-term care as the Baby Boomers age in.

17 So I don't know if the contract would permit 18 looking at this, on the reliance, because there's a huge 19 amount of state variation. For example, if you look in 20 California, about 28 percent of the population is first-21 generation immigrant. Then you look at West Virginia, it's 22 less than 2 percent. And I don't know how that lines up in

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terms of direct care workforce, but maybe the contractor can help us, because the numbers nationally are really prodigious. I don't know if you have any reaction to that or any of the other Commissioners do as well.

DR. VARDAMAN: Thanks. As Tamara mentioned, 5 we're just starting up on scoping out that work, so I think 6 that's a really helpful comment for us to think about as we 7 8 think about what we're going to ask the contractor to do. 9 CHAIR BELLA: Thank you. Brian, then Kit, then 10 Darin, then Chuck, then Stacey and Bill. Wow. Okay. 11 COMMISSIONER BURWELL: So, Kristal and Tamara, 12 thank you for a very excellent chapter, and I think many of the kind of policy issues that you've raised in this 13 14 chapter will be important ones as we move forward. I don't 15 know if the Commission is aware of the tsunami that's about 16 to happen in home- and community-based services with the 17 enactment of the American Rescue Plan, which gives states a 18 10 percent bump in FMAP for HCBS services over a one-year 19 period starting April 1st. That's about \$12.7 billion if 20 the states don't -- if the states spend the same state

21 match, 12.7 billion new dollars will be funneled into the 22 HCBS system with federal funds over the next year. That's

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a huge amount of money. California's going to get \$2
billion just to spend on HCBS; Pennsylvania, \$700 million;
I'm sure all the states are figuring this out. I know that
there are people listening to this session from the states
who are immediately being told how -- you know, starting to
think about how we can spend all this money.

7 It's interesting that Congress put a year limit 8 on states to spend this money, which obviously creates the 9 dynamic of, well, we can't spend all this money just to 10 expand services and populations and increase our waivers because if it goes away, the 10 percent goes away, we're 11 12 stuck with the expanded services. And I think there's some intention -- I don't know where it came from -- that this 13 14 money for this year is primarily intended for 15 infrastructure development, new systems, new case 16 management, new quality measurement, new workforce 17 development, all kinds of things to prepare states for the 18 \$400 billion that the administration wants to pour into HCBS under the -- I don't even know the name of the bill. 19 20 Jobs bill? Infrastructure bill? Whatever that's going to 21 follow. So we've got \$12.7 billion pushing now into HCBS 22 this year, and it's just Medicaid, followed by a \$400

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billion confusion under the second bill. Of course, we don't know what's going to happen with that. But I guarantee you, the story over the next year is going to be what these states are going to do with the \$12.7 billion that they're getting this year.

6 We were anticipating guidance from CMS in terms 7 of what exact services can be paid for with this additional 8 money, for example, you know, things that would normally be 9 covered under admin, IT kind of stuff versus direct 10 services. So we're all waiting for CMS to provide that 11 guidance, but it's going to really impact the nature of 12 HCBS system development over the next year.

13 And I want to make one final technical point. 14 Kristal, I don't know which one it was, has made the point 15 that we've got missing data now on the balance of spending 16 for institutional versus HCBS, largely, because of the 17 increasing number of states shifting to MLTSS and just 18 reporting how much they pay in premiums and not getting the 19 data behind those premiums about how the plans are spending 20 the money, the MLTSS plans. It's not due to COVID, because 21 I did these reports. It was occurring way before COVID, 22 and it's just the inability of states to get plans to

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1 submit quality encounter data.

2 So that's going to be an important issue with T-3 MSIS that plans keep track and report how they're spending 4 their LTSS dollars.

5 Sorry to take the time.

6 CHAIR BELLA: Thanks, Brian. Kit and then Darin. 7 COMMISSIONER GORTON: So a lot of people want to 8 talk. I'm going to be very succinct, and if we need to 9 follow up we can do that.

10 One, I think MACPAC, with all of the work that we 11 heard about yesterday and in the months past around 12 behavioral health, I'm glad to see that LTSS for people with mental health and substance use disorders is in scope. 13 I think that's incredibly important. I think my experience 14 15 is that that's where some of the biggest gaps are, 16 particularly with respect to housing. And so I think the in-house expertise around the behavioral health delivery 17 18 system, and what exists and what doesn't, can really 19 inform. Because while housing and workforce are a problem, 20 the problem for LTSS, for behavioral health, are the 21 service gaps that we talked a lot about yesterday. So they 22 all feed in together, and I think MACPAC could do some

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1 incredibly powerful work there.

One of the things that happens, and this is my 2 second point, is that if housing is not available, 3 4 particular in behavioral health, people tend to be put into public institutions. And I think an important thing for us 5 to look at, as we look at the institutional care and the 6 institutional bias, is where are those, and it varies state 7 8 to state, where are people being placed in private 9 facilities and where are people being placed in public 10 facilities.

Because the challenges of getting people out of public facilities in some cases are easier because the government doesn't need to be in the business of LTSS. On the other hand, it's harder because state employees make a very good wage, and so closing a public institution can be enormously difficult. And so I think we need to look at that.

I would just say, as an example, last year, when I was in Massachusetts, which was 2018-2019, there was great fanfare about the State of Massachusetts opening a new 100-plus bed facility for aging veterans. It's like, why are you opening -- I mean, granted, you need to do

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something with this, but why are states still investing in
 institutional care? I think that's an important question.

3 One of the things that's being done, and this is 4 the third thing, one of the things that's being done in my state is a move towards in-home care, and that's great. 5 But because of the workforce problems -- and I think this 6 is an important component of workforce -- there's been a 7 8 big push to move towards family caregivers, paid family 9 caregivers. And while people who do work should be paid to 10 do the work, and people who are not taking outside 11 employment or in a care facility, I don't have a problem 12 with that.

What we're seeing, in a variety of places, is 13 this increased dependency, right, because all of a sudden 14 15 the person's disability becomes an engine for the family's 16 economic stability. And you hear of people going to grievance and appeals and saying, "Well, but my nephew 17 18 needs more hours," and I don't think that was what we were 19 trying to set up, that was the problem we were trying to 20 solve with paid family caregiving.

21 But I think we need to look at that in the 22 context of the workforce. And if we're going to use paid

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1 family caregivers should they get an hourly rate or is
2 there some other way that they should be paid, and I think
3 we should shed some light on that.

4 And then the final piece, any time you're talking about institutional care, home and community services, I 5 think you're incomplete if you're not talking about 6 waitlists, because many of these things are waiverised 7 services. I think Leanna has shared with us the tremendous 8 9 waitlist. Last I heard -- and this is not from Leanna --10 in North Carolina, the waitlist for services for young 11 people with disabilities is so long that families are told 12 when their kids are born with a disability, "Get on the 13 waitlist, so maybe by the time they're teenagers you'll be 14 in line for services." Now that's perhaps apocryphal and 15 not true, but we should look into this phenomenon of 16 waitlists, because again, we tend to focus on oh, well, this is available to states. Yeah, but if there's a 15-17 18 year waiting list for it, then maybe it's not quite as accessible as it needs to be. Thanks. 19

20 CHAIR BELLA: Thanks, Kit. I think we just 21 published work on waitlists, so we can go back and see if 22 some of that needs to be pulled over.

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Kristal or Tamara, anything you want to add
 there? Otherwise, we'll just keep moving on the comments.
 No? Okay. Darin, then Toby, then Chuck, then
 Stacey, then Bill.

5 COMMISSIONER GORDON: Thank you for your work on this. One thing that I think would be helpful when we look 6 at this coalition of rebalancing is, in essence, the flow 7 8 of new entrants receiving LTSS services, you know, 9 basically trying to get a sense. And if you look at it 10 just kind of where it is now, in some states you're 11 capturing some of the legacy impact of how their model was 12 set up versus really how their model is functioning today. 13 And I say that because we experienced it. Depending on when you looked at Tennessee, you know, it took a while for 14 15 us to shift the model, and that model to start generating 16 change in what options were available to folks, whether 17 it's HCBS or institutional.

So I think that's an important nuance when we're looking at this, and I think it's helpful that it be a predictor of sorts of where it's going versus being disproportionately weighted to where it's been. Hopefully that makes sense.

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1 Secondly, you know, you talked about the different barriers that are out there. One that we didn't 2 3 highlight that I think is an important barrier is really 4 Medicare. When we look at the dual eligibles, the largest number of entrants into our program, when we looked at it 5 historically, was due to the Medicare door, and then they 6 came to us and they were in institutional settings, which 7 8 really put us in a difficult spot in trying then, at that 9 point, looking at how to move folks into the home- and 10 community-based setting.

11 So, you know, this is where I think the whole 12 dual integration discussion merges very strongly into this 13 topic, because to the extent those tools that Medicare has are available to, in the case of MA, available to MA plans, 14 15 then you might see less institutional volume than we are 16 currently seeing. So, you know, that was actually one of the reasons we went down that dual integration path was if 17 18 we can make those tools available then hopefully we can go 19 further upstream and minimize the number of folks that are 20 defaulting, to some degree, into institutional settings.

21 So just something I think that we should capture 22 in some form or fashion in this discussion. Thank you.

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1 CHAIR BELLA: Thank you, Darin. Sort of the pre-2 duals and a benefit on the Medicare side to keep them from 3 coming in and spending on the Medicare side. Good point. 4 Toby, then Chuck.

5 COMMISSIONER DOUGLAS: Great work. I'll keep my comments pretty short. The area that I was surprised that 6 7 didn't come up from the stakeholder interviews is just the 8 financial implication from a state perspective of 9 rebalancing. The problems that states face is nursing 10 facilities spend, and those that go in, it's very clear-cut 11 on eligibility and who's going to choose to be in an 12 institutional setting. When you open up eligibility for home- and community-based services, the implications become 13 14 a lot larger unless there are caps or different ways, and 15 clearly there can, but this creates the challenge for 16 states to go down this path. So definitely seeing the COVID relief package with the enhanced FMAP and the ability 17 18 to provide the 10 percent, and I think we need to look at 19 how we assess these options. I know it's only for one 20 year. And would even creating higher FMAPs, more than what 21 was under Money Follows the Person but really trying to 22 restructure.

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And this builds on, I was going to bring up the duals, because it is another area where the only way states really can justify some of these financial implications is when they have other balancing efforts from the acute side, and being able to have the full picture, equation, to work with as they're drawing out and opening up more services in a home- and community-based setting.

8 And then finally, I do want, Kit, the other piece 9 is the workforce. You know, we can't underestimate this 10 interaction with family caregivers and how much of home and 11 community services in some states also becomes an important 12 economic support for the family, and how that interacts as we think about both the right types of services and the 13 14 right skill set, and how you bring family support up to the 15 right level to provide services in the home, and that's a 16 challenge too.

17 CHAIR BELLA: Thank you, Toby. Chuck, and then18 Stacey, and then Bill.

19 VICE CHAIR MILLIGAN: Thank you both for your 20 work on this. I wanted to stay on the financing side for a 21 second. One of the barriers that I've heard exists is the 22 state dependence on nursing facility bed taxes and kind of

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provider rate maximization issues, and the potential loss of some of that leveraged federal revenue. So I want to make sure that we keep that in the frame. And I want to make sure that we connect this work with the work that Rob is leading on nursing facility rate-setting, because I think that they are interrelated in ways that we need to make sure that we're staying on top of.

8 Along those lines, I think we're likely to see more demand for rate increases on the nursing facility 9 10 side. There's movement toward single occupancy rooms. 11 There's movement toward improving infectious disease 12 controls and how nursing facilities prepare for kind of 13 pandemic-related responses. And I also think that with nursing facilities having lower occupancy rates right now 14 15 there's going to be nursing facility demand on state 16 Medicaid programs to raise their rates to deal with the 17 fact that not every bed is full.

And so as one caution about this, I think over time it's going to be less relevant or less meaningful to compare how much money is spent in HCBS versus how much is spent in nursing facilities, and those pie charts that we've been using for over 20 years that show the

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distribution of LTSS funding by setting. I think it depicts a false picture around adequacy of rates in both places, because I don't think they should be competing quite that way. We have to make sure that we're adequately funding nursing facilities too, and if that's done that isn't, to me, a defeat of HCBS or the importance of rebalancing.

8 So I want to make sure that we keep all of that 9 in the lens, and I want to make sure that this work is also 10 anchored with the work that Rob is doing to paint a fuller 11 picture.

So those are my comments. Thank you.
CHAIR BELLA: Thank you, Chuck. Stacey?
COMMISSIONER LAMPKIN: Thanks. So add me to the
list of people who are delighted that we're picking this up
and spending the time on it. It's a really important
issue, and I support the policy questions and
considerations that you all have presented.

My suggestion is that as we work our way through those policy considerations and questions that we keep an eye on, or weave in what we think the role of managed LTSS programs is on some of this, and in particular, on

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accessible community housing options and workforce
questions. I think, as we've heard before, that most MLTSS
programs have MCO reimbursement structured with a blended
rate that builds in a financial incentive to serve members
in the community, wherever possible, and it's supposed to
have a rebalancing effect.

7 What isn't really clear to the actuary setting 8 those rates, especially as the program isn't brand new 9 anymore and has reached a more mature level, is what's 10 reasonable to expect the MCOs to do about these barriers 11 when they confront them, when that starts to be the barrier 12 to rebalancing? Does the MCO have the scale to really 13 address the housing questions or the workforce questions? You know, if not, if we've kind of reached a stall point 14 15 with the managed long-term care program, what does that 16 imply in terms of what the incentives are anymore and how we finance that program? 17

18 So I hope we can keep an eye on the role of the 19 plans in rebalancing for states that have chosen to go down 20 this path.

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    CHAIR BELLA: Thank you, Stacey. Bill?
    COMMISSIONER SCANLON: Yes. Thank you very much.
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1 This is a very important area and there's a lot of very 2 interesting information sort of in your report and your 3 presentation.

4 I wanted to focus a bit on sort of what you had in Slide 6, which showed that about 80 percent of the 5 dollars for people with intellectual and developmental 6 disabilities are in home- and community-based services 7 versus only 32 percent for people with physical 8 9 disabilities or over 65. I think making that distinction 10 is important, and carrying it throughout is key, because 11 the nature of services, the size of the population, the 12 ability of states and the role of states and the public 13 sector for these two populations is very, very different.

14 Years ago, I worked on the design sort of, of 15 payment systems for nursing facilities in a state, and then 16 for the intermediate care facilities for people with intellectual and developmental disabilities. For the 17 18 nursing facilities we were dealing with 100-bed homes, on 19 average. For the ICFs we were dealing with very often 20 houses, essentially, that were serving less than 15 people, 21 and if they were not serving as an ICF it could have been a 22 single-family home. And the nature of services is totally

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1 different in terms of what people do during the day in each 2 of those institutions.

3 So HCBS versus institutional care is very 4 different in these two circumstances, and I think it's 5 important to kind of keep that in mind and understand how 6 that influences choices. I think part of that influence is 7 what Toby was talking about, which is the issue of if I am 8 a state, how well can I control these different sets of 9 circumstances?

I would also add two questions to what the focus has been, and a little bit off of what Chuck was saying, maybe we're getting tired of the pie charts in terms of what share of the pie is going to home and community-based versus institutional. To me, we also should be asking how big is the pie, and is the pie big enough to serve the population in need in states?

Many, many years ago, I did a study on people in a cohort that was defined by, they had five or six activities of daily living dependencies, they were unmarried which meant they didn't have, sort of, who would have been their primary caregiver, and they were poor. At that point there wasn't HCBS. At that point, in states

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that had a lot of nursing home beds, 90 percent of those 1 people were in nursing homes, and it was not shocking, 2 because you thought about all their needs. Well, they 3 4 needed to get service and where would you get it within a nursing home? In the states with very few beds, only 50 5 percent of those people were in nursing homes. And the 6 shock was how do those other 50 percent get by, given all 7 of those needs? And so I think that's a question that 8 9 needs to be addressed, in terms of the question of how big 10 is the pie.

11 The other question about sort of balancing is we 12 have to think about what happens when someone is not in a 13 nursing facility but is being helped at home. Nursing 14 facilities are supposed to provide 24/7 care, and yes, we 15 know that there are issues with respect to how well nursing 16 facilities do their job. Home- and community-based services are nowhere close to providing 24/7 care. It's a 17 rare, rare instance when someone will get that much care 18 19 through an HCBS program.

20 So the balancing factor there is the family ,and 21 it's just a little bit counter to what Kit was talking 22 about, which is when a family is being asked to do too much

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and is potentially not being compensated at all monetarily, what are the consequences of that for family members? I think that's another question that has to be addressed as we look forward investigating sort of home- and communitybased services.

6 Thank you very much. I'm looking forward to this 7 work as we proceed.

8 CHAIR BELLA: Thank you, Bill.

9 Anyone else?

10 Kit and Tricia, and then we're going to wrap it
11 up.

12 COMMISSIONER GORTON: So just to follow up with 13 what Bill said, it's not counter to what I was trying to 14 say. It's the other end of the spectrum. Yeah. So we're 15 in the same place. We need to look at the economic, 16 social, cultural impacts of family caregiving, paid and 17 unpaid.

18 The other thing I would say just quickly with 19 respect to Bill is I would argue we should tease out people 20 who have physical disabilities, not resulting from aging, 21 from people who have physical disabilities and mental 22 disabilities as a result of aging. Those are two different

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populations. They do tend to end up in nursing facilities, 1 but serving them in the community is very, very different. 2 And lumping them together, I think, blurs that difference. 3 4 CHAIR BELLA: Thanks, Kit. Trisha? 5 COMMISSIONER BROOKS: Very briefly. Thank you. 6 Great, great report. Not my area of expertise, but I also 7 8 think it's important for us to examine these issues from 9 the perspective of children versus adults, and I hope we can work that into the mix. 10 11 CHAIR BELLA: Thanks, Tricia. 12 Kristal and Tamara, you've heard a lot. Two 13 things that come to my mind as we're having this 14 conversation, as we to think about benefit redesign and the 15 institutional bias, I hope we will talk with some states 16 who have ideas and have requested some of those 17 flexibilities from CMS. So short of trying to flip the 18 paradigm and make HCBS mandatory in nursing home not, but 19 finding other creative ways to sort of get at that outcome, 20 and then hearing directly from them, I think was really 21 going to be important.

And second, this goes in the bucket of it's not

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22

just a Medicaid thing, but as we do talk about workforce, all of the conversations about a living wage and paid sick leave and minimum staffing ratios that have really been highlighted during COVID, I hope we'll also think about how to incorporate that into this work and what Medicaid's piece of that might be.

7 Other than that, my guess is you've heard well 8 more than you could possibly accommodate, but let me ask. Do you have any questions for us? Did you get what you 9 10 need? If the first question is, is the Commission 11 interested, I think that's a resounding yes, and the 12 second, where we're interesting, hopefully, you have a 13 pretty good sense of that. But do you have any clarifying 14 last questions?

DR. VARDAMAN: No. I really appreciated today's robust discussion, and Tamara and I are scoping out some new projects. So this will be really helpful as we think those through.

19 CHAIR BELLA: Well, that's wonderful. Thank you20 for this work. We look forward to it coming back.

21 Okay. We are going to move into our session on 22 quality in Medicaid and CHIP, and Joanne and Naomi are

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1 going to join us.

2 Just to remind folks, we'll get through this session, and then we'll take public comment on these two 3 sessions. And then we'll take a break. 4 5 There's Joanne. There's Naomi. Welcome. This is your first time in front of us. Welcome, welcome. 6 Joanne, I'll turn it over to you. 7 8 [Pause.] CHAIR BELLA: Except we can't hear you. I don't 9 10 know if you're talking. ENSURING QUALITY IN MEDICAID AND CHIP 11 ### 12 \* MS. JEE: Sorry. That darn mute button. 13 CHAIR BELLA: Yep. You're good. 14 MS. JEE: Okay. So during this session, Naomi and I will be providing you an overview of quality in 15 16 Medicaid and CHIP. Much of the presentation will really 17 just be a refresher on some of the key quality improvement 18 and measurement activities in the programs. 19 We provide this information as context that, 20 hopefully, will facilitate your consideration of potential 21 topics for future MACPAC work in this area and how some 22 additional projects might be prioritized.

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1 Slide 2 just provides an overview of what we'll 2 cover. We won't have a chance really to go too deeply into 3 each of these topics, but there's some additional 4 information in your meeting materials.

5 All right. The federal quality requirements 6 primarily reside in the Medicaid managed care rule at 42 7 CFR Subpart E. They apply to managed care entities, which 8 are managed care organizations, or MCOs, the prepaid 9 ambulatory health plans, the prepaid inpatient health 10 plans, and then the primary care case management, or PCCM, 11 entities.

12 Among the mandatory activities are the 13 development of state quality strategies and managed care 14 entity quality assessment and performance improvement 15 programs. These both involve quality improvement 16 approaches and activities, which are described in the 17 documents that states and plans have to prepare. 18 PIP topics, or performance improvement project 19 topics, are a part of the managed care entity quality 20 assessment and performance improvement projects. Those 21 topics can be state, plan, or CMS defined, and the projects

22 can really vary in duration.

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1 All PIPs must include performance measurement as 2 well as the implementation and evaluation of quality 3 improvement interventions.

4 States must also contract with external quality review organization for that review. There are four 5 mandatory external quality review activities. They are the 6 7 validation of the performance improvement projects, or the PIPs, validation of plan performance measures and 8 validation of network adequacy, and finally, review of 9 10 managed care entity compliance with quality assessment and 11 performance improvement program requirements.

12 States can also engage their external quality 13 review organization in optional activities such as 14 validating encounter data or quality of care surveys, and 15 the external quality review reports are to be posted on 16 state websites each year.

17 States also must adopt quality rating systems. 18 As a reminder, during the December 2020 Commission meeting, 19 you all had a session on this topic. Staff shared with you 20 that although the quality rating systems are not yet 21 mandatory, several states, about 13 or so, were already 22 using them in some manner, but that it was somewhat unclear

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whether beneficiaries were using the systems to help inform
 their MCO choice.

Finally, the last bullet here, federal rules 3 4 require CHIP programs to report on the Consumer Assessment 5 of Healthcare Providers and Systems, or CAHPS survey, which is a survey of beneficiary experience with care. 6 7 The range of data sources and measures for 8 quality, this slide lists some of the key ones. You are 9 familiar with the core sets. They are measures that CMS 10 developed to facilitate consistent data collection and 11 quality measurement across states. We previously reported 12 on this topic as well, specifically on state readiness to report on the child core set and the behavioral health 13 measures of the adult core set in 2024 when that reporting 14

15 becomes mandatory.

16 In addition to those two core sets, CMS has 17 developed core sets for health homes, maternity care, and 18 behavioral health.

19 I mentioned CAHPS on the last slide. The only 20 thing I'll add here is that both the child and the adult 21 core sets include the CAHPS as a measure, and that CMS has 22 developed a CAHPS survey for home- and community-based

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1 services.

As you know, state Medicaid programs must provide 2 children enrolled with all medically necessary Medicaid 3 4 coverable services through the Early and Periodic Screening, Diagnostic, and Treatment, or EPSDT, benefit. 5 States report on their performance on EPSDT in the CMS 416, 6 which provides information on whether children are getting 7 8 the screening services that they should be getting. 9 Moving on to HCBS and LTSS, there are a couple of 10 different sources of quality measures for those. For 11 example, the Section 1915(c) waiver requirements provide 12 that states must describe their quality strategies in their 13 waiver applications and in their annual reports, and that they also must report on performance measures related to 14 15 progress on their waiver activities and waiver requirements

16 and assurances.

17 Several states also report on the national core 18 indicator surveys for intellectual and developmental 19 disabilities and for aging and disabilities services to 20 measure HCBS program performance related to community 21 living and health and welfare. The aging and disability 22 services survey is included in the adult core set as a

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1 measure.

2 CMS has also been developing a national set of 3 measures for HCBS quality for voluntary use. They issued a 4 request for information in the fall of 2020 to gather 5 stakeholder feedback on the benefits and challenges of 6 using a standardized measure set.

For Section 1115 demonstrations, reporting can be a good source of quality data. MACPAC staff have presented numerous times on Section 1115 waiver evaluations, including prior to our March 2020 report, which describe challenges associated with those evaluations, such as certain methodological challenges, data challenges, and the

13 timing of those evaluations.

Lastly, on this slide, I just want to mention nursing facility quality and data related to that. I do acknowledge that it's a little bit of a different thing than quality measurement in some of the other areas that I talked about, but it is such an important issue. And we've been hearing a lot about that over the years and especially during the period of the pandemic.

21 The data sources for that include the survey and 22 certification data, nurse staffing data, and other clinical

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1 quality measures that are collected as a part of the 2 minimum data set.

CMS also has a number of quality improvement 3 4 initiatives. They really vary in terms of the scope of their activities and the intensity of state engagement. 5 For example, initiatives with a greater degree of state 6 engagement involve the maternal health, oral health, and 7 8 asthma initiatives. Examples of activities that occurred 9 under these are the establishment of improvement goals, 10 working with states to test new performance measures, and 11 learning collaboratives and state affinity groups through 12 which CMS provides states some focused technical

13 assistance.

Other initiatives appear to be more focused on the dissemination of information on state practices and approaches for quality improvement. CMS shares this information through activities like webinars and the posting of guidance and documents on its website. Examples of these types of initiative include the obesity initiative and the tobacco cessation initiatives.

21 Whoops. I think I skipped over health 22 disparities. So. with respect to disparities, CMS is

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really focused on sort of disseminating practices to reduce
disparities, identifying QI or quality improvement
opportunities, as well as improving the collection of data
on race, ethnicity, sex, primary language, and disability
status, both in terms of administration data and in survey
data.

7 All right. So, with respect to value-based 8 purchasing, you know that states and CMS have numerous 9 efforts underway to adopt and expand these models as a way 10 to drive quality improvement. We have examined and 11 reported on some of these measures over the years. Most 12 recently, you'll recall that in January, staff presented on 13 findings from an analysis of value-based purchasing for maternity care, and evidence on the effectiveness of those 14 15 initiatives to improve quality were somewhat mixed.

Before we leave this slide, I just want to mention that with the new administration, it's hard to know right now what their approach will be on these initiatives. They may choose to continue them or modify them or perhaps identify new priorities altogether.

21 And next, I'll turn it over to Naomi who will go 22 through some data findings.

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1 \* MS. SHIN: Thanks, Joanne.

2 So CMS identifies core set measures that can be 3 trended based on three criteria, including if the measure 4 was publicly reported, if at least 20 states reported the 5 measure, and if the measure's technical specifications were 6 comparable year to year.

7 We selected a sample of the identified measures 8 that can be trended in fiscal years 2017 through 2019 to 9 explore their performance trends and found that performance 10 on core set measures can vary widely.

11 Here, we show median performance on two adult and 12 two child core set measures from the primary care access 13 and preventive care domain. You will observe that the 14 median performance for the cervical cancer screening and 15 chlamydia screening measures show little to no change from 16 2017 to 2019. However, the median performance for adolescent well-care steadily increases while median 17 18 performance for developmental screenings has an overall 19 decrease. The variability was observed throughout the core 20 set measures that can be trended in this time period. 21 Next slide, please. We also looked at outcomes

22 and results from PIPs. External quality review

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organizations, or EQROs, perform annual validations for the
 PIPs. Thus, we looked at a few EQRO technical reports for
 PIP validation information.

The existence of significant and sustained quality improvement is one subset of validation criteria. However, validation is also comprised of several checks on the procedures of designing a PIP, including selecting topics, target populations and variables and more. Thus, we explored both validation outcomes and quality

10 improvement outcomes separately.

11 We found that states have mixed results on 12 validation and quality improvement. States often had significant proportions of PIPs that did not meet their 13 14 performance improvement targets or did not show improvement 15 in the targeted quality measure. Your memo provides some 16 examples of states. We also found that validation 17 assessment and quality improvement outcomes did not 18 necessarily correlate. A PIP could show improvement in the 19 targeted quality measure but could receive a validation 20 status indicating that the PIP did not meet validation 21 criteria; conversely, a PIP could also show little to no 22 improvement in the targeted quality measure but could be

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1 scored as having met validation criteria.

It's unclear what happens or what the next steps are when PIPs end. Several states encourage plans to maintain successful PIP interventions and continue to monitor performance, but there's no federal requirement to integrate successful interventions. It's also unclear what the implications are for plans that have PIPs not meeting validation criteria or not resulting in quality

9 improvement.

10 Next slide. Here, we show two rates for EPSDT 11 for eligible children over five years in 2015 through 2019. 12 The top row depicts the trend in the participant ratio, which is the percentage of eligible children receiving at 13 least one screening service. The bottom row depicts the 14 15 trend in the screening ratio which is the percentage of 16 eligible children receiving the appropriate number of 17 screenings based on the state's periodicity schedule.

In 1990, CMS had the goal for all states to achieve a participant ratio of 80 percent by 1995. You can see here that in the period from 2015 through 2019, the participant ratio has seen a slight increase, but as of fiscal year 2019, the national participant ratio was 20

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percentage points below the initial goal. The screening
 ratio in 2015 was 100 percent but has declined since then.
 Both ratios also vary by age group, with younger
 children more likely to have received screening services
 than older children.

Now I'll turn it back over to Joanne to wrap up7 the presentation on next steps.

8 MS. JEE: All right. So, Commissioners, 9 hopefully, this overview has been a good reminder that CMS 10 and states are involved in numerous activities on quality 11 improvement and measure. However, based on our limited 12 look at core set performance and results on the performance 13 improvement projects that Naomi just went over, it's hard to discern just how effective those efforts have been, and 14 15 this might point to some areas where MACPAC may wish to 16 consider additional work for understanding how these activities support the goal of achieving sustained quality 17 18 improvement.

For example, MACPAC could update its chapter on quality. This was last issued in 2011, so a lot has changed since then.

22 We could examine how states are using their

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1 contracted external quality review organizations to drive 2 meaningful quality improvements. We could dig deeper into 3 the performance improvement projects, or the PIPs, to 4 understand their effectiveness and how states and plans are 5 using these projects.

We could consider work to understand where states 6 7 and CMS are with respect to disparities in quality, 8 including data collection efforts and their approaches. We 9 also could look into how states and CMS are addressing 10 quality improvement for beneficiaries with special health 11 care needs. This could include, for example, specific 12 populations like children or users with LTSS; behavioral 13 health is another example.

And, of course, there might be other areas of interest to you all. It would be helpful to hear from you on where you think MACPAC might be most helpful here and what direction you'd like to see us go. And I just want to acknowledge that there's probably a ton of work that we could do, so if you could sort of indicate where you think we could prioritize work, that would also be useful.

21 Thank you.

22 CHAIR BELLA: Thank you both. It's obviously --

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I appreciate the update. It's an important thing for us to keep an eye on. I think given the work that has gone into it, no matter what else we decide, we should be publishing an update. You have the information, and it's important information to have out there.

I think what's going through my head is while 6 this is important, besides publishing the update and 7 keeping an eye on it, like where can we add unique value 8 9 and unique impact, particularly in light of all the other 10 things we said, even in the past two days, that we want to 11 be looking at. So I would ask Commissioners to think about 12 kind of impact and prioritization as we consider where we 13 might want to have additional work, and also, you know, 14 people should feel free if they don't want to update or 15 publish the chapter, but I'm going to guess that you're all 16 in favor of updating based on this work.

17 Peter, then Martha, then Kathy.

18 COMMISSIONER SZILAGYI: Great. Thanks, Joanne,19 and welcome, Naomi. Very nice presentation.

I would agree, first of all, I think this is really important. Many people may see this as dry, but if we don't keep measuring quality, we will have no idea where

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1 we are.

2	The second point is I would suggest updating
3	another report, and I'd love to see a focus on two areas,
4	both of which you mentioned. And one reason to keep
5	monitoring this is that during the pandemic there has been
6	a remarkable decline in quality of care through no fault of
7	anybody except for the pandemic. Anything from
8	immunizations to receipt of care to receipt of needed care
9	has gone down. There's concern that it may not bounce
10	back, and
11	CHAIR BELLA: Peter, we are losing you. Peter,
12	can you I'm going to go to Martha, and then we'll bring
13	Peter back. Martha?
14	COMMISSIONER CARTER: Thank you. Yeah, so thank
15	you for this chapter. I do think we need to publish it, or
16	not the chapter but oh, there's Peter, maybe.
17	COMMISSIONER SZILAGYI: Yeah, I see that. Can
18	you hear me now?
19	COMMISSIONER CARTER: Yes.
20	CHAIR BELLA: No.
21	COMMISSIONER SZILAGYI: All right. Okay. Go
22	ahead.

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1 COMMISSIONER CARTER: My question was: Are you aware of any states that routinely include Medicaid 2 beneficiaries or their careqivers in the design of quality 3 4 improvement, especially the performance improvement programs, or require the MCOs to include beneficiaries in 5 the design of the programs? It seems -- it's not good that 6 these PIPs happen and then there's no follow-up, and I'm 7 8 wondering if what's being designed is really meaningful and 9 whether there's a way to look into that, especially 10 including beneficiaries in the design.

MS. JEE: So states and plans have all sorts of, you know, committees, advisory committees that could include beneficiaries. So I think some states do. I don't know which those are, and I can't quantify, but that's something that we could certainly take a look at.

16 CHAIR BELLA: Peter, you want to finish your
17 thought?

18 COMMISSIONER SZILAGYI: Oh, if I'm back. Sorry, 19 I was having internet problems. Can you hear me now? 20 Okay. So one point was that the importance of this 21 particularly post-pandemic, I'd love to see continued focus 22 on disparities within the Medicaid program and within CHIP.

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I think this is super important. We need to keep
 highlighting it. And I would love to connect a couple
 parts for this session.

4 I would love to continue to focus on the PIPs, particularly mental health and behavioral health, which 5 would connect us to some of the other foci that we're 6 really interested in. I'm not surprised that many PIPs --7 8 that it's not 100 percent positive. If we weren't doing 9 performance improvement in areas that are hard to improve, 10 then we're not doing our jobs. And so I think kind of a 11 deep dive into what seems to be working, why certain ones 12 appear to be working better, even if that's qualitative, to 13 what extent does payment or other modalities drive improvement in PIPs versus other PIPs that don't help, and 14 15 maybe kind of a focus on not all PIPs but on mental health 16 and behavioral health might be one way to go.

17 Thank you.

18 CHAIR BELLA: Thank you, Peter. Kathy, then19 Tricia, then Brian.

20 COMMISSIONER WENO: I'll echo Peter's comments. 21 I don't find this dry at all, and I think it's really 22 important. And I thank you guys, wonderful summary of all

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of the quality improvement things that are going on at CMS. 1 And, you know, as it is quite an extensive list and as 2 someone who has worked on a lot of these oral health 3 4 initiatives, I have had a lot of trouble raising enthusiasm in states and among providers for quality improvement based 5 on a lot of this measurement and performance quality review 6 fatigue issue, especially in the oral health components 7 8 that are optional, getting a state to participate when 9 something is optional and they are already participating in 10 several other PIP programs, it's very difficult to get 11 their attention, especially around an oral health issue. 12 I'm wondering -- we tried several efforts to try 13 and align some of these quality improvement measures so a 14 state could only have to, you know, be able to use some of 15 the performance measures in multiple PIP programs. I was 16 wondering what other efforts you guys had heard about to 17 try and align performance measurements in order to reduce some of these burdens. And I also am interested 18 19 specifically among disparities in the PIPs and the EQRs, 20 like what has been working and the efforts of states to 21 integrate those into the program on a long-term basis. 22 MS. JEE: Okay. So thanks for that, Kathy.

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There has been a lot of effort to align measures and reduce burden. I think that is a sort of well-recognized challenge to all of the activities. CMS sort of reimagined its agency-wide quality plan, and a big focus of that was to look at the measures. I mean, it's actually called "Meaningful Measures," is the framework, so to look at which measures are sort of the most useful ones.

8 CHAIR BELLA: Sorry. I am having trouble 9 unmuting myself. Tricia, then Brian, then Fred.

10 COMMISSIONER BROOKS: Joanne, this is an amazing 11 body of work, pulling together all of these various 12 components into one document. The compilation is 13 extraordinary, and I was actually going to suggest that we 14 at least release this as a brief. If this isn't in line 15 for a June report, I'd hate to wait until next March to get 16 something out in the public domain.

I'm a little concerned that, you know, we've got mandatory reporting of the core set coming in 2024. We've seen no guidance from CMS on that. I worry that it might get pushed back as a result of COVID, no matter how many years we've had to prepare.

22 You also noted at one place in the report about

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stakeholders finding it difficult to find quality data, to 1 find the EQRO reports. We certainly try to educate the 2 child health advocacy community on this. We suggest they 3 4 look for the quality strategies, look for the EQR reports, search for child, search for pediatric, and when you can 5 find it, many -- perhaps "many" is an overstatement, but a 6 number of states don't even have any focus on child quality 7 8 whatsoever. But the lack of transparency and the ability 9 to get your arms around what is or isn't happening in a 10 state I think is very difficult, so I'd really like to see 11 a little more emphasis on that.

The other piece that I've been grappling with a 12 13 little bit, because we trend out the core set data for 14 specific states that we work really closely with, so I'm 15 very sensitive to the performance of states that varies due 16 to things like socioeconomic status of the region, ready access to health care. CMS put out one report on who were 17 18 the leaders in quality back in 2015 after we first started 19 to get our feet really wet on the child core set. And the 20 Northeast states were the ones that weren't selling, and 21 the Northeast states have, you know, higher education 22 levels, higher income levels, you know, a lot of pretty

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fabulous medical centers, and yet the South, you know,
comes up short because of some of these particular issues.
And I just think that when we're comparing state to state,
we need to lift that up a little bit more, and that it's
not so much about, you know, becoming a leader but doing
better than what your baseline is and always, you know,
looking to improve over where you are.

And then, lastly, the disaggregation needs to happen not only on race and ethnicity, but by managed care plan. We have a team that's been looking very closely at this, and, you know, there are certainly some states -- I give kudos to Darin. Tennessee has done a really good job of presenting a lot of the data on an MCO basis.

14 Pennsylvania does as well. We need to see more of that so 15 that we can really hold plans accountable for quality as 16 well.

17 CHAIR BELLA: Thank you, Tricia. Brian and then18 Fred.

19 COMMISSIONER BURWELL: I put myself very much in 20 the Martha camp about my interest in consumer grouping, 21 quality metrics, and where do CAHPS surveys fall in the 22 range of measures that states use to assess providers and

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1 health plans and make those data available to consumers.

MS. JEE: So CAHPS is optional for states, with 2 the exception of CHIP. But I think several states, 3 4 probably most states are doing CAHPS. Through the core set work, we learned that states sometimes have a hard time 5 doing the CAHPS every year because the cost of doing the 6 CAHPS we understand is guite high, and so they have to make 7 8 some decisions. Sometimes they might alternate doing the adult CAHPS one year and the child CAHPS another year. But 9 10 it is certainly a survey that states are using.

11 As far as where they are publishing those data, 12 you know, to the extent that -- if it's in the EQRO report, 13 you know, they would -- it would be -- there would be some 14 mention of it, and the EQR report is a public report. And 15 if they intend to use it as a part of their sort of 16 overarching quality approach, states would probably have described that in their quality strategy. And then, again, 17 18 for the plans, you know, as plans are doing it, and, you 19 know, usually what you see is that a state would require a 20 plan to do it in their contract, but I would expect to see 21 that the plans would also note that in their quality 22 assessment and in their quality -- the plan, sorry, quality

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1 improvement plan.

2 CHAIR BELLA: Thanks, Joanne. Fred? 3 COMMISSIONER CERISE: Thanks. So Peter mentioned 4 the two points I was going to make, but I will elaborate 5 just a little bit. So the first one is about stratifying 6 according to subgroups. I think that's important work to 7 do, and others have mentioned that, and I'm on board with 8 that as well.

9 And then regarding PIPs, I thought, again, Peter 10 made an important point about not all those should be 11 expected to be positive. It did look like the mandatory 12 PIPs had a higher success rate than the plan-driven ones, 13 and there may be some lessons there.

14 You mentioned the fact that we've talked before 15 about the demonstration waivers and not having consistent 16 reporting of outcomes there. And I think that would be 17 something to drive home again. These are demonstration 18 waivers. They should be expected to see some outcomes. 19 And then, you know, perhaps you could look in terms of the 20 mandatory PIPs or the PIPs that you would push out to 21 plans, you know, you could develop a menu of the ones that 22 we know improve quality and lower costs, and there may be a

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select few, but, you know, have a balance of mandatory ones 1 that we learn from experience are effective and push those 2 3 out, you know, use the information that we're getting a 4 little bit more -- you know, in a more structured way. CHAIR BELLA: Thank you, Fred. We have a 5 comment, and then we'll be making our way to public 6 comment. I see Kit's hand as well. Toby? 7 8 COMMISSIONER DOUGLAS: Yeah, I'm just going to touch -- there's one piece, Joanne and Naomi, that you talk 9 10 about in the report as related to this, the EHRs and the IT 11 infrastructure. I really don't want us to forget that one 12 of the biggest pieces here is the ability for providers, 13 for the delivery system to have the capacity to provide the care and have the tools. And there was the HITECH Act, and 14 15 I don't know when we and MACPAC looked at the implications, 16 the impact on that, on really advancing infrastructure different than this. But I do think if we're going to talk 17 18 about quality, we need to remember that these tools are so 19 essential for really driving quality. And we need to look 20 at the investment again and how that is played out within -- or even MITA. So just something different, off base, but 21 I think really important. 22

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1 CHAIR BELLA: Thank you, Toby. Kit. COMMISSIONER GORTON: So just in terms of 2 subpopulations, I do think we also need to keep in mind 3 4 that we -- I do this, too -- an arc to managed care because there's a much more robust quality infrastructure built 5 there. Many states still have significant fee-for-service 6 populations, and some of them are very vulnerable special 7 8 needs populations. And the statewide measures, 9 particularly in states with large managed care penetration, 10 the managed care performance will shade out the performance, or lack thereof, in the fee-for-service 11 12 population. So I do think that it's important where we can 13 -- and it's hard to do. States have struggled for years. I don't want to suggest it's easy. But where we can, make 14 15 sure that there's a little bit of light shed on management 16 of quality in the fee-for-service side of the program. I think that's an important thing to include. 17 18 CHAIR BELLA: Thank you, Kit. I have not seen any other Commissioner hands. Okay. Joanne and Naomi, 19 20 thank you again. Do you have what you need from us? 21 MS. JEE: Yeah, with lots of food for thought, so

22 that helps. Thanks.

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1 CHAIR BELLA: And I think just to clarify, we can 2 do an update any point. We don't have to wait until a 3 chapter in a report to address Tricia's point, I believe is 4 correct. Is that right?

5 MS. JEE: Yeah, I mean, we have other types of 6 publications that aren't tied to the March-June time frame, 7 but if we wanted it to be a chapter, you know, it would be 8 May and June.

9 CHAIR BELLA: Okay. All of that is meant to say 10 we have some flexibility there. Okay. Wonderful. Thank 11 you very much.

12 We are going to now turn to public comment on these sessions or other comments. And I will remind 13 14 commenters, please indicate that you'd like to speak by 15 hitting the little hand icon, and that as mentioned 16 yesterday, we are asking comments to stay within three minutes, so we can make sure that we have time to get to 17 18 all of them. If you hit your three-minute mark you will 19 hear from me, thanking you, and letting you know that your 20 time has expired and asking you to please wrap it up. And 21 if for some reason you don't wrap it up I will turn you off, but I haven't had to do that yet. 22

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1 So we will open that up now.

2 MS. HUGHES: All right. Amber, you have been 3 unmuted. You can unmute your line as well.

## 4 ### PUBLIC COMMENT

5 \* MS. CHRIST: Hi. This is Amber Christ with Justice in Aging. Thank you to the Commission for taking 6 up the topic of rebalancing. I want to emphasize the 7 8 inequities in rebalancing across states and across 9 populations. As Commissioner Scanlon noted, and was in the 10 slide, the average spending on older adults and those with 11 physical disabilities is just 32.8 percent, and, in fact, 12 half of the states are spending less than 33 percent on 13 HCBS for this population.

I also note that there are inequities based on disability among older adults. For example, 75 percent of older adults at age 80 with Alzheimer's and dementia are in a nursing home, compared to just 4 percent of the general population at age 80.

So as many Commissioners noted, we do need specific strategies to address these inequities and why states are spending so little on HCBS for older adults, that take into consideration who is being

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disproportionately harmed by the institutional bias,
including older adults of color, and the strain on families
who are serving as unpaid caregivers to fill the gaps, that
also disproportionately harms women of color.

5 I also want to emphasize that these strategies 6 for older adults must go beyond clearing waiting lists. 7 Thirty-three states have no zero older adults on their 8 waiting lists, yet 28 of those states are spending 9 significantly more on institutional care for older adults 10 than on HCBS.

11 And lastly, I want to emphasize the need for 12 missing data, as Commissioner Burwell noted. Almost 13 exclusively the data is missing from managed LTSS states, and it is particularly problematic since these states are 14 15 supposed to be testing, and CMS is supposed to be 16 monitoring how well managed care plans are delivering long-17 term services and supports. How can we possibly be 18 assessing how well these plans are doing if we do not have 19 that data? And, additionally, there is no LTSS data based 20 on demographics beyond the major population groups, including race and ethnicity, which makes it difficult if 21 22 not impossible, to assess the extent of disparities more

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1 broadly.

2 So again, thank you for taking up this important 3 issue and for the opportunity to provide public comment, 4 and it's great seeing you all.

5 CHAIR BELLA: Thank you, Amber.

6 MS. HUGHES: All right. We have Nataki. You 7 have yourself unmuted.

8 MS. MacMURRAY: Good. Good afternoon, all. This 9 is Nataki MacMurray from the Office of National Drug 10 Control Policy, and I also join with others in thanking the 11 Commission for their continued diligence and intelligence 12 on these issues.

I just wanted to make a comment, and hopefully 13 we'll hear more, about the quality measures looking at 14 15 screening. And I know we talked about screening and also 16 the use of the EPSDT option for children. And I'm not sure if we are closing the loop in our discussion of the quality 17 18 when we focus only on the screening, which, of course, we 19 see is not at full capacity. But also understanding whether or not that screening leads to services, especially 20 21 in places where we know children may be screened positive 22 for various conditions, syndromes and diseases, disorders,

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1 but may not actually be able to access care for quite some 2 time after their diagnosis.

3 So I'm sure that as you all have been looking at 4 that there may be some thought about that. I hope that I 5 will see that in the recommendations and report of how we 6 closed the loop on moving past just ensuring we're doing 7 the screening but making sure that we're also providing the 8 services that address what the screens show as positive and 9 need for action afterwards. And thank you again.

10 CHAIR BELLA: Thank you, Nataki. You are our 11 most consistent participant in public sessions, so thank 12 you.

MS. MacMURRAY: Is there a prize, or gold star or a red star or something? Thank you all.

15 CHAIR BELLA: A verbal gold star, yes. Thank 16 you.

MS. HUGHES: And Camille, you have been unmuted.You can unmute your own line and make your comment.

MS. DOBSON: Good morning, Commissioners. Camille Dobson, Deputy Executive Director at ADvancing States. We represent the aging and disability directors that deliver LTSS to those Medicaid and non-Medicaid

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individuals across the country. I wanted to commend you on the work on rebalancing. It continues to be a significant issue that our members are worried about. We have spent some time also looking at barriers, focused on those states that are underperforming, if you want to call it, in terms of serving folks in the community.

7 I wanted to echo two comments from the Commissioners. One is Chuck's comment around nursing home 8 financing and not missing the significant issue of the 9 10 reliance on nursing home taxes, the taxes for financing the 11 program. It's problematic to include those in a managed 12 care setting. It tends to be one of the biggest barriers 13 for states moving to a managed care system, which we 14 continue to try and think through -- which I was surprised 15 it didn't come up, especially in a couple of the states 16 that you talked to. They are a very, very large percentage 17 of the states' LTSS budget, almost all of it, in fact. 18 And then the other issue was I wanted to echo the

19 concern that Kit mentioned about reliance on paid family 20 caregivers and the dichotomy that occurs when the family 21 members' care for the loved on becomes the primary source 22 of income and the difficult position that places consumers.

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We have a number of states that are increasing self-1 direction as a way to address the workforce shortage, 2 because they can usually find a family member or a friend 3 4 faster and easier than they can find a paid worker from an agency. But it comes with unintended consequences, and our 5 states continue to struggle with that, especially during 6 COVID, when many states expanded the use of paid family 7 8 caregivers to address the lack of day activities for folks.

9 So I just wanted to say thank you again. I don't 10 envy Kristal and Tamara trying to wade through all of the 11 topics that were raised today and offshoots of the work. 12 And we're also actually very interested in the benefit design issue that Melanie raised. You know, there are a 13 handful of states that have successfully built a pre-duals, 14 15 at-risk population benefit package and have been 16 successful, based on their evidence, in diverting or 17 delaying full Medicaid eligibility. And so I think that's a really interesting area for you to pursue as well. Thank 18 19 you.

20 CHAIR BELLA: Thank you, Camille. You also get a 21 gold star for consistent participation, and we appreciate 22 your input very much.

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1 MS. DOBSON: Thank you.

MS. HUGHES: Sue, you have been unmuted.
MS. PESCHIN: Hi, did you say Sue?

4 MS. HUGHES: Yes.

MS. PESCHIN: Oh, hi. Okay. Thank you. My name 5 is Sue Peschin and I serve as President and CEO of the 6 Alliance for Aging Research, and the Alliance is the 7 8 leading nonprofit that promotes research to improve aging 9 and health. And I am here today to try to urge you to 10 please delay the votes on the proposals for limited Medicaid coverage for accelerated approval drugs, and I 11 12 have three quick reasons why.

First is we joined the Partnership to Fight Chronic Diseases and 31 other patient-focused groups in a comment letter that I think you all have, highlight an economic analysis by Dr. Ken Thorpe at the Rollins School of Public Health at Emory, and Chair of the Partnership, and Doug Holtz-Eakin, who is a former economics professor at Syracuse and former Director of CBO.

And these guys are worth listening to, and they found that the accelerated approval drugs account for less than 1 percent of overall Medicaid spending a year, between

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1 2007 and 2018, but those drugs often represent the only 2 treatment options available for beneficiaries. And they 3 had the commentary in AJMC, where they said, "Limiting 4 Medicaid coverage for accelerated approval drugs would have 5 a devastating impact on patients benefitting from these 6 treatments, while having a de minimis impact on spending."

So the bottom line is you're not going to get a
lot of juice for the squeeze, except hurting patients with
rare and complex diseases that don't have other options.

10 I wanted to give a shout-out to Commissioner Tom 11 Barker, who is correct when he suggests that issues with 12 the accelerated approval program should be addressed by the They know it and they are taking action, and, in 13 FDA. fact, they have a meeting next week with Friends of Cancer 14 15 Research to discuss this very topic. And the FDA's 16 Oncologic Drugs Advisory Committee is holding a three-day 17 meeting at the end of the month on confirmatory studies.

18 The FDA Oncology Center of Excellence Director, 19 Richard Padzur, has called for a re-examination of the 20 accelerated approval strengths and weaknesses and 21 consideration for changes within the 21st Century Cures 2.0 22 legislation. So why vote now before the experts on this

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1 issue convene?

And my last point is that comments made by some 2 yesterday about sharing risks, putting pressure on 3 4 industry, not to mention the one about how this will help patients, are just plain wrong. In many instances, 5 industry is going to respond by abandoning clinical 6 development for rare diseases with small populations, and 7 even ISER said this in a recent policy paper they had on 8 9 the subject. In short, and this is a quote, "AAP might dry 10 up entirely with companies only willing to invest in the 11 areas where they can use the regular approval pathway." 12 And I don't know if any of you have personal family experiences with cystic fibrosis, sickle cell 13 diseases, or rare cancers, not to mention HIV/AIDS, who 14 15 have all benefitted from accelerated approval drugs. This 16 is life or death for them. Delays in access barriers are going to have deadly consequences. 17 18 So I want you to please let the FDA do their work

10 So I want you to please let the FDA do their work 19 on this over the next 6 to 12 months, and delay this vote. 20 You will not regret it. Please do it.

21 CHAIR BELLA: Thank you, Sue. I want to see if 22 we have any other comments and then I just want to clarify

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1 a couple of points for the record. It doesn't look like we 2 have any other comments.

Just to clarify, on the recommendation, nothing 3 4 in that recommendation changes the accelerated approval process, nor does it limit Medicaid coverage of the drugs. 5 So I want to be very clear. Medicaid will still be 6 required to cover those products, and we are not at all 7 8 making any changes to the accelerated approval process. 9 And so if that is not clear we are happy to have additional 10 conversations outside of this meeting, but it's very 11 important to make sure that we are clear on the record for 12 that. Nothing changes in the coverage of Medicaid of these products with this recommendation I will be voting on this 13 14 afternoon. But I do appreciate your comments. Thank you. 15 Okay. We are wrapping up this session and 16 heading into a break. We will come back at 1:15, after the break, and we will vote on the recommendations for the June 17

18 report. Following the vote on the recommendations, we will 19 have an update on T-MSIS and then we will finish the day 20 with a panel discussion on what states are learning from 21 the expanded use of telehealth.

22 Thank you, everyone.

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1	Thank you, Commissioners, thank you to the public
2	who joined, and we will reconvene at 1:15. Thank you.
3	* [Whereupon, at 12:19 p.m., the meeting was
4	recessed, to reconvene at 1:15 p.m. this same day.]
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AFTERNOON SESSION

2

1

[1:16 p.m.]

3 CHAIR BELLA: Welcome back, everyone. I'll try 4 to figure out how to get my face back up there, but I don't 5 want to delay the votes.

I think we are ready to turn to the vote. Chuck,did you want to do the conflict of interest?

8 ### VOTES ON RECOMMENDATIONS FOR JUNE 2021 REPORT TO 9 CONGRESS

10 \* VICE CHAIR MILLIGAN: Yes, happy to.

11 This is a voting meeting, and as a result, 12 MACPAC's conflict of interest rules apply. Our policies 13 are posted on the MACPAC website under the tab about 14 MACPAC.

15 On March 22nd, the MACPAC Conflict of Interest 16 Committee met by conference call and determines that for purposes of our votes today, under the particularly, 17 directly, predictably, and significantly standard that 18 governs our deliberations, no Commissioner has an interest 19 20 that present a potential or actual conflict of interest 21 related to the recommendations under consideration today. 22 CHAIR BELLA: Thank you, Chuck.

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Anne, do you want to take us through the votes? EXECUTIVE DIRECTOR SCHWARTZ: Sure. We're going to go through the votes. We have six votes. I apologize. It will be a little bit tedious because we're also going to read the recommendation language off the slides so they'll be in the transcript.

7 Chris is here with us. Chris, do you mind
8 advancing the slide to the first recommendation
9 accelerating approval drugs?

10 MR. PARK: Okay. Recommendation 1 reads: 11 "Congress should amend Section 1927(c)(1) of the Social 12 Security Act to increase the minimum rebate percentage on 13 drugs that receive approval from the U.S. Food and Drug 14 Administration through the accelerated approval pathway 15 under Section 506(c) of the Federal Food, Drug, and 16 Cosmetic Act. This increased rebate percentage would apply until the manufacturer has completed the postmarketing 17 18 confirmatory trial and been granted traditional FDA 19 approval. Once the FDA grants traditional approval, the 20 minimum rebate percentage would revert back to the amount 21 listed under Section 1927(c)(1)(B)(i)."

22 EXECUTIVE DIRECTOR SCHWARTZ: Okay. Thanks,

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1 Chris.

2		I'm going to call the roll in alphabetical order,
3	the chair	last, and you can vote yes, no, or abstain.
4		Tom Barker?
5		COMMISSIONER BARKER: No.
6		EXECUTIVE DIRECTOR SCHWARTZ: Tricia Brooks?
7		COMMISSIONER BROOKS: Yes.
8		EXECUTIVE DIRECTOR SCHWARTZ: Brian Burwell?
9		COMMISSIONER BURWELL: Yes.
10		EXECUTIVE DIRECTOR SCHWARTZ: Martha Carter?
11		COMMISSIONER CARTER: Yes.
12		EXECUTIVE DIRECTOR SCHWARTZ: Fred Cerise?
13		COMMISSIONER CERISE: Yes.
14		EXECUTIVE DIRECTOR SCHWARTZ: Kisha Davis?
15		COMMISSIONER DAVIS: Yes.
16		EXECUTIVE DIRECTOR SCHWARTZ: Toby Douglas?
17		COMMISSIONER DOUGLAS: Yes.
18		EXECUTIVE DIRECTOR SCHWARTZ: Leanna George?
19		COMMISSIONER GEORGE: Yes.
20		EXECUTIVE DIRECTOR SCHWARTZ: Darin Gordon?
21		COMMISSIONER GORDON: Yes.
22		EXECUTIVE DIRECTOR SCHWARTZ: Kit Gorton?

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1	COMMISSIONER GORTON: Yes.
2	EXECUTIVE DIRECTOR SCHWARTZ: Stacey Lampkin?
3	COMMISSIONER LAMPKIN: Yes.
4	EXECUTIVE DIRECTOR SCHWARTZ: Chuck Milligan?
5	VICE CHAIR MILLIGAN: Yes.
6	EXECUTIVE DIRECTOR SCHWARTZ: Sheldon Retchin?
7	COMMISSIONER RETCHIN: Yes.
8	EXECUTIVE DIRECTOR SCHWARTZ: Bill Scanlon?
9	COMMISSIONER SCANLON: Yes.
10	EXECUTIVE DIRECTOR SCHWARTZ: Peter Szilagyi?
11	COMMISSIONER SZILAGYI: Yes.
12	EXECUTIVE DIRECTOR SCHWARTZ: Kathy Weno?
13	COMMISSIONER WENO: Yes.
14	EXECUTIVE DIRECTOR SCHWARTZ: Melanie Bella?
15	CHAIR BELLA: Yes.
16	EXECUTIVE DIRECTOR SCHWARTZ: Okay. That's 16
17	yea, 1 nay.
18	Okay. Chris, if you could advance the slide.
19	MR. PARK: Okay. Recommendation 2 reads:
20	"Congress should amend Section 1927(c)(2) of the Social
21	Security Act to increase the additional inflationary rebate
22	on drugs that receive approval from the U.S. Food and Drug

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Administration through the accelerated approval pathway 1 under Section 506(c) of the Federal Food, Drug, and 2 3 Cosmetic Act. This increased inflationary rebate would go 4 into effect if the manufacturer has not yet completed the postmarketing confirmatory trial and been granted 5 traditional FDA approval after a specified number of years. 6 7 Once the FDA grants traditional approval, the inflationary 8 rebate would revert back to the amount typically calculated 9 under Section 1927(c)(2)." 10 EXECUTIVE DIRECTOR SCHWARTZ: Thank you. 11 Okay. Calling the roll. Tom Barker? 12 COMMISSIONER BARKER: No. 13 EXECUTIVE DIRECTOR SCHWARTZ: Tricia Brooks? 14 COMMISSIONER BROOKS: Yes. 15 EXECUTIVE DIRECTOR SCHWARTZ: Brian Burwell? 16 COMMISSIONER BURWELL: Yes. EXECUTIVE DIRECTOR SCHWARTZ: Martha Carter? 17 18 COMMISSIONER CARTER: Yes. 19 EXECUTIVE DIRECTOR SCHWARTZ: Fred Cerise? 20 COMMISSIONER CERISE: Yes. 21 EXECUTIVE DIRECTOR SCHWARTZ: Kisha Davis? 22 COMMISSIONER DAVIS: Yes.
1	EXECUTIVE DIRECTOR SCHWARTZ:	Toby Douglas?
2	COMMISSIONER DOUGLAS: Yes.	
3	EXECUTIVE DIRECTOR SCHWARTZ:	Leanna George?
4	COMMISSIONER GEORGE: Yes.	
5	EXECUTIVE DIRECTOR SCHWARTZ:	Darin Gordon?
6	COMMISSIONER GORDON: Yes.	
7	EXECUTIVE DIRECTOR SCHWARTZ:	Kit Gorton?
8	COMMISSIONER GORTON: Yes.	
9	EXECUTIVE DIRECTOR SCHWARTZ:	Stacey Lampkin?
10	COMMISSIONER LAMPKIN: Yes.	
11	EXECUTIVE DIRECTOR SCHWARTZ:	Chuck Milligan?
12	VICE CHAIR MILLIGAN: Yes.	
13	EXECUTIVE DIRECTOR SCHWARTZ:	Sheldon Retchin?
14	COMMISSIONER RETCHIN: Yes.	
15	EXECUTIVE DIRECTOR SCHWARTZ:	Bill Scanlon?
16	COMMISSIONER SCANLON: Yes.	
17	EXECUTIVE DIRECTOR SCHWARTZ:	Peter Szilagyi?
18	COMMISSIONER SZILAGYI: Yes.	
19	EXECUTIVE DIRECTOR SCHWARTZ:	Kathy Weno?
20	COMMISSIONER WENO: Yes.	
21	EXECUTIVE DIRECTOR SCHWARTZ:	Melanie Bella?
22	CHAIR BELLA: Yes.	

1 EXECUTIVE DIRECTOR SCHWARTZ: Okay. 16 yes and 1 2 no. 3 That completes the accelerated approval drugs. Next, we have the two recommendations from the 4 chapter on mental health services for adults. 5 6 [Pause.] 7 EXECUTIVE DIRECTOR SCHWARTZ: Okay. I don't know if Erin is going to join us. It's not absolutely 8 9 necessary. Oh, there she is. Okay. 10 Erin, you can advance the slide, and if you would 11 read the recommendation. 12 MS. McMULLEN: Okay. Give me one second. Sorry. It looks like I'm having trouble advancing them. 13 14 MR. BOISSONNAULT: Erin, you have the mouse now. 15 MS. McMULLEN: Thanks. There we go. All right. 16 So Recommendation 2.1 reads: "The Secretary of the U.S. Department of Health and Human Services should 17 direct the Centers for Medicare & Medicaid Services and the 18 Substance Abuse and Mental Health Services Administration 19 20 to issue joint sub-regulatory that addresses how Medicaid 21 and the state Children's Health Insurance Program can be used to fund a crisis continuum for beneficiaries 22

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1	experienci	ng behavioral health crises."
2		EXECUTIVE DIRECTOR SCHWARTZ: Okay. Call in the
3	roll.	
4		Tom Barker?
5		COMMISSIONER BARKER: Oops. Sorry. I was on
6	mute.	
7		I vote yes.
8	:	EXECUTIVE DIRECTOR SCHWARTZ: Tricia Brooks?
9		COMMISSIONER BROOKS: Yes.
10		EXECUTIVE DIRECTOR SCHWARTZ: Brian Burwell?
11		COMMISSIONER BURWELL: Yes.
12	:	EXECUTIVE DIRECTOR SCHWARTZ: Martha Carter?
13		COMMISSIONER CARTER: Yes.
14		EXECUTIVE DIRECTOR SCHWARTZ: Fred Cerise?
15		COMMISSIONER CERISE: Yes.
16		EXECUTIVE DIRECTOR SCHWARTZ: Kisha Davis?
17		COMMISSIONER DAVIS: Yes.
18		EXECUTIVE DIRECTOR SCHWARTZ: Toby Douglas?
19		COMMISSIONER DOUGLAS: Yes.
20		EXECUTIVE DIRECTOR SCHWARTZ: Leanna George?
21		COMMISSIONER GEORGE: Yes.
22		EXECUTIVE DIRECTOR SCHWARTZ: Darin Gordon?

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1	COMMISSIONER GORDON: Yes.
2	EXECUTIVE DIRECTOR SCHWARTZ: Kit Gorton?
3	COMMISSIONER GORTON: Yes.
4	EXECUTIVE DIRECTOR SCHWARTZ: Stacey Lampkin?
5	COMMISSIONER LAMPKIN: Yes.
6	EXECUTIVE DIRECTOR SCHWARTZ: Chuck Milligan?
7	VICE CHAIR MILLIGAN: Yes.
8	EXECUTIVE DIRECTOR SCHWARTZ: Sheldon Retchin?
9	COMMISSIONER RETCHIN: Yes.
10	EXECUTIVE DIRECTOR SCHWARTZ: Bill Scanlon?
11	COMMISSIONER SCANLON: Yes.
12	EXECUTIVE DIRECTOR SCHWARTZ: Peter Szilagyi?
13	COMMISSIONER SZILAGYI: Yes.
14	EXECUTIVE DIRECTOR SCHWARTZ: Kathy Weno?
15	COMMISSIONER WENO: Yes.
16	EXECUTIVE DIRECTOR SCHWARTZ: Melanie Bella?
17	CHAIR BELLA: Yes.
18	EXECUTIVE DIRECTOR SCHWARTZ: 17 yes.
19	Next recommendation.
20	MS. McMULLEN: Okay. Recommendation 2.2 reads:
21	"The Secretary of the U.S. Department of Health and Human
22	Services should direct a coordinated effort by the Centers

1	for Medicare & Medicaid Services and the Substance Abuse
2	and Mental Health Services Administration to provide
3	education and technical assistance on the implementation of
4	a behavioral health crisis continuum that coordinates and
5	responds to people in crisis in real-time. Additionally,
6	the Secretary should examine options to use existing
7	federal funding to support state-level activities to
8	improve the availability of crisis services."
9	EXECUTIVE DIRECTOR SCHWARTZ: Okay. Tom Barker?
10	COMMISSIONER BARKER: Yes.
11	EXECUTIVE DIRECTOR SCHWARTZ: Tricia Brooks?
12	COMMISSIONER BROOKS: Yes.
13	EXECUTIVE DIRECTOR SCHWARTZ: Brian Burwell?
14	COMMISSIONER BURWELL: Yes.
15	EXECUTIVE DIRECTOR SCHWARTZ: Martha Carter?
16	COMMISSIONER CARTER: Yes.
17	EXECUTIVE DIRECTOR SCHWARTZ: Fred Cerise?
18	COMMISSIONER CERISE: Yes.
19	EXECUTIVE DIRECTOR SCHWARTZ: Kisha Davis?
20	COMMISSIONER DAVIS: Yes.
21	EXECUTIVE DIRECTOR SCHWARTZ: Toby Douglas?
22	COMMISSIONER DOUGLAS: Yes.

1	EXECUTIVE DIRECTOR SCHWARTZ:	Leanna George?
2	COMMISSIONER GEORGE: Yes.	
3	EXECUTIVE DIRECTOR SCHWARTZ:	Darin Gordon?
4	COMMISSIONER GORDON: Yes.	
5	EXECUTIVE DIRECTOR SCHWARTZ:	Kit Gorton?
6	COMMISSIONER GORTON: Yes.	
7	EXECUTIVE DIRECTOR SCHWARTZ:	Stacey Lampkin?
8	COMMISSIONER LAMPKIN: Yes.	
9	EXECUTIVE DIRECTOR SCHWARTZ:	Chuck Milligan?
10	VICE CHAIR MILLIGAN: Yes.	
11	EXECUTIVE DIRECTOR SCHWARTZ:	Sheldon Retchin?
12	COMMISSIONER RETCHIN: Yes.	
13	EXECUTIVE DIRECTOR SCHWARTZ:	Bill Scanlon?
14	COMMISSIONER SCANLON: Yes.	
15	EXECUTIVE DIRECTOR SCHWARTZ:	Peter Szilagyi?
16	COMMISSIONER SZILAGYI: Yes.	
17	EXECUTIVE DIRECTOR SCHWARTZ:	Kathy Weno?
18	COMMISSIONER WENO: Yes.	
19	EXECUTIVE DIRECTOR SCHWARTZ:	Melanie Bella?
20	CHAIR BELLA: Yes.	
21	EXECUTIVE DIRECTOR SCHWARTZ:	Okay. 17 in favor.
22	Okay. That concludes that ch	apter, and we're

1 moving on to children and adolescents.

2 Melinda, go for it.

MS. ROACH: "The Secretary of Health and Human 3 Services should direct the Centers for Medicare & Medicaid 4 Services, the Substance Abuse and Mental Health Services 5 Administration, and the Administration for Children and 6 7 Families to issue joint sub-regulatory guidance that 8 addresses the design and implementation of benefits for 9 children and adolescents with significant mental health 10 conditions covered by Medicaid and the state Children's 11 Health Insurance Program." 12

12 EXECUTIVE DIRECTOR SCHWARTZ: Okay. Tom Barker?13 COMMISSIONER BARKER: Yes.

14 EXECUTIVE DIRECTOR SCHWARTZ: Tricia Brooks?

15 COMMISSIONER BROOKS: Yes.

16 EXECUTIVE DIRECTOR SCHWARTZ: Brian Burwell?17 COMMISSIONER BURWELL: Yes.

18 EXECUTIVE DIRECTOR SCHWARTZ: Martha Carter?

19 COMMISSIONER CARTER: Yes.

- 20 EXECUTIVE DIRECTOR SCHWARTZ: Fred Cerise?
- 21 COMMISSIONER CERISE: Yes.
- 22 EXECUTIVE DIRECTOR SCHWARTZ: Kisha Davis?

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1	COMMISSIONER DAVIS: Yes.	
2	EXECUTIVE DIRECTOR SCHWARTZ:	Toby Douglas?
3	COMMISSIONER DOUGLAS: Yes.	
4	EXECUTIVE DIRECTOR SCHWARTZ:	Leanna George?
5	COMMISSIONER GEORGE: Yes.	
6	EXECUTIVE DIRECTOR SCHWARTZ:	Darin Gordon?
7	COMMISSIONER GORDON: Yes.	
8	EXECUTIVE DIRECTOR SCHWARTZ:	Kit Gorton?
9	COMMISSIONER GORTON: Yes.	
10	EXECUTIVE DIRECTOR SCHWARTZ:	Stacey Lampkin?
11	COMMISSIONER LAMPKIN: Yes.	
12	EXECUTIVE DIRECTOR SCHWARTZ:	Chuck Milligan?
13	VICE CHAIR MILLIGAN: Yes.	
14	EXECUTIVE DIRECTOR SCHWARTZ:	Sheldon Retchin?
15	COMMISSIONER RETCHIN: Yes.	
16	EXECUTIVE DIRECTOR SCHWARTZ:	Bill Scanlon?
17	COMMISSIONER SCANLON: Yes.	
18	EXECUTIVE DIRECTOR SCHWARTZ:	Peter Szilagyi?
19	COMMISSIONER SZILAGYI: Yes.	
20	EXECUTIVE DIRECTOR SCHWARTZ:	Kathy Weno?
21	COMMISSIONER WENO: Yes.	
22	EXECUTIVE DIRECTOR SCHWARTZ:	Melanie Bella?

1

CHAIR BELLA: Yes.

2 EXECUTIVE DIRECTOR SCHWARTZ: 17 in favor.3 Last one.

4 MS. ROACH: "The Secretary of Health and Human Services should direct a coordinated effort by the Centers 5 for Medicare & Medicaid Services, the Substance Abuse and 6 Mental Health Services Administration, and the 7 8 Administration for Children and Families to provide 9 education and technical assistance to states on improving 10 access to home- and community-based behavioral health 11 services for children and adolescents with significant 12 mental health conditions covered by Medicaid and the state 13 Children's Health Insurance Program. Additionally, the 14 Secretary should examine options to use existing federal 15 funding to support state-level activities to improve the 16 availability of these services."

17 CHAIR BELLA: Okay. Tom Barker?

18 COMMISSIONER BARKER: Yes.

EXECUTIVE DIRECTOR SCHWARTZ: Tricia Brooks?
 COMMISSIONER BROOKS: Yes.

21 EXECUTIVE DIRECTOR SCHWARTZ: Brian Burwell?22 COMMISSIONER BURWELL: Yes.

1	EXECUTIVE DIRECTOR SCHWARTZ:	Martha Carter?
_		narena career.
2	COMMISSIONER CARTER: Yes.	
3	EXECUTIVE DIRECTOR SCHWARTZ:	Fred Cerise?
4	COMMISSIONER CERISE: Yes.	
5	EXECUTIVE DIRECTOR SCHWARTZ:	Kisha Davis?
6	COMMISSIONER DAVIS: Yes.	
7	EXECUTIVE DIRECTOR SCHWARTZ:	Toby Douglas?
8	COMMISSIONER DOUGLAS: Yes.	
9	EXECUTIVE DIRECTOR SCHWARTZ:	Leanna George?
10	COMMISSIONER GEORGE: Yes.	
11	EXECUTIVE DIRECTOR SCHWARTZ:	Darin Gordon?
12	COMMISSIONER GORDON: Yes.	
13	EXECUTIVE DIRECTOR SCHWARTZ:	Kit Gorton?
14	COMMISSIONER GORTON: Yes.	
15	EXECUTIVE DIRECTOR SCHWARTZ:	Stacey Lampkin?
16	COMMISSIONER LAMPKIN: Yes.	
17	EXECUTIVE DIRECTOR SCHWARTZ:	Chuck Milligan?
18	VICE CHAIR MILLIGAN: Yes.	
19	EXECUTIVE DIRECTOR SCHWARTZ:	Sheldon Retchin?
20	COMMISSIONER RETCHIN: Yes.	
21	EXECUTIVE DIRECTOR SCHWARTZ:	Bill Scanlon?
22	COMMISSIONER SCANLON: Yes.	

1 EXECUTIVE DIRECTOR SCHWARTZ: Peter Szilagyi? COMMISSIONER SZILAGYI: Yes. 2 3 EXECUTIVE DIRECTOR SCHWARTZ: Kathy Weno? COMMISSIONER WENO: Yes. 4 EXECUTIVE DIRECTOR SCHWARTZ: Melanie Bella? 5 CHAIR BELLA: Yes. 6 7 EXECUTIVE DIRECTOR SCHWARTZ: Okay. That 8 concludes the voting with six recommendations adopted. The 9 record of the vote on each becomes a part of each chapter 10 when our June report is published. 11 CHAIR BELLA: Okay. Thank you, Anne. Thank you, 12 Commissioners. We are now going to roll into our second-to-last 13 14 session which is an update on the T-MSIS work. Aaron and Chris are joining us for this session. I turn it over to 15 16 you guys whenever you're ready to get started. 17 ### UPDATE ON WORK WITH T-MSIS 18 \* MR. PERVIN: Thank you, Commissioners. 19 In 2019, Chris provided an overview of the 20 Transformed Medicaid Statistical Information System, or T-MSIS. Today Chris and I will provide an update on that 21 22 dataset.

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Also, even though Chris and I are presenting this
 work, many others have helped in T-MSIS assessment,
 including Jerry Mi, Kirstin Blom, Ashley Semanskee, and
 also Kacey Buderi on the NEMT work.

5 So I wanted to provide an overview of the presentation; first of all, provide a little bit of 6 background on T-MSIS. Then we will provide a summary on 7 8 how data has improved between the 2016 and 2018 data years. We will then walk you through a couple of examples of our 9 10 T-MSIS validation process. Then we will discuss some of 11 the challenges with working with T-MSIS data and also some 12 of its limitations. Finally, we will conclude the 13 presentation by showing how we are incorporating T-MSIS 14 into our 2022 report cycle.

15 First, as a little bit of background, T-MSIS is 16 an update of the old Medicaid Statistical Information System, and states started transitioning to T-MSIS starting 17 18 in 2013 and most recently completed their transition by 19 2016. T-MSIS also remains the only Medicaid data source 20 for information on eligibility, demographics, service use, 21 and spending at the person level. Compared to MSIS, there 22 are 1,400 data elements, and CMS runs over 2,800 automated

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quality checks. There are eight data files, which includes a demographic and eligibility file, four claim files for patient, inpatient, drugs, long-term services and supports, and other services. There's also managed care and a thirdparty liability file.

As of this year, all states, D.C., Puerto Rico, and the U.S. Virgin Islands are regularly submitting data. Parts of this presentation will also include data from CMS's Data Quality Atlas. The DQ Atlas is a must-read for data wonks and summarizes the quality of state-level data submissions.

12 Overall, the quality of data has improved since 13 our previous presentation on 2016 data. We used CMS's DQ 14 Atlas to update some of the analyses we presented in 2019. 15 The Data Quality Atlas categorizes states as having a low, 16 medium, or high concern or unusable data for specific 17 variables. This chart provides an example of how 18 enrollment data improved between the 2016 and 2018 data 19 years.

20 We looked at the variables that are used to 21 identify overall Medicaid enrollment, enrollment among the 22 Medicaid expansion population, those who are dually

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eligible for both Medicare and Medicaid, and the managed 1 care enrollment. As you can see, the number of states that 2 3 are either a low or medium concern, according to CMS, increased within three of these categories and stayed the 4 same for managed care enrollment. It should also be noted 5 that states are rarely submitting uniformly good data. 6 Different states are good at submitting different kinds of 7 8 variable, but states with a low concern for dually 9 eligible, that does not mean they are a low concern for 10 newly eligible.

11 For example, we see here that there are 31 states 12 that are the low or medium concern for the Medicaid 13 expansion population and 36 states that are low or medium concern for managed care enrollment. If we wanted to do an 14 15 analysis on the newly eligible within managed care, 16 however, we would only have 24 states that are low or 17 medium concern. Therefore, when validating our results, we 18 can't just assume that a state with good data for some 19 variables has good data for the other variables. Any time 20 we add a parameter to our analyses, we need to assess its 21 validity for each state.

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22 We have used T-MSIS in two different publications
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this year. We were able to use Fiscal Year 2018 T-MSIS 1 data for the 2020 MACStats data book. This included 2 enrollment and spending by states and eligibility groups. 3 4 We were also able to use this data in our mandatory report 5 to Congress on non-emergency medical transportation, which Kacey presented yesterday. The NEMT report uses T-MSIS to 6 determine NEMT use eligibility group and some selected 7 8 diagnoses, and it was also used to calculate NEMT spending.

9 The data team has relied on a couple of methods 10 to ensure the reliability of different analyses. One 11 method that we used is to aggregate enrollment for spending 12 into large and recognizable buckets. When we aggregate the 13 data into all the tables, for example, that tends to be more accurate than if we looked at a more granular 14 15 eligibility group such as qualified disabled and working 16 individuals.

17 Similarly, if we aggregate some spending data 18 into all acute care spending, that is more accurate than 19 just looking at diagnostic and screening services. We also 20 find that states tend to be better are reporting variables 21 that were also reporting in MSIS, likely due to the 22 familiarity that they had in reporting that information.

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Thirdly, we also find when we rely on variables that are
 required for provider payment, such as diagnosis or
 procedure codes, there tends to be greater reliability in
 our findings.

5 This chart shows how reported T-MSIS spending 6 compared to reported CMS-64 spending on the financial 7 management reports, or FMRs. As you can see, 43 states are 8 within 20 percent of the FMRs. Again, however, when you 9 start looking at more granular spending buckets,

10 inaccuracies may increase.

I will now turn the presentation over to Chris who will provide a few examples for how we validate our results.

14 \* MR. PARK: Thanks, Aaron. If you could go to the 15 next slide.

So even though we were able to use T-MSIS data to produce state-level estimates on enrollment and spending for MACStats we still need to review each state's data if we want to do a more granular analysis, for specific populations or specific services. The MACStats methodology aggregates services into large categories that allow us to make adjustments to match the CMS-64. This adjustment to

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the CMS-64 smooths out some of the problematic spending anomalies that we saw in the earlier slide. This adjustment cannot necessarily be applied to analyses of more granular data such as specific services and provider types, so we will need to continue to review each state's results for anomalies to determine if they should be included in the specific analysis.

8 As mentioned earlier, states are generally 9 reporting a reasonable number of total enrollees, but there 10 may be some large differences at the specific eligibility level. For example, as noted in our MACStats exhibits, 11 12 Vermont did not report any enrollment in the new adult group for fiscal year 2018, but has reported approximately 13 58,000 average monthly enrollees on the CMS-64 enrollment 14 15 report. Because Vermont's total enrollment in T-MSIS 16 matched fairly well with the CMS-64 enrollment report, it 17 indicates that the state likely classified beneficiaries 18 that should have been in the new adult group under some 19 other adult category.

Additionally, there may be multiple variables that can be used to identify a particular type of service, such as home and community-based services. States may not

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be consistently classifying a claim the same way across these different variables, and we need to do investigations on which variables to use to identify those services. I'll walk you through this example in the next couple of slides.

5 Finally, we will need to investigate the 6 completeness of managed care encounter data. Our early 7 analyses have shown that states are submitting more 8 encounter data than they did previously, but we must still 9 check to see if all plans in the states are reporting 10 sufficient encounter data for all types of services.

11 Next slide.

12 On these next couple of slides I'll walk you through the work we did to identify non-institutional long-13 14 term services and supports or LTSS for MACStats analyses. 15 This graph shows the amount of spending identified by the 16 multiple variables that could be used to identify non-17 institutional LTSS, including program type, type of service, HCBS service codes, CMS-64 service codes, and 18 19 waiver type. We also used procedure codes to identify 20 personal care services.

21 We looked at each of these variables individually 22 to see how much non-institutional LTSS spending was

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identified compared to what was reported on the CMS-64. We also looked at the aggregate of non-institutional LTSS spending identified by any combination of these variables, which is this first bar, labeled "any variable," on the left.

Amounts of spending under each variable was also 6 identified by one of the other variables. The green part 7 8 of the bar shows how much spending overlapped with other 9 variables, and the dark blue part shows the amount of 10 spending that was identified by the variable alone, that 11 is, the amount of spending that was identified by that 12 variable but no other variable. For example, of the \$59.7 billion that was identified by type of service, \$12.3 13 14 billion was only identified by type of service while \$47.4 15 billion was identified by at least one other variable.

As shown on the graph, using any combination of these variables, the far-left bar, overstated the amount of non-institutional LTSS spending, \$83.9 billion in T-MSIS nationally compared to the \$71.5 billion reported on the CMS-64. However, each variable by itself did not show enough spending compared to the CMS-64. The most by any single variable was \$59.7 billion under type of service.

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Next slide.

I'll walk through this slide in more detail, but the main takeaway here is that because spending from any single variable was too low and the spending from all variables together was too high, we had to look at different combinations of the variables to see if we could improve the identification algorithm.

8 The dark blue line at the top shows the national amounts of spending, identified as non-institutional LTSS, 9 10 on the various combinations of variables. The dark green 11 bars at the bottom show the number of states with T-MSIS 12 spending that was within 20 percent of the value the state 13 reported on the CMS-64. Starting from the left, the "any variable" category is the same as the previous slide. The 14 15 next category, "at least two variables," means that at 16 least two variables on the claim corresponded to noninstitutional LTSS. This approach would be less likely to 17 18 falsely identify a claim as non-institutional LTSS, because 19 at least two variables would be in agreement. But it is a 20 conservative approach. As you can see, it only identified 21 \$56.4 billion in spending, in the blue line at the top, and 22 32 states in the green bar at the bottom were within 20

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1 percent of the CMS-64.

2	Next we moved to a combination of program type or
3	type of service, which is combination A on the chart, since
4	those two variables identified the most spending
5	individually. This combination identified \$69.6 billion in
6	spending and got close to the CMS-64 total of \$71.5
7	billion, and 38 states were within 20 percent.
8	Moving right to combination B, we then added the
9	CMS-64 service category variable to the previous
10	combination. That moves us even closer with \$70.3 billion,
11	and we still had 38 states within 20 percent. We then move
12	to combination C, which added personal care procedure codes
13	to combination B. Spending moved even closer to the CMS-64
14	benchmark, but it reduced the number of states within the
15	20 percent range, to 36. And then in combination D, which
16	added waiver type, we see that we go over the CMS-64
17	benchmark and even fewer states are within that 20 percent
18	range.

19 So ultimately we used combination B, which is 20 highlighted in the red square, because it had the best 21 match of both the national spending level and the most 22 states that were within 20 percent of the state's CMS-64

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1 spending.

2

Next slide.

As mentioned previously, states are submitting 3 4 more encounter data in T-MSIS compared to MSIS. Our work for the June chapter on NEMT identified several million 5 NEMT encounter claims from both comprehensive managed care 6 and transportation plans. However, this analysis only 7 looked at a subset of all encounters and of all plans, and 8 9 not all plans in the state were submitting similar amounts 10 of encounter data. Although we included encounter data as 11 part of our analyses for the NEMT chapter, more work is 12 needed to determine whether encounter data is complete for other analyses. For example, CMS has identified eight 13 states in 2018 as having inpatient encounter data that are 14 15 either a high concern or unusable.

16

Next slide.

As we move forward, there will be ongoing challenges in using the T-MSIS data for certain analyses. Certain services do not have a standard definition. States have a large degree of autonomy in how these services are defined. For example, behavioral health does not have a specific type of service value and could be included in

multiple categories, such as physician or clinic services.
Additionally, there is not a standard set of services, and
states vary in what services they cover, including services
offered through a waiver that may use state specific
billing codes. Consequently, MACPAC may need to come up
with a state-specific selection criteria to define these
set of services.

As we presented last September, there are high 9 rates of missing or unknown values for race and ethnicity 10 for states within T-MSIS. It is difficult to know whether 11 this is because the state is not reporting these data 12 properly or whether these data are not collected on the 13 application. Individuals may choose not to disclose their 14 race or ethnicity when applying for or renewing coverage.

Additionally, many of the data improvements that have been made have only been applied going forward, and we don't know if states will eventually go back to making improvements to earlier time periods. As such, the data for earlier years may not be as complete and we may have difficulty in using these data from those years.

21 Next slide.

22 While T-MSIS provides a wealth of information,

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data are generally limited to beneficiary information 1 collected on the application and service utilization and 2 3 spending information captured on claims. It does not have 4 information on the beneficiary experience such as satisfaction or unmet needs, which may be captured by 5 surveys. Additionally, while medical claims can measure 6 utilization, they cannot be used to measure certain health 7 8 outcomes or complications. T-MSIS does not include 9 information that is captured in medical records but not 10 included on a claim, such as lab test results. This means 11 that T-MSIS is limited in its ability to identify certain 12 outcomes.

13 Next slide.

14 Looking forward, MACPAC expects to use T-MSIS for 15 several purposes. We will assess the usability of T-MSIS 16 for other projects, but our current priorities include the 17 following. We will update the MACStats data book for the 18 2021 publication. We are also planning on doing the joint 19 data book with MedPAC on beneficiaries dually eligible for 20 Medicare and Medicaid. As you heard earlier this morning, 21 we will be looking at data for beneficiaries under Money 22 Follows the Person. We will also do analyses on

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beneficiaries with behavioral health diagnoses. And as we go along, we will still continue our work on assessing the completeness and accuracy of additional variables for other projects.

5 And with that I'll turn it back over to the 6 Commission for any questions or comments.

7 CHAIR BELLA: Thank you both. I think I can 8 speak on behalf of all of us to say that we appreciate the 9 regular updates, and I am happy to see that you are showing 10 us some areas of progress, along with some ongoing 11 challenges.

Let me open it up to Commissioners to see if you have questions or clarifications. Again, this is solely meant to be an update at this point, but certainly you all might have some comments or questions.

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16 Darin?
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17 COMMISSIONER GORDON: So when I think about some 18 of the variation, Chris, the assumption is that how things 19 report on the 64, you know, that they're being done 20 accurately, and I don't mean total amounts, but by buckets. 21 I remember, and you all will have to tell me kind of where 22 it is from a current state of things, but I remember awhile

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back where some states were bucketing things incorrectly on 1 the 64, and CMS, you know, at times they would catch it and 2 3 they would get them to try to make adjustments, but other 4 times it would go through. And I give a very big example 5 of this, but it dates back really far, but, you know, there's questions in the back of my mind, where for the 6 longest time they had us report, in Tennessee, everything 7 under managed care. And so you had no breakdowns of 8 9 anything. And then, obviously, over time, they would look 10 to break that out in greater detail.

I don't know if that might be an issue today, but I I'm just curious of your thoughts to the degree of sophistication and improvement on the proper classification of spending within the 64s.

15 MR. PARK: Sure, and that's one of the reasons 16 why we don't necessarily apply this matching between T-MSIS 17 and the 64 on a much more granular level. We're generally 18 aggregating it to large categories like hospital, or 19 bucketing all of the other acute services into a large 20 category. And that's specifically, to the point that 21 you're talking about, sometimes states may classify things 22 different on the CMS-64 versus how they do it in T-MSIS,

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1 even though they may have the exact same name, like home
2 health services.

So it's difficult for us to say, you know, 3 4 specifically how accurate the classification is on the CMS-5 64 versus T-MSIS, since we don't necessarily have another benchmark that we trust as reliably as the CMS-64. So, you 6 know, we will try to look for other state reports and 7 things like that, if necessary, to kind of confirm the 8 9 findings that we're seeing, but certainly states, because 10 the matching rate is generally the same for most services, it's not like a huge deal that a state recorded spending 11 12 under inpatient supplemental payments versus the inpatient hospital line, at the end of the day. But that is 13 definitely something, you know, we certainly struggle with, 14 15 but I don't think we have a good handle of exactly how 16 accurate states are reporting on the CMS-64.

17 COMMISSIONER GORDON: But to your point, if in 18 the aggregate they are reasonably close then that should 19 give you some degree of confidence. It's just a matter of 20 bucketing correctly. You know, I think of how states who 21 may transition programs, let's say, from fee-for-service 22 into managed care, did they appropriately update how

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they're reporting those things on the 64? 1 So your points are extremely valid. You know, I 2 was just thinking whether or not that could still be an 3 issue, and it sounds like it could be, but still using that 4 -- and I agree with you. I think it's probably your best 5 resource or tool for doing some high-level confirmation on 6 the accuracy and completeness of the T-MSIS data. I 7 8 appreciate your comments. 9 CHAIR BELLA: Other questions? 10 Chris, I apologize if you said this and I missed 11 it, but what's the time frame for the duals data book? 12 MR. PARK: Sure. We are doing some additional validation work, to look at the T-MSIS data, and I think 13 14 we're beginning discussions with MedPAC to try to work out 15 a schedule. The plan would be to publish it on the 16 timeline that we had previously, so with the data book coming out early next year. 17 18 CHAIR BELLA: Okay. Great. Brian, it looks like 19 you have a question? 20 COMMISSIONER BURWELL: A couple of questions. Is it still true, Chris, that 64 data are date of payment and 21

22 T-MSIS data are date of service?

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1 MR. PARK: The T-MSIS data do have both date of 2 payment or date of service. The research files, the T-MSIS 3 analytic file, the TAF file that CMS produces, that is by 4 date of service. But we do have access to the raw T-MSIS 5 data, and so we could look at it either way.

6 COMMISSIONER BURWELL: So the comparisons made in 7 this presentation are date of service to date of payment?

8 MR. PARK: So for MACStats we did use date of 9 service, and so that is one place why we wouldn't expect 10 100 percent agreement. And another reason why we might not 11 except 100 percent agreement is one I presented a year ago 12 about the prior period adjustments and how that can lead to 13 certain anomalies on the CMS-64.

14 COMMISSIONER BURWELL: Right. And the T-MSIS 15 data, when you're making comparisons, are these some kind 16 of files that have gotten a certain stamp of approval, like 17 these are the file, files and there are not going to be any 18 more adjustments or more lagged claims come in, that are 19 going to be changed in the future? How does that work? 20 MR. PARK: Everything we're running is pulled out

21 as of a certain date. So certainly states are continuing 22 to make adjustments, and some of the early work we're doing

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to the data, now we've been looking back at the 2018 data, and we do see some differences between what we had, based on data as of the end of 2020 versus the data based on the end of 2019. So they always kind of reflect a point in time, you know, estimate, based on how much information they submitted, and it depends on whether they go back and make any adjustments the prior years.

8 COMMISSIONER BURWELL: As researchers start using 9 the T-MSIS files more, is there a cutoff date where, say, 10 this the file?

11 MR. PARK: At least for MACStats we'll generally 12 say these reflect T-MSIS data as of like whatever, like 13 August 2020, or something like that. For the research-14 ready files, the TAF files, CMS usually basically, you 15 know, there's one version of that and they cut it off at a 16 certain date, usually with 12 months of claims run out. I don't know if they have any plans of re-releasing any of 17 18 the years as they move forward. So, you know, there's 19 always going to be potentially a slight disconnect between 20 what we find in our analyses and what another researcher 21 might find for the same time period, using the TAF files. 22 COMMISSIONER BURWELL: Would you say that the

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1 more granular the analysis the more likely there may be 2 discrepancies?

MR. PARK: That's certainly possible if states --Iike the example I showed on Vermont was they didn't classify the new eligible, the new adult group. It looks like maybe this year they went back and reclassified those adults as the new adult group. So if we rerun the 2018 data, we may find that Vermont has enrollees in the new adult group now.

10 COMMISSIONER BURWELL: Mm-hmm. In your first 11 slide you showed a bar graph of changes in quality of the 12 data, those that were either of low or medium concern. Is 13 that correct? Little or medium?

MR. PARK: Aaron, do you want to go back?
COMMISSIONER BURWELL: Low or medium concern. I
wonder why you chose to group those two together. I mean,
would we see any different trends if you just showed low or
showed medium?

MR. PERVIN: I don't remember. We grouped it this way mostly because medium is where there's a 20 percent cutoff, to make it consistent with the slide later on. But we can get back to you with an answer to that.

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COMMISSIONER BURWELL: Low concern is - MR. PERVIN: We actually expect that [inaudible]
 quality. Sorry. Go ahead, Chris.
 MR. PARK: Oh, I think it's within 10 percent

5 difference.

COMMISSIONER BURWELL: So we obviously want to 6 increase the number of states with low concern too, right? 7 8 MR. PARK: Certainly. We're hoping to see improvement as we go along, like year over year, hopefully, 9 10 the number of states with low concern will keep increasing. 11 COMMISSIONER BURWELL: Has the number of states 12 with data that is considered unusable been declining? 13 MR. PARK: It depends on the variable. 14 COMMISSIONER BURWELL: Okay. 15 CHAIR BELLA: Did you have any further questions, 16 Brian? 17 COMMISSIONER BURWELL: No. I'm sorry. 18 CHAIR BELLA: That's fine. Anyone else have 19 questions? 20 [No response.] 21 CHAIR BELLA: Okay, Chris or Aaron, any final

22 words?

1 MR. PARK: No. We certainly hope as we move 2 along over the year we'll be bringing back more analyses 3 using the data.

4 CHAIR BELLA: That's great. Well, thank you for 5 keeping us updated.

6 Okay. With that, we can go get ready for our 7 next session. We're a few minutes early, so we may be waiting on the panelists, but we can get set up for that. 8 9 MR. OCHIENG: All right, I'm making myself the 10 presenter. And now I'm giving the controls to Joanne. 11 CHAIR BELLA: All right. So we are in the home 12 stretch, everybody. Thank you for hanging in there. We're going to have a panel on telehealth, which 13 is something that we talk about often and I know is near 14 15 and dear to many of our hearts. Joanne and Michelle are 16 going to lead us through that. I think Joanne's probably going to lead us through it. And I realize we're a couple 17 18 minutes early. We can start, Joanne, whenever everyone's 19 here and we're ready to go.

20 So the goal for today is to hear from our three 21 speakers and leave a little bit of time for discussion, and 22 then we will let them off the hook at 3 o'clock, and we can

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1 continue to have a little bit of Commissioner discussion.

# 2 ### PANEL DISCUSSION: WHAT STATES ARE LEARNING FROM

# 3 EXPANDED USE OF TELEHEALTH

4 \* MS. JEE: Great. Okay, so I do see all of our
5 panelists, so if that's fine, then we'll go ahead and get
6 started.

7 Commissioners, this afternoon we're really happy 8 to have a panel of leaders from three states to discuss 9 what states are learning from expanded use of telehealth 10 during the pandemic. Let's see. I can just -- oh, there 11 we go.

12 So our panelists are Dr. Chethan Bachireddy. He 13 is the chief medical officer from the Virginia Department 14 of Medical Assistance Services.

Next we'll have Tracy Johnson, who is the Medicaid director from the Colorado Department of Health Care Policy and Financing.

And last, but not least, we'll have Dr. Sara Salek, who is the chief medical officer from the Arizona Health Care Cost Containment System.

I won't say any more about their bios than that.You have more details in your meeting materials. I know we

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have a lot to say, the state officials have a lot to say, so we're just going to jump right in with Dr. Bachireddy. DR. BACHIREDDY: Hi. Good afternoon. Can you hear me okay?

5 MS. JEE: Yes.

DR. BACHIREDDY: All right. Well, good 6 afternoon. Thanks so much for inviting us here and 7 8 spending some time to hear about some of what we've been 9 learning, some of the key questions we've been wrestling 10 with, and maybe even some recommendations for future policy 11 development and where we think telehealth is going and how we might be able to collaborate to take it there. My name 12 is Chethan Bachireddy. I'm the chief medical officer at 13 14 Virginia Medicaid, and I'm also a practicing physician, so 15 I've had the experience of this telehealth transformation, 16 evolution, revolution as a policymaker, a payer, a practitioner physician, and as a patient. And it has been 17 18 quite incredible, and so I look forward to the discussion. 19 First of all, I'll be sharing a few slides, and

20 folks here will be keeping me on time as well. Please do 21 not be shy about doing that.

22 Next slide, please.

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1 All right. And so really I think all of us understand this in spades, everyone here, that the COVID-19 2 pandemic has really highlighted the potential that 3 4 telehealth can play in ensuring equitable access to care, 5 to health services, and, of course, this is nowhere more important than in Medicaid. What we're learning is that 6 almost 70 percent of primary care providers, at least in 7 8 Virginia, were motivated to use telehealth to meet patient 9 needs and reported lower no-show rates with telehealth 10 compared to in person, and I saw this in my own clinic as 11 well where we went from 27 percent no-show rate to a 3 12 percent no-show rate when we were primarily using virtual 13 care.

14 In our Medicaid data, we saw that telehealth use 15 increased almost more than 15-fold during the public health 16 emergency and remains at an elevated level. It's been a 17 force for equity in our state and for our program and 18 pretty good for racial equity. We saw in our data -- we 19 see in our data that telehealth use has increased 20 disproportionately among African-American populations 21 who've experienced particularly rapid uptake. 22

Finally, telehealth has had an outsize impact and

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has really been concentrated, again, in Virginia Medicaid, among those with substance use and behavioral health conditions. Indeed, the top nine of ten coded diagnoses for telehealth fit into one of these buckets -- behavioral health or substance use disorders.

We're doing additional internal analyses in 6 understanding that telehealth and, in particular, audio-7 8 only services, which we reimbursed during the pandemic, have ensured access to care for those with opioid use 9 10 disorder. There were two policies in particular that made 11 that possible. One was SAMHSA, DEA, HHS at the federal 12 level waived the Ryan Haight Act requirement for in-person 13 evaluation for buprenorphine initiation, which meant as the 14 pandemic worsened, more and more folks were able to 15 initiate buprenorphine in particular, the audio-only or 16 audio-visual, and at that the state Medicaid level, of course, we also opened up reimbursement for audio-only 17 18 services, which made that possible to ensure access to 19 care, and particularly for buprenorphine for those with 20 opioid use disorder.

21 The Commonwealth, our state, is taking important 22 steps as well to facilitate long-term telehealth, so

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there's a lot of excitement in our state, and we just 1 finished our state legislative session, and from that 2 3 session a number of policies were put forth and memorialized related to telehealth. One was removal of 4 restrictions on originating site from the Virginia code, 5 and then the second is really around telehealth services 6 and modalities. So our state also authorized remote 7 8 patient monitoring for selected populations and conditions -- e-consults, store-and-forward, audio-only services, in 9 10 addition to audio-visual telemedicine services, all beginning in July 2021, and this is a focus on not so much 11 12 what did we do during the pandemic, but what does mediumterm and long-term telehealth look like? 13

14 Next slide, please.

15 And so as we've been really experiencing this 16 tremendous interest and surge in telehealth and have had lots of support internally and certainly at the state level 17 18 and nationally and among our providers, we've been learning 19 a fair amount about what our goals are with telehealth and 20 some key operating principles as we think about medium-term 21 and long-term telehealth policy. So the two goals that are 22 front and center for us are, you know, first and foremost,

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1 increase and sustain Medicaid members', patients' equitable 2 access to service, while maintaining and improving quality 3 through coverage and evaluation.

4 Then to really meet that first goal, the second goal is to increase and sustain providers' willingness to 5 offer services delivered via telehealth by establishing 6 appropriate incentives and certainty, and this is really 7 8 just maybe the obvious point that if we want to meet the 9 goals and improve the health of our members, our patients, 10 we really have to invest in our providers as well, and 11 telehealth policy is a big part of that.

12 And so some of the operating principles that we've put down on paper to guide us in our discussions and 13 14 as we think about medium- and long-term telehealth, the 15 first is that telehealth is a modality. I heard someone 16 once call it "electricity," and it should be governed by the same parameters as in-person care, where appropriate. 17 18 Telehealth policy development should allow for inherent 19 uncertainty, and along with that uncertainty is a 20 nimbleness as well in terms of policy development and 21 course correction. And this really leads into the next 22 point, which is that key to telehealth policy is to

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establish robust monitoring and evaluation structures so 1 that we can make those data-driven corrections, something 2 3 that we don't always do in Medicaid, but that feels 4 extraordinarily important with telehealth, as we're just at the beginning of this, of opening up this field. Outcomes, 5 access, experience, costs, the things we care about, they 6 need to be defined at the patient and population level, not 7 8 only at the billing and service level. The risk of provider misuse must be weighed against the benefits of 9 10 provider flexibility in determining the optimal modality of 11 care for their patients, and really what this gets at is it 12 really, you know, connects to the earlier point, that there 13 is so much uncertainty here that often when from a payer 14 perspective there is certainly a focus on not only member 15 outcomes, patient outcomes, but also on fraud, waste, and 16 abuse. And in an area where there is uncertainty worth thinking about our policies in terms of the risks and 17 18 benefits of provider misuse against the benefits of 19 provider flexibility.

And then the last is that simplicity is essential, that, you know, from a provider perspective, if you have ten different payers and payer policies that

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you're trying to figure out, that will stunt your ability
 to be able to invest in telehealth over the long term.
 Next slide, please.

4 So the next slide is really key questions. So what questions are we asking ourselves and really trying to 5 tackle and understand in detail and make good on? So the 6 first is: What are the components of robust monitoring and 7 8 evaluation? And how does this align with established 9 quality standards like NCQA? Should services delivered via 10 synchronous audio-visual telehealth be reimbursed at parity with in-person visits? Really, with this idea that audio-11 12 visual telehealth initially will require investments in 13 infrastructure, work flows, technology, new way of doing business. And so if we do that, how long should that last? 14 15 And how does that impact providers' willingness to deliver 16 audio-visual telehealth over the longer term? What services should be allowable via audio-only telehealth and 17 18 at what reimbursement rate compared to in-person visits? 19 There is a consensus that audio-only telehealth

20 is inferior to synchronous audio-visual telehealth. Of 21 course, there's much more evidence and data that we need to 22 establish that fact, but that's the general consensus among

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1 many providers. And so with that in mind, what should the 2 reimbursement rate be?

3 On the flip side of that, we understand certainly 4 in Medicaid programs across the country that about 20 5 percent of our members live in households without reliable access to broadband. So when we talk about audio-only 6 telehealth, we have to talk about -- yes, we have to talk 7 8 about quality and how does that compare to other services, 9 but we also have to talk about equitable access. And so 10 this is a really important question for us.

11 The last question that we're really wrestling 12 with is: How can telehealth policy be simple, be more 13 closely aligned across payers to make it easier for 14 providers to adopt, with this idea that the more complexity 15 we introduce into the system, the more costly it is for 16 providers to adopt and really invest in stepping into the 17 potential of telehealth.

18 Next slide, please.

All right. So if I may be so bold, here are some areas of possible federal policy development that we've come to, and this list is by no means exhaustive, but I think it's a start. It's certainly where we could benefit

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from additional dialogue and so forth. The first is 1 evaluation. I've mentioned this a few times. What does 2 "good" look like when we talk about telehealth? And so to 3 4 the extent that we can develop national evaluation 5 frameworks, that would be very helpful. Certainly -- we're a Medicaid program -- FMAP is very important to us, as is, 6 you know, investing in evaluation. In this time of fiscal 7 8 austerity at the state level, to make sure that we can 9 invest in the learning that we need to do and this sort of 10 rapid evaluation and course correction that we'll need to do along the way, it would be beneficial to have some level 11 of enhanced FMAP to invest, incentivize evaluation for 12 Medicaid agency telehealth policy. 13

14 The second one is related to the first, that to be able to really extract insights from our data, we need 15 16 to have some standards around audio-only telehealth 17 billing. Some states have figured it out. Many have not. 18 And in conversations with other states, and certainly in 19 Virginia, we have a difficult time actually distinguishing 20 between audio-only and audio-visual. So the data we get is 21 from the health system level, not from the payer, not from 22 our own data. And so any way there could be assistance

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1 there, it would be much appreciated.

The final two -- the next one is focus on 2 3 infrastructure, again, understanding that we're just at the 4 beginning of this journey. It's not enough to just open up policies. I've seen firsthand how we all have improved in 5 terms of telehealth from March of last year to March-April. 6 When I was in clinic this morning and they had telehealth, 7 8 we have gotten a lot better -- patients, providers, clinic 9 work flow. And so a question -- and we don't want to stop 10 that momentum, so to continue to build that momentum, we 11 really need to think about investing in infrastructure at 12 the community level, think broadband, provider level, 13 education, you know, maybe this is payment, and at the patient level, technology in particular, digital literacy 14 15 as well.

And then the last -- and, again, this may be an obvious point, and I may really be preaching to the choir here, but at the end of the day, you know, telehealth is a modality, and it's really a tool in the toolkit. We really want to move from paying for health care to paying for health, and so value-based payment is key to really allowing all of us to put these pieces together and

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1 ultimately unlock the potential of telehealth to achieve 2 the outcomes we care about -- experience, cost, access, and 3 equity.

And so, with that, I'll stop talking, and I just want to say thank you again for the invitation. Thank you for the interest and your work, and I look forward to the conversation.

8 \* DR. JOHNSON: Okay. I think I'm up next. I'm 9 Tracy Johnson, Colorado Medicaid Director, and you'll hear 10 some pretty similar themes from my presentation.

11 Next slide, please.

12 Just to level set for you, Colorado had an existing telemedicine policy prior to the pandemic, but in 13 March 2020, which was the start of the first wave in 14 15 Colorado, we were one of the earlier states; we did expand 16 our policy, and we actually made it permanent in state statute just a few months later, in June 2020. So 17 18 highlighted here are some of the changes we made. We 19 allowed telephone-only modality, for certain services 20 anyway, and live chat, so that was in addition to the 21 preexisting policy of audio-visual. We allowed new 22 providers to bill the state directly. We are partially a

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1 fee-for-service state. We're fee-for-service in the 2 physical health side, and we do capitated behavior health, 3 so this really refers to our fee-for-service policy.

Our newly eligible providers were FQHCs, rural health centers, Indian Health Services, community mental health centers, a variety of therapists and home health services, and we pay parity, which was a preexisting policy that we continued for these emergency and then permanent rules.

10 Next slide.

11 We have completed a full evaluation, and so I'm 12 going to share some data with you so you can see what we're learning. On the left is our fee-for-service data that, 13 14 again, is primarily physical health services with a few 15 carved out behavioral health service. And on the right is 16 our capitated behavioral health data provided by our health plans. And in both instances, you can see a dramatic ramp-17 18 up peaking in April that attenuates over time, but it comes 19 down more for physical health services. It peaked a little 20 bit above 30 percent in April and came down closer to 15; 21 whereas, for behavioral health it peaked closer to 60 22 percent and did not attenuate quite as much, down to about

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1 50 percent. And in both instances, we're hearing from 2 providers that telemedicine is here to stay.

3 Next slide.

4 In terms of who's using telehealth and telemedicine and how, for children the major utilization is 5 in the therapy category, and that has to do with, that we 6 allow therapists to use telemedicine, which not all states 7 8 do, and that early intervention services went all virtual 9 in Colorado, and they're reimbursable by Medicaid, so this 10 is a trend driven particularly by young children using 11 early intervention.

12 As the prior speaker noted, opioid dependence was one of the top diagnoses for our adults, and that had to do 13 14 with both federal and state policy changes, as well as 15 depression and anxiety. We were initially surprised to see 16 so much of that, you know, behavioral health service use in our fee-for-service data, but, again, it speaks to the 17 18 demand for those kinds of services, the policy changes, 19 and, you know, just the need. The other thing we saw was 20 chronic disease management. For our adults with 21 disabilities and our waiver populations, they too use 22 telemedicine most commonly for chronic disease management.

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1 Next slide. Here's some data -- it's a little bit of a busy 2 3 slide -- that shows services eligible for telemedicine, and 4 the blue bars represent in-person care, and then the orange bars represent telemedicine services. And here you can see 5 some of the differentials between rural and urban 6 providers. The top two charts are federally qualified 7 8 health centers divided according to rural or urban status. 9 We have lots of rural areas in Colorado, so you can 10 imagine. And while both sort of have the same shape that, 11 you know, dramatic ramp-up through March-April, kind of 12 attenuating over time, you can see the ramp-up was higher 13 in the urban areas. And so while having telephone-only services did help with the digital divide, a lot of our 14 15 rural providers have, you know, trouble with broadband 16 access and things like that, it did not fully close that 17 rural-urban divide.

18 The other thing to notice is just the difference 19 between, say, the rural FQHCs and our rural health centers. 20 Our rural health centers, you know, did have a ramp-up. 21 You can actually see the waves if you look very carefully, 22 like with a magnifying glass, in that data. In Colorado,

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our waves were, you know, in April -- March-April, late 1 summer-early fall, and December-January. You can see a 2 3 little blip up in orange in each of those time frames. But 4 what was interesting to me about this data is that, you know, again, the rural FOHCs could ramp up more than the 5 rural health centers. And when I asked our rural health 6 center partners, you know, why, I got a variety of reasons, 7 8 but one sort of touched on the prior presentation. You 9 know, the rural health centers don't have quite the 10 administrative infrastructure that the federally qualified 11 health centers do, and the fact that, you know, Medicare, 12 commercial, Medicaid, all had different payment policies 13 and, you know, the uncertainty about what would continue, 14 you know, just sort of was a barrier to ramping up more 15 dramatically. So just to show you some data to support the 16 point in the earlier presentation.

17 Next slide.

18 The other thing we noticed was some interesting 19 substitution that we wondered if we could be more 20 intentional about going forward. We looked at emergency 21 department use, which was down, you know, across the board, 22 but in particular, for potentially avoidable visits related

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to pediatric upper respiratory infections. And again on 1 the left you see the final quarter in our fiscal year, in 2 2019, so prior to the pandemic, and then the final quarter 3 4 in 2020, during the pandemic, and, you know, in-person visits were down dramatically, which, again, was not 5 particular to this service. But what we saw was, you know, 6 a big tick up in telemedicine for this particular 7 diagnosis. And so we're wondering, you know, since this is 8 a policy area we've been working on for a long time, if we 9 10 might be able to be more intentional about this going 11 forward and encourage people to use telemedicine as an 12 alternative to going to the ED for these kinds of services. 13 Next slide.

I think the final thing I'll close with is you've asked us to reflect on key considerations going forward, and as I noted, we've codified a lot of our emergency policies into permanent state statute. But there's still a great deal of work and need for regulatory and subregulatory guidance to really distinguish our emergency policies from our permanent policies.

21 By way of example, we allow well-child checks to 22 happen vis telemedicine during the ongoing public health

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1 emergency, and we don't anticipate doing that post2 pandemic. So there's a lot of those kind of decisions that
3 need to be made.

4 Additionally, Colorado has dedicated nearly two decades to focus on building primary care capacity and 5 ensuring that our members have high-quality medical homes 6 and coordinated medical neighborhoods, and we want to make 7 8 sure we're layering in this telemedicine capacity in a way 9 that's well integrated and complementary and doesn't in any 10 way undercut those sort of hard-won health reform achievements in our delivery system. 11

12 So, as we emerge from the pandemic, we're going 13 to continue to monitor access, quality, equity, 14 utilization, and cost, a lot of those same things you heard 15 from the prior presentation.

One trend we're watching with a great deal of interest is the rapid growth in entities that provide exclusively telemedicine services or nearly so, and here, we see both opportunities of potential to address longstanding access challenges, but also some risk. As I said, Colorado has large rural areas. We have a lot of small and rural providers, and some of them are starting to

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report destabilizing competition from these kinds of providers. And we're wanting to sort of balance preserving access to in-person care while continuing to expand virtual opportunities for our members. So we think there's a lot of policy work, some of which is regulatory and subregulatory, that could be done in that area.

7 In a partially fee-for-service state, these 8 entities largely exist outside our current regulatory 9 framework, and so some of our work in the coming year will 10 be really thinking about that accountability framework as 11 described again in the prior presentation broadly, but also 12 as it pertains to this category of entity, telemedicine 13 entity.

Then, finally, we're monitoring federal policy changes. We agree very much with the comments from the prior presentation around the need to align as much as possible and looking for payment policy that was valuebased payment models that will allow us to continue to innovate in a way that's hard sometimes with fee-forservice.

So thank you very much for inviting me.
DR. SALEK: Great. Thank you very much.

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My name is Sara Salek. I'm the medical director for the Arizona Medicaid Program, and I'm the last speaker. I know we're in the homestretch, and it's Friday afternoon. So, hopefully, you all have your cup of coffee with you. I know I've got mine. It's morning still here in Arizona.

6 What I wanted to focus on is really some more 7 detailed policy decisions in Arizona, and Arizona has 8 actually really leveraged telehealth for decades now, 9 including in the tele-behavioral space. And I'll go a 10 little bit more into detail on that.

But we were very fortunate in that we had a very vocal stakeholder group that said our telehealth coverage policy needed to change, years before the pandemic hit, and so we implemented the vast majority of changes to our telehealth coverage policy prior to the onset of the pandemic, which put us in a really helpful position during the very difficult time.

So some of those changes we made prior to the pandemic included broadening the place of service, allowable for both distance sites where the practitioner is located, as well as originating site where the member is located. So where we had to quickly shift gear and provide

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services based on stay-at-home orders to members located in
 at home, we had already permitted that pre-pandemic.

Additionally, we broadened our coverage decisions related to telemedicine, remote patient monitoring, and asynchronous technologies prior to pandemic, and I'll go a little bit more into detail what that looked like.

7 We also clarified that we covered telehealth in 8 both rural as well as urban communities, and prior to the 9 pandemic, we allowed our managed care organizations to 10 determine when they wanted to leverage telehealth within a 11 network versus not.

12 Next slide. All right. So prior to our major policy changes, prior to pandemic -- so that was 10/1 of 13 14 '19 -- we in Arizona Medicaid policy limited telemedicine, which is that that synchronous audio/video coverage to 17 15 16 specific disciplines outlined in policy, and we switched gears and determined that as the payer, we were going to 17 18 rely upon the standard of care as well as the licensing 19 boards to determine what was within the scope of practice. 20 And so there were certain licensing boards that said, for 21 example, that a licensed practitioner such as a physical 22 therapist could not conduct telemedicine physical therapy,

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1 and so we really deferred to licensing boards and opened up 2 our policy around coverage.

Next slide, please. And then in regard to asynchronous, prior to 10/1/19, we covered asynchronous in very limited circumstances, but starting 10/1/19, we covered these nine specific disciplines based on both our public policy work group as well as public comment.

8 Next slide. And then prior to 10/1/19, we did 9 cover telemonitoring but only for congestive heart failure 10 based on the evidence but removed that diagnostic 11 restriction starting 10/1/19 and really again deferred to 12 what was medically necessary, cost effective, and as my colleagues had mentioned in regards to really focused on 13 quality as well as bending the cost curve in reverse to 14 15 keeping individuals out of the hospital and out of the 16 emergency department.

Next slide. And so I'm going to just take you through some of the major updates that we made to our telehealth policy during the pandemic.

20 Next slide. And so we were really engaged with 21 our provider member and other stakeholders during the 22 pandemic, and it was very clear early on that both from the

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1 member as well as provider-based perspective, we needed to 2 expand our audio-only coverage.

I did want to note that we covered audio-only services prior to the pandemic, although much more limited and greatly expanded audio-only coverage for the reasons previously mentioned.

7 We also expanded our coverage by adding 8 additional codes to both synchronous and as well as 9 asynchronous technologies, and based on executive orders 10 here in Arizona as well as policy decisions here, we 11 required our managed care organizations to shift. So prior 12 to the pandemic, we allowed them flexibility in telehealth coverage, but during the pandemic, we required them to 13 cover it and at the same rate as in-person services. 14

15 Next slide. So we do actually have a pretty 16 detailed coverage chart here, which is also on our telehealth Web page that we created. I did want to note 17 18 early on in the pandemic, we had to make the decision on do 19 we continue with this modifier usage as well as identify a 20 modifier for audio-only services, or do we basically take 21 the approach of please provide the service. We recognize 22 it's going to be a combination of in-person as well as

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1 telehealth modalities.

So, fortunately, we did make the decision to stay 2 course and still continue to require modifiers and 3 4 identified a non-use modifier for audio-only, and so we do have the ability to differentiate audiovisual versus 5 asynchronous versus audio-only based on those decisions. I 6 won't go into additional detail, but I did want to note 7 8 that we have a coding-based solution that assists us with 9 some of those more detailed monitoring and data analytics 10 that my colleagues had mentioned.

11 Next slide. All right. So what is the data 12 telling us? I'm just going to provide really two high-13 level graphics, although we do have more detailed 14 information as well, but due to the interest of time, I'll 15 just stick with these two.

So the first is looking at all of our Title XIX and XXI programs for state fiscal years '20 as well as '21, and it's looking at it from the perspective of the percentage of enrolled members with one or more telehealth claims or encounters and telehealth in this context includes audio-only, and we're looking at a rolling 12 months.

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1 So prior to the pandemic, about 10 percent of our 2 members have one or more telehealth claims, and as the 3 pandemic hit, we see this slope upward and continued 4 increased growth, and part of that is just controlling 5 through that 12-month rolling, and now we see almost 30 6 percent, receiving one or more services via telehealth.

7 Next slide. And then this graphic is looking at 8 a different snapshot, which is number of services rendered per 10,000 enrolled members by month, and it's separating 9 10 it out based on diagnostic, ICD diagnostic code, mental 11 health versus physical health versus substance use. And 12 not surprisingly and similar to experience in other states, 13 mental health is our number one in regards to number of services rendered per 10,000, followed by physical health, 14 15 and then subsequently substance use.

We have seen, as Tracy had mentioned, a significant uptick in opioid-related diagnoses being treated via telehealth, which is important because of the increased opioid-related morbidity and mortality we're seeing confounded by the COVID pandemic.

21 Next slide. All right. So what are we doing 22 post-pandemic in Arizona for planning?

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1 Next slide. As my colleagues had mentioned, we are evaluating audio-only coverage and weighing three major 2 3 factors, including clinical appropriateness, health care 4 access in regards to that ongoing concern related to broadband access for our members, and from my perspective 5 and what I've heard, both from the provider as well as 6 member experience, audio-only coverage is critically 7 8 important until we have that broadband coverage issue 9 resolved, and so based on multiple interviews, based on 10 multiple engagements with our provider community, including 11 pediatricians, and the ongoing concern around despair 12 during the pandemic, we really do feel audio-only coverage is critically important until that broadband issue 13 throughout our nation is addressed. 14

In addition, we're also cognizant of the impact that performance measure stewards have on our coverage, and so I did want to note that, ultimately, we're only as good as how we're measured, right? So NCQA as well as CMS played a huge role in regards to what Arizona and what other states determine is coverage, covered via telehealth modalities.

22

Then we have had our ongoing fiscal analysis. I

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wanted to note that we have seen an offset in non-emergency medical transportation, which we expected to see. We obviously also saw a decrease in in-person visits that also offset the utilization, but we are seeing an increased trend as far as utilization. We're monitoring that, including for any signs of fraud, waste, or abuse through our Office of Inspector General.

8 Last but not least, it's important -- and I think 9 this is a great note to end on, which is member 10 satisfaction. We have our CAHPS survey right now going on, 11 and we actually adopted Oregon's supplemental telehealth 12 questions to get a better understanding of what the member 13 experience is specific to telehealth.

So, with that, I'll turn it back to Joanne.
MS. JEE: Great. So thanks to the panelists, and
I will go ahead and turn it back over to Melanie.

17 CHAIR BELLA: Well, thank you. First, I want to 18 say how much we love to hear from states, so thanks to all 19 three of you for spending your time with us. Second, you 20 couldn't have given us a better presentation in terms of 21 like pre/post. Then, third, anytime you tell us what we 22 could be doing or what policy recommendations are, that's

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1 wonderful. You checked all three boxes.

Having said that, I know that my fellow
Commissioners will have many questions for you. So let me
get started with Kit and then Peter and then Fred and then
Martha and then Sheldon.

COMMISSIONER GORTON: So a quick observation with 6 regard to time lapse. When I became Pennsylvania's first 7 Medicaid chief medical officer in 1996, I was one of 10 in 8 the country, and none of us were full-time. You can just 9 10 see how far states have upgraded their capability in the 11 course of the last 25 years, and I think it's wonderful. No slight at all on the non-clinical professional staff who 12 13 have also upgraded substantially.

14 So for those of us who have been watching 15 Medicaid a long time, it's very reassuring to see what the 16 states have done with their investments.

My question for you is -- for all three of you, whoever wants to go first, is this. When you went into the changes that came with the public health emergency, there were changes that you made that you thought, yeah, this is going to work. It will be fine. No brainer. We'll do this and this, and it will all be fine. Or,

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alternatively, you went into stuff and said, well, people 1 are asking for this, and it will never fly, but it's a 2 3 public health emergency, so what the heck. We're just 4 going to throw everything at the wall and see what sticks. 5 So what I'm interested in is what surprised you? What did you see over the course of your opening up, 6 particularly of audio-only telehealth, that worked, that 7 8 you didn't expect to work, or that fell flat on its face 9 that you thought was going to be a slam-dunk? 10 Thanks. 11 DR. SALEK: I'm happy to -- oh, go ahead, please. DR. JOHNSON: This is Tracy from Colorado. 12 13 I would say that the thing that surprised me, but 14 pleasantly, was the creative ways we were able to use 15 telemedicine to help high-risk populations. The opioid 16 dependence issue was referenced, I think, in all three of 17 our presentations. 18 Another example I'll give you is for homeless 19 persons, a lot of folks during the pandemic were put in 20 hotels or motels to keep them safe if they were positive, 21 and that sort of created an opportunity where people had 22 phones. And so there was a lot of creative use of

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1 telemedicine to really sort of keep eyes on a population
2 that was isolated.

There's also been some really creative use of kind of smart backpacks, where nurses could go to shelters or encampments and provide telemedicine-enhanced direct services, you know, street medicine, and there were just lots and lots of examples of that, group therapies, things you never thought you could be doing via telemedicine. People were trying, and some of it worked.

10 DR. SALEK: And then just commenting from Arizona's perspective, I think one thing that surprised me 11 12 is that we didn't really see a huge uptick in EPSDT wellchild visits at all, and I think a couple reasons for that. 13 I think as far as pediatricians and family practitioners, 14 15 it's still kind of new versus in the behavioral health 16 space we've been using it for years. And there's ongoing 17 concern around how do you get that objective data. 18 Obviously, when you need immunizations, you got to go in 19 person, but for some of the other things, such as, you 20 know, being able to do otoscopic exam or cardio exam, there 21 are unique tools via telehealth, and it's just not yet 22 taken off.

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1 So that was one thing that kind of I was 2 interested in because a very low uptick in EPSDT well-child 3 visits being done via interactive audio-video in Arizona to 4 date.

DR. BACHIREDDY: Hi. This is Chethan.

6 So I love that question because there's a lot 7 that surprised me throughout the pandemic as we opened up 8 telehealth. We went from basically minimal, about 5,000, 9 6,000 telehealth visits a month to over 100,000 a month in 10 a very short time. We didn't have quite the same robust 11 pre-pandemic telehealth policy as some of my colleagues 12 mentioned. So there's a lot that surprised us.

13 So one of them was -- one of the services -- as I 14 was digging through the evidence, how much more we have to 15 learn, that surprised me, how much more we have to learn 16 about telehealth, and how much -- just in the practice, like I said, as a practitioner in my own clinic, the amount 17 18 of somewhat cultural workflow change, we had to go through 19 but were willing to go through. What we're reckoning with 20 and many others is what does this look like for the future, 21 and a big part of that, I think, has to do with 22 reimbursement and policy.

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1 Relatedly, we can really -- one thing that telehealth for sure has given us that I'm very grateful for 2 is access, and like I said, our no-show rate went from 27 3 4 percent to 3 percent in our practice, in our primary care, 5 and addiction clinic. When we look at our data across the state, we see that not only was care maintained, but it was 6 actually slightly increased. Now, we're checking to see 7 how significant that is, but for opioid use disorder, 8 9 that's quite significant. I did not expect that, and 10 certainly, there's more need. But I really did not expect 11 that, and telehealth has allowed that to come into being. 12 So really, this new modality that increases 13 access, of course, will have an impact on outcomes as well, and I think the question is how much and for what 14 15 conditions. So I think we're at this really exciting time, 16 but I think of it as the beginning of really investing in 17 telehealth. The last thing I'll say just to really reinforce 18

10 The fast thing I'll say just to really reinforce 19 that last point about investing in capabilities all 20 throughout community, provider, patient is e-consults. So 21 we opened up e-consults, remote patient monitoring for 22 COVID-19 in particular, and for something like e-consults,

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my understanding of it is that it's sort of a win all the 1 way around, increased access, increased efficiency, 2 decreased costs. It may put a little more burden on the 3 4 primary care provider. Overall, though, a win, something that we can all say fairly objectively would be high value. 5 When we looked almost a year later at the number 6 of visits, there were just no visits for e-consults, and 7 8 that has everything to do with the fact that to develop an 9 e-consult system -- I mean, maybe this is obvious for folks 10 who have done it -- you have to invest in it. You have to build it out. You have to feel as if investing in that 11 12 will be -- the juice will be worth the squeeze, that there will be a reimbursement moving forward. 13 14 So an important principle for us is as we're providing that certainty moving forward to our stakeholders 15 16 and providers, so a lot of things that surprised me. 17 Thanks. 18 CHAIR BELLA: That's great. Thank you. 19 Peter and then Fred and then Martha. 20 COMMISSIONER SZILAGYI: Thank you very much. 21 This was a really exciting and very thoughtful 22 presentation. I'm a general pediatrician. I've had a fair

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amount of experience with telehealth prior to COVID in
 Rochester, New York, with a very high-risk Medicaid
 population, and, obviously, during COVID. I have a couple
 questions, but first a comment.

5 My experience prior to COVID was that with a 6 robust telemedicine program, we actually had data about 7 patient satisfaction, reduced ED visits in the pediatric 8 world when we did telehealth, and lack of drift or 9 unnecessary telehealth use, and some of that has been 10 published.

11 My question for you is: The pediatric community 12 across the United States is kind of in many places 13 reverting back to the work as it was prior to COVID, and 14 I'm worried that there is an opportunity that may be 15 missed, that there was real changes during COVID, and in 16 some areas -- maybe not in your states but in other states -- in some areas people are just kind of going back to 17 18 business as usual. What are the one or two policy changes 19 that would enable high-level telemedicine to continue? 20 And my second question was: What do you know 21 about patient satisfaction with telemedicine? Because my 22 experience is very high patient satisfaction with

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1 telemedicine.

2 CHAIR BELLA: Anybody want to go first? DR. SALEK: I'm happy to take it first. Yeah, 3 4 thank you so much, and it's helpful to kind of hear a 5 pediatric perspective on things as well. You know, I think from my standpoint, where we're seeing that there is shift 6 towards sustainable change is through like our integrated 7 8 clinic to using a hybrid-based approach. And so I think 9 when you think about the medical coding structure, it 10 doesn't necessarily contemplate that you can do certain 11 visits, like certain parts of the EPSDT visit in a virtual 12 visit versus other components needs to be done in person. And so I think probably as we're thinking about 13 leveraged telehealth moving forward, in particular around 14 15 the well-child visit, how do we expand and understand how 16 to update our coding system to account for that hybrid-17 based model. So that would be, you know, one of the major areas that I would like to see addressed at the federal 18 19 level. 20 And then remind me, Peter, of your second 21 question?

COMMISSIONER SZILAGYI: The level of patient

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22

1 satisfaction with telehealth.

2 DR. SALEK: Oh, yeah.

3 COMMISSIONER SZILAGYI: You mentioned that you're 4 doing the CAHPS with telemedicine, but we didn't hear 5 results.

DR. SALEK: Yes, and so it actually just launched 6 this month in April, so we should have preliminary results 7 no later than early fall, and so I'll be able to tell you 8 from a systematic perspective what the patient satisfaction 9 10 is. But anecdotally, absolutely, as you said, on the 11 patient-based perspective, anecdotally very happy, and the 12 provider-based perspective very happy because the no-show 13 rates, as Chethan had mentioned, are down anecdotally. And I can just tell you, I mean, similar to Chethan, you know, 14 15 I've had that experience both as a practicing clinician 16 providing telehealth services as well as being a patient, right? And I know many of us probably received telehealth 17 18 services during the pandemic, and it is an easy way to 19 access care, especially because we are so busy. And so I'm 20 looking forward to sharing the results of our CAHPS, and 21 because we did adopt Oregon's supplemental questions, we 22 can do some cross-state analysis as well.

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1 DR. JOHNSON: I can go next. This is Tracy again from Colorado. I think building on the comments that Sara 2 3 made, I think, for example, the well-child example, I think 4 there's a payment piece, too. How do you figure out a way in which you don't end up paying twice for one well-child 5 visit, for example, which is essentially what we're doing 6 now, and, you know, we're in a public health emergency, 7 visits are down. You know, we're doing that. But that's 8 9 the most common child service, and so taking the most 10 common child service and multiplying by two is not going to be practical going forward. And so sort of -- there's some 11 12 payment policy there as well.

We are also in the same place where we have 13 14 survey questions added to a state-level survey on telehealth, so we'll know more about what people think 15 16 actually across payers, but we can disaggregate by Medicaid in the fall. We've done a convenience survey. We have a 17 18 virtual member advisory committee, and those data, which 19 are, you know, self-selected people who participate in that 20 and tend to be higher risk on average, very satisfied with 21 telemedicine.

22

In my slides, there was a link to our evaluation

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1 report, and so I invite you to go look at those data if you
2 are curious to see more precisely.

DR. BACHIREDDY: So I'll say a word here, again, 3 4 echoing a lot of what my colleagues have brought up. One 5 is a signal particularly from the national -- the federal government that telehealth is here to stay, both from what 6 are we paying for and what we're willing to pay for, and 7 8 allow providers flexibility to decide and use their 9 judgment in terms of what type of service they want to 10 deliver or not via telehealth. Part of that, again, is 11 policy. Another part is to the extent that we can at the 12 state level and at the national level really encourage 13 payer alignment to make it as easy as possible.

14 And then the last thing I'll say regarding signaling, both in terms of policy, payer alignment, is 15 16 investment in infrastructure. I brought that up a few times, and I think that if there is proactive investment 17 18 now, we're able to really capture the excitement, the 19 momentum, the sort of positive spillover effect of the 20 disaster that has been COVID, you know, which is 21 telehealth.

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And so all of that will be very helpful in terms

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of maintaining the momentum and excitement that really 1 exists, and, again, I've also seen in my own clinic where 2 3 we have drifted back and, you know, part of what we're 4 trying to ask ourselves is: Do we really need for a visit to be in person, you know, particularly if we know the 5 patient, they're very stable, and there are no other 6 services that they need at that particular visit? So we're 7 trying to push and really implement protocols at the front 8 9 desk so that we can create that work. But it's taking 10 time. It's taking time, and my trying to convince folks 11 that, you know, telehealth is here to stay, but you guys 12 know I'm very positive on the outlook of telehealth.

The last thing I'll say -- and I said it before -13 14 - is really value-based payment will help us figure out and 15 right-size what the appropriate amount of virtual care is 16 or isn't, and so you could have a virtual visit every 17 single day and that could be entirely appropriate. And 18 value-based payment really allows that, and I've seen this 19 in my colleagues who work in capitated environments, 20 they've been able to use virtual care in a way that is not 21 possible in a lot of clinics that are fee-for-service, even 22 if we reimburse for virtual care. And so we're seeing it

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in Medicare Advantage. We're seeing it in other capitated 1 environments. And so to the extent that we can replicate 2 that across the system, I really think that -- now that 3 folks have had a shift in their cultural mind-set and 4 understand the possibilities of telehealth, if we can 5 support that as much as possible and invest in it, then I 6 think we'll be very proud of ourselves five years from now, 7 8 and virtual care will really look quite a bit better and 9 different than it is today.

10 COMMISSIONER SZILAGYI: Thank you very much. 11 CHAIR BELLA: Thank you. Just to level set, we 12 have about ten minutes left with our guests, and I want to 13 be sensitive to their time. We have at least four of you 14 left to ask questions, so please keep that in mind as we're 15 trying to glean as much as we can from these folks. Fred, 16 no pressure. Fred, then Sheldon, then Toby.

17 COMMISSIONER CERISE: Chethan has really 18 elaborated on a lot of my questions. I just loved all the 19 presentations, and you really are hitting on what in my 20 mind are the critical points. What I'm seeing is lots of 21 utilization, audio-only, not a lot of results yet in terms 22 of outcomes, but I suspect they're going to be positive.

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You're starting to see it come out, and we've had some come out of our shop as well, both on satisfaction and on clinical outcomes. You're not losing anything with the audio-only.

5 So to shorten this for the sake of time, I'd just say I appreciate you pointing us in the right direction 6 because I think things around supporting evaluation and 7 8 billing guidance seems like it's going to be important. 9 But like everything else, this is a modality, and to be 10 effective it's got to line up with the practices. And so 11 things like you talked about with e-consults are going to 12 be important to get alignment from the provider side.

Let me just ask if any of you want to elaborate 13 14 on the alignment and -- you know, alignment of payers and 15 how do you see that -- how important is that in order so 16 these changes gaining traction within Medicaid if the 17 others are not aligned. And then, Tracy, you hit on 18 something that I hadn't really thought a lot about, but I 19 thought it was a terrific point, and that is, destabilizing 20 components for other providers, if the sort of easy stuff 21 kind of goes off on audio-only and then the people on the 22 ground are left with more complex stuff and there's payer

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1 parity, how worried are you about that?

2 CHAIR BELLA: Anybody on either -- Tracy, do you 3 want to go on your specific one? And then you guys can 4 talk about care alignment.

DR. JOHNSON: Sure, I mean, as I teed up, we've 5 been giving a fair amount of thought to, you know, the 6 opportunities and the risks associated with great interest 7 8 honestly in the Medicaid program newly among these entities 9 that provide telemedicine-only services, and so how do we 10 capture the potential of those kinds of entities that are 11 fairly new to the Medicaid program -- you know, increased 12 access, that kind of thing. But, again, for a fee-forservice state, we pay parity. You know, there's a 13 possibility -- there's, you know, a number of possibilities 14 15 that when we create an accountability framework, we want to 16 kind of create guardrails around. We don't want highvolume, low-value care. We want connections to our medical 17 18 homes and our medical neighborhoods, so, you know, EHR 19 data, is it flowing between the entities? Those kinds of 20 considerations. And we don't want to see our smaller, 21 particularly rural providers destabilized such that in-22 person care is not available to our members. We want, you

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know, telemedicine to add and not, you know, actually
 create new kinds of health equity concerns.

So those are the sorts of things we're thinking 3 4 about as we think about an accountability framework, and I quess the only other thing is just, you know, quality 5 metrics. You know, what are the appropriate metrics to put 6 in place for telemedicine in general, but also for this 7 8 category of provider that, as I said, right now kind of 9 exists outside of all of our current practices. And we've 10 been engaging with telemedicine entities like this, and they're very interested in working with us. So we're 11 12 really hopeful that we can find a balance there, and that's going to be actually a very active area of inquiry in 13 14 Colorado this coming year.

15 CHAIR BELLA: Would anyone like to make 16 additional comments?

DR. BACHIREDDY: I'll just make some quickpoints. I'm sorry. Go ahead, Sara.

DR. SALEK: No -- just really I'll be really brief. I think the more that we can align within coding, the better we'll be as far as being able to do cross-state analysis and also at a national level. So, you know, I

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think it would be really helpful, and I think it is a 1 relatively simple solution. Of course, I say that, but 2 it's always complicated. But, you know, we've been able to 3 4 figure out a coding structure that we can differentiate the 5 different forms of telehealth. So I know it is feasible. And for Arizona, it would be beneficial as far as if our 6 7 commercial private payers adopted a similar approach, just 8 from a simplicity standpoint for providers. So that's a 9 frequent complaint from the provider system, that every 10 payer does it a little bit differently.

DR. BACHIREDDY: So on the alignment piece -- and 11 12 I'll try to be brief here -- that will, I imagine, have to 13 be something that's led at the state level, maybe with guidance at the federal level or a strong recommendation. 14 15 Ultimately a lot of us look to Medicare. I know we do, and 16 certainly we have specific, very Medicaid-specific 17 considerations, obviously, but also, you know, Medicare makes a statement -- right? -- and, you know, really sends 18 19 a powerful signal. To the extent that, you know, Medicare 20 policy is sort of acceptable, and to the extent that states 21 at the highest levels are willing to lead that sort of all-22 payer alignment, it will make a great deal of difference in

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1 terms of reducing the costs of engaging in telehealth.

And I just want to seque to that other point as 2 well. Tracy, thank you for bringing that up. It is really 3 important, and one sort of consideration -- we haven't 4 fully thought this out -- is whether short term there 5 should be payment parity. You heard me say short term, 6 medium term, long term. Maybe short to medium term, 7 there's payment parity, and then longer term the costs may 8 9 change reflective of, you know, what overhead is necessary 10 or not. So I haven't fully thought that through, but that 11 might be one option.

12 The other two things I'll say is in Virginia we're putting in our regulation and our subregulation 13 14 statements around patients having their medical records 15 send to their medical home or primary care provider if the 16 telehealth provider is not part of their medical home. And 17 the second is that telehealth providers be able to have 18 some sort of relationship with an on-site provider in the 19 case of an urgency or the need to really convert a 20 telehealth visit to an in-person visit.

21 Now, what that will actually do and what that 22 will translate to is anybody's best guess, but those are

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small ways that we're trying to address that very question.
 COMMISSIONER CERISE: Yeah, that's important.
 That's a big deal.

4 CHAIR BELLA: Thank you. Can I ask the three of 5 you, are you able to stay a few minutes over, or do you 6 need to right at 3 o'clock? Okay.

So they have very kindly given us some extra time. We have four of you who still want to talk, so please try to direct your question to a specific panelist if you can. Martha and then Sheldon and then Toby and then Chuck.

12 COMMISSIONER CARTER: I'm listening for areas 13 that we as a Commission could make recommendations to 14 support ongoing use of telehealth. This app is going to do 15 a really good job of this, so I was going to elaborate what 16 I heard, but I think I won't.

But I think one of the things to pull out is the whole question of creating standard codes that allow differentiation between audio-only, audio-visual, and synchronous modalities so that we can then, you know, address the issues that we had in the T-MSIS data that we can't distinguish what's what, so that these same codes can

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1 be used for quality metrics. I think it's a very 2 fundamental foundational type of action and recommendation 3 that the Commission could take.

The other question that -- that wasn't really a question. That was just a statement, and I'd like to hear if you agree with me about that that's really sort of a basic step that needs to happen.

8 I had a question about the business about making 9 permanent dropping the requirement for in-person visit for 10 initiation of buprenorphine. Was that made permanent? Or 11 is there room for us to talk about that? Dr. Bachireddy, I 12 think that was you.

13 DR. BACHIREDDY: Oh, yeah, sure.

14 COMMISSIONER CARTER: I think that was you who 15 said that.

DR. BACHIREDDY: Yeah, I did mention it. You know, if you'd be willing to make a recommendation, I would certainly be delighted for you all to do that. You know, the initial guidance came out from SAMHSA, DEA, and HHS to waive a restriction from the Ryan Haight Act, specifically focused -- you know, which required an in-person exam and visit before actually initiating prescriptions of

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buprenorphine. And so during the pandemic, as soon as that 1 was lifted, that really allowed us in Virginia and across 2 the country -- so many of my colleagues as well have really 3 4 thought of this as a wonderful opportunity to lower the 5 threshold for entering into treatment. And so one of the models that we've developed even just in the short -- I 6 quess this past year at a number of health systems in 7 Virginia is a virtual bridge model. And so really it's --8 9 you know, if folks come into the emergency room, they're 10 leaving jail or prison, their risk for overdose can be as 11 high as 120 times higher than the general population, 12 overdose deaths. And they can initiate treatment with buprenorphine which can cut that risk in more than half. 13 They can initiate virtually, right? And so if they have 14 15 challenges with transportation -- like one of my patients 16 couldn't make it today because his transportation didn't 17 work out, but guess what? Because of telehealth, because 18 of virtual visits, because of audio-only, I was able to 19 prescribe him buprenorphine. And so the idea is to allow 20 that for new patients who are even at higher risk than my 21 patient was today, who I know very well. Newer patients 22 who are at much higher risk, how do we lower that

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1 threshold?

So from a practitioner, from a public health, from a patient perspective, absolutely wonderful recommendation because of how relatively safe buprenorphine is and how significant the impact could be and has been on patients' lives in the past year.

7 COMMISSIONER CARTER: Thank you. I've heard 8 practices talk about doing buprenorphine initiation in the 9 patient home, and that works well in some situations. And 10 I just wondered if there was an action that needed to 11 happen or was that a temporary lifting or has that been 12 made permanent? Or maybe that's something the staff can 13 explore in more detail.

14DR. BACHIREDDY: Yeah, and I'll just say one word15if it's okay. It's temporary right now. It's temporary.

16 COMMISSIONER CARTER: Okay. Thank you.

17 CHAIR BELLA: And, Martha, we can bring it up 18 after -- when we have our discussion after this panel, if 19 you want to --

20 COMMISSIONER CARTER: Great. Thanks. I can't 21 promise that we'll make a recommendation. I just wanted to 22 know if there was -- if that was an area that was -- that

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1 we should consider. Thank you.

DR. SALEK: Yeah, and this is Sara. You know, I 2 am also a buprenorphine-waivered clinician. I've provided 3 4 addiction virtual services via telehealth. And, you know, 5 I wish that there was like a simple answer to that question. I think folks within addiction medicine may feel 6 7 differently, but obviously it's becoming more of a primary 8 care, which is great as far as increased access to care. 9 I would say that definitely for addiction 10 services it's not a one-size-fits-all, and some individuals 11 are better served through opioid treatment programs than 12 through, you know, Suboxone through an OBOT. The only other thing I would add is that similar to what I was 13 14 describing earlier around some of the challenges around the 15 objective data, like urinalysis, for example, when it comes 16 -- you know, urine drug screens or other labs, you know,

17 Breathalyzer, et cetera, that there's still room for

18 ongoing improvement in regard to a hybrid-based model for 19 opioid addiction treatment.

20 CHAIR BELLA: Thank you. Sheldon, Toby, Chuck, 21 and a friendly reminder to please keep your questions 22 targeted.

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1 Sheldon, I think you're on mute. 2 COMMISSIONER RETCHIN: This is going to be really 3 targeted. So Tracy, in the early '90s -- actually, 4 perhaps, really quick -- most of the discussions I heard 5 about telehealth involve its ability to be a proxy 6 substitute technology for analog medicine. Can we do what 7 we do in person, do it digitally?

8 I haven't heard novel increases or expanded uses that might be superior to an analog experience, and in 9 10 particular, in the early '90s there was a physician, I 11 don't know if you know about this, John Scott, out of 12 Denver, who introduced what he called group visits, which 13 later became shared medical appointments. And the idea was 14 to get primary care physicians to get all their type 2 15 diabetics in a room, and then they would be almost a group 16 medical therapy. And he showed incredible results. And I 17 went out and observed them, actually, as part of a grant. 18 It kind of faded away, and there may be some

19 semblance of that, but I wonder if telehealth might be an 20 opportunity to revive it. For example, the best-known 21 mechanism for encouraging somebody who has vaccine 22 hesitancy for COVID vaccine is if their own physician

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1 recommends it and is able to answer their questions. And
2 I've wondered why primary care physicians haven't used
3 telehealth to get to panels, large group panels, 300
4 patients at a time, because I've down town halls like that
5 on COVID, that might decrease vaccine hesitancy and other
6 uses. I don't know if any of the panelists have tried
7 doing anything like that.

8 DR. JOHNSON: Since you mentioned me I'll answer 9 first and let others chime in. I'm aware of group visits 10 on the behavioral health side. I'm not aware of group 11 visits on the physical health side, but it's possible I 12 just haven't heard about that. But there definitely has been some experimentation and, anecdotally anyway, some 13 success with group visits on the behavioral health side. 14 15 CHAIR BELLA: Thank you. Toby, and then Chuck. 16 COMMISSIONER DOUGLAS: Great. Great presentations, and as always, it's great to hear from the 17 18 states.

My question is really around FQHCs and telehealth, and really the tension. I haven't heard that being -- I'm putting on my state Medicaid hat -- there's always concerns around the PPS and that the payment rate,

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and clearly, with telehealth and audio, and this question -1 - I'm making sure, Melanie, I'm being direct -- has Tracy 2 given you guys' past legislation that allows for audio-3 4 only, when that means that you're going to have to pay at the PPS, and this tension, which might be the right thing 5 but it is a financial implication and inability to change 6 the rates to align with audio, you know, with the concept 7 8 here of aligning payment to the type of modality.

9 And so question for you, Tracy, is if that came 10 up. Others can chime in if they're thinking about how FQHC 11 payment policies could be incorporated within telehealth.

DR. JOHNSON: Yeah, great question. Thank you. I mentioned earlier about, you know, our well child check dilemma, and it being a payment issue. It really is an FQHC payment issue. We're able to figure out how to spread a single payment across two visits on the fee schedule side. We just haven't been able to figure it out on the FQHC side, so your point is well taken.

What we're doing in Colorado, and this predates the pandemic, is we are working with our FQHC partners to develop a prepayment modality. So it's not quite a capitation but it has some of that per-member payment

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1 aspects. And that was already something that the FQHCs wanted to do, because it frees them up clinically a little 2 3 bit, but particularly post-pandemic, we're waiting for CMS 4 approval on this, but, you know, the three pilot sites have other FQHCs stacking up behind them, wanting to 5 participate, because, you know, the downsides of being a 6 fee-for-service provider were made evident during the 7 8 pandemic when people had no visits, and so a per-member 9 payment would have been stabilizing during the pandemic, 10 and to your point, allows telemedicine to be provided more 11 flexibly, and so could get around some of those tensions 12 you're referencing.

13 COMMISSIONER DOUGLAS: Great. Is this an 14 alternative payment methodology that you guys are looking 15 at?

DR. JOHNSON: Yeah. We already have an alternative payment methodology, but this is one that would allow us to really sort of take an attributed member population and calculated based initially on past utilization, you know, what a per-member payment would be. And then going forward, you know, maybe adjust that with some sort of inflationary type factor. So we have a policy

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like this sitting in front of CMS right now, looking for
 approval.

3 COMMISSIONER DOUGLAS: Thank you.

CHAIR BELLA: Thank you. Chuck, last question.
VICE CHAIR MILLIGAN: Thank you all very much,
and Tracy, I wanted to ask you a question as well. I think
the former Medicaid directors are picking on you a little
bit here.

9 My question is really about dual eligibles and 10 the bi-play with Medicare. And we had a discussion earlier 11 today about rebalancing, so I want to just help focus the 12 question by thinking about somebody in a home and community-based setting but they need primary care. 13 They're often a dual eligible. To be said that Medicare 14 15 doesn't stay as flexible or as expanded as Medicaid, the 16 Medicaid program might have some jeopardy around 17 rebalancing, because you have lost the modality of in-home 18 care through telehealth for some of the people with ADL 19 limitations. But also you might have a financial impact 20 because you've lost the ability to coordinate benefits with 21 Medicare if you expand your telehealth modality beyond what 22 Medicare covers and Medicaid suddenly becomes primary

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1 instead of secondary.

And so I'm curious about whether the Medicaid 2 directors, you or others, are advocating through your 3 delegations or advocating with CMS around the relationship 4 for duals and the importance of Medicare from a 5 coordination of benefits financial part of it, but also in 6 support of rebalancing efforts for home-based telehealth 7 care. So that's the kind of area I just wanted to ask what 8 9 the state of play is.

DR. JOHNSON: Yeah. I think there's another Medicare issue that's worth mentioning, so I'm going to answer your question a little bit indirectly, but you know, it sort of underlines your point that coordinating Medicaid and Medicare policy is going to be really helpful here.

15 During the pandemic, as I said, we initiated our 16 rules and then our public health agency that certifies -- I don't know if I'm using quite the right word -- home health 17 18 agencies contacted us and said, "We didn't know you were doing this, and we're hearing from home health agencies 19 that we need to address our policies." And it took me a 20 21 second to get my head around what the issue was, but 22 basically home health agencies, that see both Medicare and

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Medicaid patients and duals, are kind of getting 1 conflicting guidance from the Medicare policy on 2 telemedicine and with our new emergency policies on the 3 Medicaid side. And so while Medicaid would have been 4 permissive about doing certain forms of telemedicine, 5 Medicare was saying those things were not actually allowed. 6 And so we had to quickly get our state public health agency 7 8 aligned.

9 And so having differences across Medicaid and 10 Medicare has a lot of those kind of impacts, and so as my 11 colleague from Virginia said, really having policies 12 aligned as much as possible is helpful on a number of 13 different fronts.

14 VICE CHAIR MILLIGAN: And Dr. Bachireddy, I would 15 have directed it toward you, but we've run out of time. 16 But I do think, Tracy, it's not just the issue you 17 mentioned but I think there is a risk of cost-shifting the 18 Medicaid of otherwise previously Medicare-covered services 19 if you expand beyond where they've expanded, and now you're 20 primary. So thank you all.

21 CHAIR BELLA: Thank you, Commissioners. But more 22 importantly, thank you, Chethan, Sara, and Tracy. If there

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are things that you didn't get to say or that you think 1 afterwards, "Boy, I wish I would have said that," please 2 3 feel free at any time, because this is an area of great 4 interest to us and where we can help you is what matters to us. So please don't hesitate to reach out if anything 5 comes up. And I want to thank you for not only making the 6 time but staying past time with us. So please enjoy the 7 8 rest of your Friday and thank you very much again.

9 DR. SALEK: Thank you.

10 DR. BACHIREDDY: Thanks so much. Bye.

## 11 ### FURTHER DISCUSSION BY THE COMMISSION

12 \* CHAIR BELLA: Okay. We have a little bit of time 13 left, I'm going to say about 15 minutes, to have some 14 discussion and to share some more thoughts with Joanne and 15 Michelle. And let me to say to Joanne and Michelle, thank 16 you for pulling those three together. That was a fabulous 17 panel. Those kinds of panels are so informative and so 18 valuable to our work, so thank you for that.

Who would like to share some feedback. Kisha?
COMMISSIONER DAVIS: Thanks. That was a great
panel. You know, in thinking about some next steps I would
love to see us wrestle a little bit with the value-based

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care aspect of telehealth. You know, so there's certainly 1 benefit of being able to say to a provider, say to a 2 3 primary care physician, "You own the patient relationship 4 and you know and trust your patient enough to be able to make the call on whether that patient needs to be seen in 5 person, on the phone, via audiovisual, and to get 6 7 compensated accurately for that and not have to worry 8 about, I have to bring that patient in because I'm not 9 going to get paid enough to do it."

10 And there's the flip side of that, you know, 11 fraud, waste, and abuse piece, so that that's not abused 12 and that patients are getting seen, and that patients who 13 don't have access to broadband and telehealth are not 14 getting left out of that equation.

So there are complexities there, and so just how we wrestle with the payment piece of it so that we're not tied down into, "Yeah, well, you've got to come in because that pays more," but really coming at it from what's best for the patient.

20 CHAIR BELLA: Thank you, Kisha. Others? Martha, 21 was that your hand?

22 COMMISSIONER CARTER: Yeah, thanks. I think

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there are just so many places that we could go with this.
I do want to think about a system of coding convention or a
set of codes that really help distinguish the types of
telehealth. And I don't know if that's an area that we
would do or if that's CMS, or make a recommendation that
that happens, because it seems like it's foundational.

7 I think the other place that I heard -- lots of 8 places -- investment in infrastructure, to make sure that states have the capacity to do the analysis to set up 9 10 quality measuring, to set up patient satisfaction. And by 11 the way, I think there's another potential sort of national 12 recommendation around adding like -- I forget who it was 13 who talked about adding specific telehealth questions to 14 the CAHPS, so that everybody is doing it the same, because 15 right now as states are innovating they're going to wind up 16 with a bunch of different products and it makes it hard to compare across states and to look at national data. 17

I would like to look at that business about dropping a requirement for in-person visits for initiation of buprenorphine. I think that's huge, and to the extent that we can weigh in on that I think would be extremely beneficial. So it's related to telehealth, because you'd

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1 still have to have some kind of a visit. You'd still have
2 to have some kind of a monitoring, but it could be done
3 through telehealth rather than in person.

4 Right now the person has to sit around, they get a dose -- Kisha can talk to this -- but they get a dose and 5 you wait and see if that eliminates their cravings or their 6 7 withdrawal, and then they get another dose and you decide 8 where they land and then they go home. And there's probably more to it, Kisha, but there's a fair amount of 9 10 time spent in the office that can be done at home, but 11 there still needs to be some interaction with a health care 12 provider through all this. So I think that's an area ripe for some work on our behalf. 13

MS. JEE: Can I just hop in there for just a quick sec, on that issue, Martha? Erin is reminding me that the administration has signaled that they're looking into this issue. You know, they still have to do the work of it. So that's sort of one point.

19 The second point is that, you know, just a 20 reminder that that policy is a policy of the Drug 21 Enforcement Agency and SAMHSA, so lives outside of 22 Medicaid, unfortunately. I just put that out there. You

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1 know, it doesn't make it less of an issue, but it might put
2 some limitations on sort of like how far MACPAC could go
3 with that.

4 COMMISSIONER CARTER: Sure, although we make
5 recommendations that other agencies look at different
6 things. We did that today. I get your point, though.
7 It's not something that is directly controlled by Medicaid.
8 Thanks.

9 CHAIR BELLA: Other folks?

10 CHAIR BELLA: All right. Well, while people are 11 thinking let me turn to the public to see if we have any 12 public comment on our afternoon sessions. If you would 13 like to make a comment please indicate so by hitting your 14 little hand icon.

15 [Pause.]

16 **### PUBLIC COMMENT** 

17 \* [No Response.]

18 CHAIR BELLA: No hands coming. We just lost 19 Joanne and Michelle. I assume could tell -- there's Joanne 20 -- you could see a lot of the areas of interest by the 21 questions that were asked, and so my sense is a lot of that 22 isn't getting repeated here, but I saw you taking furious

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notes on all those things, and the states were wonderful in sort of teeing up for us, here's what would be helpful, from a policy perspective.

4 So we don't have any public commenters. Did we 5 have any additional Commissioners comments, or Joanne or 6 Michelle, anything else you need from us to indicate where 7 we'd like to take some of this additional future work?

MS. JEE: I mean, you've definitely given us a 8 lot of food for thought. I mean, I think that there's 9 10 going to be -- we going to need to sort of think about how 11 we prioritize some of these things, right, and then the 12 memo had some other areas of potential work. So just 13 thinking about the things that we discussed today, that you 14 all discussed today with that. But I think I have a good 15 sense of some of the key areas.

16 CHAIR BELLA: Yes, we have prioritization to do 17 across all of our areas, so point well taken.

18 All right. Oh, Sheldon, did you have a comment? 19 COMMISSIONER RETCHIN: Yeah. I wanted to just 20 circle back a little bit, real quickly, with something Fred 21 had brought up, and it caught my attention as well. With 22 every novel technology there is something that's disrupted,

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and as you start to round out the portfolio for telehealth, 1 it would be interesting just to track the growth of public 2 3 and private companies that are going across state lines or 4 providing a competitive service, and addressing that, not just in terms of the frontier, in-person practices that may 5 be disrupted but urban, inner city. But they're going to 6 provide a service, and so there are a bunch of questions 7 that come out of that, among them the moral hazard of 8 9 providing that.

10 Anyway, it's an interesting area, but there's 11 going to be a lot of other issues that are going to arise 12 if this technology stays as robust as it looks now.

13 CHAIR BELLA: Thank you, Sheldon. Any other 14 comments?

15 All right. Well, I want to take just a minute. 16 As Commissioners, we've had a chance to thank our colleagues, but I want to publicly recognize that this is 17 18 the last meeting for five of our Commissioners, and 19 publicly acknowledge their service and thank them, although 20 some of them are popping off the screen, which is not cool. 21 So this is the last meeting for Chuck, for Sheldon, for 22 Peter, for Leanna, and for Tom. And so I am speaking on

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behalf of the Commission and the staff as well in saying what an exceptional group of leaders and Commissioners those five have been, and there will be a huge gap, big shoes to fill by the next group that comes in. And thank you, all of you, for your service.

And I'm not kidding. I expect to see you in the audience, making public comment with the areas that we know are near and dear to your heart.

9 So anything else to say? No. I thought we'd 10 also, on behalf of all the Commissioners, I want to thank 11 Anne and the staff. Once again, this is thoughtful 12 information, and thoughtful work for us to try to do our 13 duty. So I really appreciate that and the continued effort 14 you're making during the less-than-normal pandemic time, so 15 thank you very much.

16 I'm looking to see if there's any last hands.
17 Any final jokes from anyone? No? Okay.

18 Once again, thank you very much.

19 COMMISSIONER BURWELL: We'll miss you guys.

20 CHAIR BELLA: Thank you, everybody. Have a 21 wonderful weekend.

22 \* [Whereupon, at 3:22 p.m., the meeting was

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1 adjourned.]