MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Thursday, April 13, 2023 10:49 a.m.

COMMISSIONERS PRESENT:

MICHAEL CHERNEW, PhD, Chair AMOL S. NAVATHE, MD, PhD, Vice Chair LYNN BARR, MPH LAWRENCE P. CASALINO, MD, PhD ROBERT CHERRY, MD, MS, FACS, FACHE CHERYL DAMBERG, PhD, MPH STACIE B. DUSETZINA, PhD MARJORIE E. GINSBURG, BSN, MPH DAVID GRABOWSKI, PhD JONATHAN B. JAFFERY, MD, MS, MMM, FACP KENNY KAN, CPA, CFA, MAAA GREGORY POULSON, MBA BETTY RAMBUR, PhD, RN, FAAN WAYNE J. RILEY, MD, MPH, MBA JAEWON RYU, MD, JD DANA GELB SAFRAN, ScD SCOTT SARRAN, MD

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1 PROCEEDINGS 2 [10:49 a.m.] DR. CHERNEW: Hi, everybody, and welcome to our 3 4 last meeting of this 2022-23 MedPAC cycle. As is the norm 5 in April, we have a number of chapters we have been discussing over the course of the year, and we will be 6 7 having votes on the recommendations that we have developed, and without further ado, we are going to start with a 8 9 particularly large and important area, which is Medicare 10 Part B. So am I turning it over to you, Nancy? So, Nancy, 11 take us away. 12 MS. RAY: Good morning. The audience can 13 download a PDF of the slides on the right-hand side of the 14 screen. 15 Here is the journey that we have taken in 16 improving payment for Part B drugs. Today's session is a 17 continuation of this work that focuses on approaches that aim to maintain incentives for innovation with 18 19 affordability for beneficiaries and taxpayers. 20 Today we will continue our January and March 21 discussion of three policies to improve Medicare's payment 22 for Part B drugs. The first two address manufacturers'

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pricing behavior and uncertainty about the clinical benefit of some accelerated approval drugs and the lack of price competition among existing drugs with therapeutic alternatives. And the last policy addresses the add-on payment and providers' financial incentives.

Kim and I will review each policy, and you will
vote on the three draft recommendations. This work will be
published in the June 2023 report.

9 The Medicare program and beneficiaries spent \$43 10 billion on Part B drugs in 2021. Spending is growing 11 rapidly -- about 9 percent per year on average over the 12 last decade. The largest driver of spending growth has been the rise in the average price Medicare Part B paid for 13 14 drugs. Under the Part B payment system based on ASP, the 15 program is a price taker. Manufacturers set their own 16 prices for new drugs and, historically, have set high 17 prices whether or not there is evidence that the drug is more effective than the standard of care. While the 18 19 Inflation Reduction Act contains changes to Part B drug 20 payment, it has not negated the policy package that we will 21 be discussing today.

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22
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The first policy addresses payment of accelerated

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approval drugs. The accelerated approval pathway expedites 1 the approval of potentially promising products by reducing 2 the development time needed to bring a drug to market 3 4 compared with the traditional approval process. However, 5 for some drugs, there is uncertainty about their impact on beneficiaries' outcomes, because accelerated approval is 6 based on a surrogate or intermediate clinical endpoint that 7 8 is reasonably likely to predict a clinical benefit rather 9 than a direct measure of clinical benefit.

Medicare lacks tools to differentiate payment for accelerated approval drugs whose clinical benefit is not verified, whose confirmatory trial is late, or when the product is covered under a coverage with evidence development policy. The statute requires the Secretary to pay for single-source drugs based on the drug's ASP.

Because there is no differential payment, some manufacturers might lack incentives to complete their confirmatory trials efficiently.

A policy that would cap payment of select accelerated approval drugs as we discussed last month would spur manufacturers to complete their confirmatory trials promptly and help ensure Medicare is not overpaying when a

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1 product's clinical benefit is not confirmed.

2 Setting the payment cap based on the clinical 3 benefit and cost of the accelerated approval drug relative 4 to the standard of care would recognize the potential 5 clinical benefit of these products.

6 The Secretary could operationalize the cap using 7 a rebate approach, which is already in use under the IRA 8 inflation rebate policy.

9 Once a manufacturer verifies a drug's clinical 10 benefit, the cap on the payment rate would revert to 11 current law.

And so this leads us to draft recommendation 1, which reads: The Congress should require the Secretary to cap the Medicare payment rate for Part B drugs and biologics that are approved under the accelerated approval program (with limited circumstances for the Secretary to waive the payment cap) if:

a) Postmarketing confirmatory trials for the
product were not completed within the deadline established
by the manufacturer and the Food and Drug Administration,
b) The product's clinical benefit was not
confirmed in postmarketing confirmatory trials, or

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c) The product is covered under a coverage with
 evidence development policy.

In addition, the Congress should give the Secretary the authority to cap the Medicare payment rate of Part B drugs and biologics that are approved under the accelerated approval program if their price is excessive relative to the upper bound estimates of value.

8 This draft recommendation is expected to decrease 9 program spending relative to current law. The policy is 10 expected to generate savings for beneficiaries through 11 lower cost sharing, and it is not expected to adversely affect beneficiaries' access to needed effective medicines. 12 This draft recommendation is expected to result in more 13 14 timely development of evidence about the clinical benefit 15 of accelerated approval drugs for beneficiaries and 16 providers. We also expect continued provider willingness 17 and ability to care for Medicare beneficiaries.

MS. NEUMAN: Under the Part B drug payment system, there is insufficient price competition among drugs and biologics with similar health effects because Medicare pays for these products based on their own ASP.

22 In 2017, the Commission recommended a combined

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billing code policy for biosimilars and originator
 biologics, which is a type of reference pricing that would
 pay these products the same average rate to spur price
 competition.

5 Building on that recommendation, a policy to 6 extend reference pricing beyond biosimilars by applying a 7 single ASP-based payment rate to drugs and biologics with 8 similar health effects would spur price competition.

9 As we discussed in March, here is how the policy 10 could be structured.

Each product in a reference group could remain in its own billing code.

Medicare could set the payment rate based on the weighted average ASP of all products in the group.

In defining reference groups, the Secretary could consider various factors, including clinical indications, drug classification, and ease of implementation, starting with: biosimilars and originator biologics; drugs approved under FDA's 505(b)(2) pathway and related brand and generics; and drugs for which reference pricing has been implemented or previously considered.

22 So this brings us to the draft recommendation.

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It reads: The Congress should give the Secretary the
 authority to establish a single average sales price-based
 payment rate for Part B drugs and biologics with similar
 health effects.

5 In terms of implications, the draft 6 recommendation is expected to decrease Medicare program 7 spending by spurring price competition among manufacturers 8 and creating incentives for providers to select lower-9 priced products.

In terms of beneficiaries, the draft recommendation is expected to generate savings for beneficiaries, and it is not expected to adversely affect beneficiaries' access to needed medicines.

14 In terms of providers, payments to providers are 15 expected to decrease over time as manufacturers reduce drug 16 prices, and this translates into lower drug purchase prices 17 for providers and lower ASPs.

18 The next policy focuses on improving financial19 incentives under the Part B drug payment system.

20 Medicare pays providers for most Part B drugs 21 based on the average sales price plus 6 percent. In 22 addition, Medicare makes a separate payment to providers

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1 for drug administration services under the physician fee 2 schedule or outpatient prospective payment system. Like 3 all Medicare services, payments for Part B drugs are 4 subject to the 2 percent sequester until 2032.

5 While clinical factors play a central role in 6 prescribing decisions, financial considerations can also 7 play a role.

8 There is concern that the percentage add-on to 9 Medicare's ASP may create incentives for providers to 10 select higher-priced products when a lower-priced product 11 is available to treat a patient's condition.

12 There is also concern about Medicare's add-on 13 payment for drugs that lack ASP data. For those drugs, 14 Medicare pays a percentage add-on to the drug's wholesale 15 acquisition cost, or WAC, which is generally a higher price 16 than ASP.

Policy changes could be made to improveincentives under the Part B payment system.

First, for drugs paid based on ASP, the uniform 6 percent add-on could be replaced with an approach that seeks to minimize the relationship between price and add-on payments by reducing add-on payments for costly drugs.

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1 This general approach would: for low-priced 2 drugs, maintain the 6 percent add-on; for mid- and high-3 priced drugs, reduce the percentage add-on and add a fixed 4 fee; and for the costliest drugs, apply a fixed dollar cap 5 to add-on payments.

To help illustrate the approach, we modeled the following policy as an example: ASP add-on equals the lesser of 6 percent, 3 percent+\$24, or \$220 per drug per day.

10 Of course, policymakers could consider other 11 percentages and dollar amounts.

Second, for drugs lacking ASP data that are paid based on WAC, a policy that eliminates add-on payments for these drugs would also improve financial incentives.

15 This brings us to the draft recommendation. It 16 reads: The Congress should require the Secretary to: 17 Reduce add-on payments for costly Part B drugs 18 and biologics paid based on average sales price in order to 19 minimize the relationship between average sales price and 20 add-on payments, and

21 Eliminate add-on payments for Part B drugs and22 biologics paid based on wholesale acquisition cost.

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In terms of implications, the draft
 recommendation is expected to decrease Medicare program
 spending by at least \$250 million over one year and at
 least \$1 billion dollars over five years.

5 In terms of beneficiaries, it is expected to 6 generate savings for beneficiaries through lower cost 7 sharing and is not expected to adversely affect 8 beneficiaries' access to needed medicines.

9 In terms of providers, add-on payments to 10 providers would generally decrease except for lower-priced 11 drugs. There could be increased financial pressure for 12 some providers (depending on factors such as manufacturer's 13 pricing response to the policy); overall, the policy is not 14 expected to affect providers' willingness and ability to 15 serve beneficiaries.

16 So that brings us to the end of the presentation. 17 We look forward to your discussion, and we turn it back to 18 Mike.

DR. CHERNEW: Thank you both. We have time for a few comments. Remember, we have three votes to get to, so let's do comments on any aspect of this, and then we'll do the three votes just back-to-back. Jim, is that -- okay.

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1 So I think in this context, Stacie, you're number one.

2 DR. DUSETZINA: Thank you. This is exceptional 3 work, and I'm really glad to see we've gotten here --4 probably not as glad as you both are reaching this 5 particular milestone.

I just had a couple of broad comments about 6 7 Policy 1 and Policy 3. Policy 2, I think no specific 8 changes. These are really kind of reflecting some of my 9 prior feedback, I think, where for Policy 1 on the 10 accelerated approval, I still think it would be really 11 great to have like a stand-alone sentence that says clear 12 and consistent criteria are needed for any exceptions, like for both selecting a product that is outside of the bound 13 of value and for giving an exception to products that 14 otherwise meet the criteria from the first three bullet 15 16 points. So I think it would be great to just really hammer 17 that home, because that's going to take a lot of work to 18 figure out what those exceptions are to avoid gaming, but 19 also to give the industry clear guidance on what is 20 expected of them.

21 The other thing is, you know, I think the chapter 22 is great, there is, you know, a section where we go down

the road of talking about R&D cost, and I actually think it might be distracting from the main point. It might be worth removing because I think rational people could have a lot of disagreement. There's not a lot of literature in this space, and I think anything that could help just keep us really laser focused on the problem at hand would be fantastic.

8 The other thing is I noticed -- and I was trying 9 to go back to look in the chapter -- in the draft 10 recommendation presented on the slide for Recommendation 1, 11 there's the parenthetical about exceptions, yeah, so with 12 limited circumstances. I would actually take that 13 parenthetical out right there and add it after you tell us 14 what the three different bullet points are. So it's like 15 in these situations, this should happen: a, b, c. And 16 then a separate sentence right after that that just says 17 "with limited circumstances the Secretary could waive the 18 payment cap" even among products who meet these. It's just 19 one of those things where, when you said it, the flow of 20 it, I was, like, oh, wait, it kind of breaks it up in a way 21 that I don't think is as helpful. And maybe the text 22 doesn't have the parenthetical in it.

DR. CHERNEW: We're not changing any wording in
 the recs.

DR. DUSETZINA: No, no. Just where the 3 4 parentheses are. Like if you took that "with limited 5 circumstances for the Secretary to waive" --DR. CHERNEW: I'll look to Jim, but I think the 6 way the words are now is the wording on the rec is going to 7 8 stay the wording in the rec. Jim, so you want to weigh in 9 on that? 10 DR. DUSETZINA: Same words but different 11 location? DR. CHERNEW: No, I get what you're saying. I 12 13 understand. 14 UNIDENTIFIED SPEAKER: I was also getting tripped 15 up on that. 16 DR. DUSETZINA: It just became clear to me when 17 Nancy said it out loud, I was like, oh, that sort of adds 18 more confusion than I think is intended, because I think these are really clear. It's just that parenthetical I'd 19 put after you say "c." "There could be limited 20 21 circumstances where the Secretary could waive this." I'm totally fine if you end up not going in that direction. I 22

1 just think it adds confusion with the parenthetical there.

2 DR. MATHEWS: Okay. We do need to vote on a 3 recommendation. If there is a push to change this, we 4 would have to revise the recommendation, put it back up, 5 and I would --

DR. CHERNEW: I think we're going to go with the 6 wording in the recommendation as the wording is literally 7 8 written. I mean, I think it -- I'm not going to dispute 9 the substance of what you're saying. It's just process-10 wise, where we are now, there's just not opportunity to 11 change the word -- in the text we can do whatever we want, 12 but the wording is not the way that the process is going to qo. Is that how I hear you -- yeah. 13

14 DR. DUSETZINA: Okay. And my last point is on 15 Policy 3. It's related again to this ASP+6, and I do 16 really appreciate the efforts made in the chapter to make 17 this clearer that these are examples, you know, like -- I 18 do think, though, this is something that people who work in this infusion space are highly sensitive to. I think where 19 20 we first say 6 percent anywhere, we should mention the 21 sequester and say it's 4.3 percent in the text. Or we 22 could potentially remove some of those numbers, because I

think you could say percentage markup and just kind of --1 you could say up front that it's 6 percent, but actually 2 4.3, because I continue to worry that if someone is reading 3 4 that, they're going to think we're suggesting that we -you know, the number could be all the way back down to ASP 5 plus like 1 percent when we move it down to 3, or reduce it 6 by 3 percent. So that would just be the other thing, is 7 8 trying to remove text about 6 percent where we can to just 9 say "and a markup."

But I really think this is excellent work, and I'm really happy to see where we've gotten with these recommendations.

13 MS. KELLEY: Scott.

14 Yeah, I'm very impressed with the DR. SARRAN: 15 work, very pleased with the conclusion in the policy 16 recommendations. Just a brief comment largely building off 17 of Stacie's, and it's just that as we move via the IRA and 18 our work towards a set of approaches that begins for the 19 first time in this country to align payment for drugs with 20 the value created for the beneficiaries, it's important to 21 continue to emphasize the critical nature of the build-out 22 of the foundational elements that will allow that work to

go ahead successfully and with the required multi-1 stakeholder support. So anything we can do to call out the 2 continued importance of developing a consistent approach to 3 4 cost-effectiveness analysis and the exercises around definition of and comparisons to standard of care, let's 5 just think about it and, Jim and staff, if there's a way to 6 beef up what you've already got in there, which is 7 8 excellent, around - gosh, this is a lot of work and it's 9 going to need to be multi-stakeholder and it's going to 10 need to be continuous for all the policies that we're 11 putting forward to be successfully operationalized.

12 DR. SARRAN: Dana, you're next, and you'll be 13 last, and then we'll go through our votes.

DR. GELB SAFRAN: Thanks. I also want to really applaud this work, and the comment I was going to make was very similar to Scott's, just the excitement, especially as this is my last MedPAC meeting, to see us moving in this direction of really being able to use value as part of pricing for drugs in U.S. health care is really nothing short of transformational.

21 I did have a question, and this is probably 22 because of my having missed the March meeting and

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discussions there, but with respect to Policy 1, I'm trying to understand how you're saying that a cap would be based on value but where we don't have information yet on value.

4 MS. RAY: Right, so in some instances, there may still be enough information from the accelerated approval 5 drug's clinical trials -- accelerated approval trial that 6 that's what got them to the FDA approval, that the 7 8 Secretary could consider in using. And in the instances in 9 which that's not available, then there are the other two 10 options that we described in the paper as well. But we are 11 thinking that in most instances the Secretary can -- would 12 be -- that the clinical trial information evidence that the manufacturer used for the accelerated approval could be 13 14 used.

15 DR. CHERNEW: Okay. So we're going to go through 16 the voting process. I think we'll start with 17 Recommendation 1, if you can put it up. I quess since 18 Scott and Dana talked -- why don't we start with Scott 19 first -- right, so we'll start with you, Scott, since you 20 commented, and that will be reverse alphabetical order, so 21 that's the order in which we're going to go. The question 22 on the table is now just we're voting on Recommendation 1.

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1 Do I need to do anything else, Dana? Is that appropriate 2 parliamentary procedure?

MS. KELLEY: I think I have to read it. 3 4 DR. CHERNEW: Oh, okay. 5 MS. KELLEY: Okav. So voting on Recommendation 1, which reads: The Congress should require the Secretary 6 to cap the Medicare payment rate for Part B drugs and 7 8 biologics that are approved under the accelerated approval 9 program (with limited circumstances for the Secretary to 10 waive the payment cap) if: 11 a) Postmarketing confirmatory trials for the 12 product were not completed within the deadline established by the manufacturer and the Food and Drug Administration, 13 14 b) The product's clinical benefit was not 15 confirmed in postmarketing confirmatory trials, or 16 c) The product is covered under a coverage with 17 evidence development policy. 18 In addition, the Congress should give the Secretary the authority to cap the Medicare payment rate of 19 20 Part B drugs and biologics that are approved under the 21 accelerated approval program if their price is excessive

22 relative to the upper bound estimates of value.

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1		Voting yes or no, Scott?	
2		DR. SARRAN: Yes.	
3		MS. KELLEY: Dana?	
4		DR. GELB SAFRAN: Yes.	
5		MS. KELLEY: Jaewon?	
6		DR. RYU: Yes.	
7		MS. KELLEY: Wayne?	
8		DR. RILEY: Yes.	
9		MS. KELLEY: Betty?	
10		DR. RAMBUR: Yes.	
11		MS. KELLEY: Sorry. Just looking for	pictures
12	here.	Greg? We have a thumbs up from Greg.	
12 13	here.	Greg? We have a thumbs up from Greg. Kenny?	
	here.		
13	here.	Kenny?	
13 14	here.	Kenny? MR. KAN: Yes.	
13 14 15	here.	Kenny? MR. KAN: Yes. MS. KELLEY: Jonathan?	
13 14 15 16	here.	Kenny? MR. KAN: Yes. MS. KELLEY: Jonathan? DR. JAFFERY: Yes.	
13 14 15 16 17	here.	Kenny? MR. KAN: Yes. MS. KELLEY: Jonathan? DR. JAFFERY: Yes. MS. KELLEY: David?	
13 14 15 16 17 18	here.	Kenny? MR. KAN: Yes. MS. KELLEY: Jonathan? DR. JAFFERY: Yes. MS. KELLEY: David? DR. GRABOWSKI: Yes.	
13 14 15 16 17 18 19	here.	Kenny? MR. KAN: Yes. MS. KELLEY: Jonathan? DR. JAFFERY: Yes. MS. KELLEY: David? DR. GRABOWSKI: Yes. MS. KELLEY: Marge?	

1		MS.	KELLEY:	Cheryl?
2		DR.	DAMBERG:	Yes.
3		MS.	KELLEY:	Robert?
4		DR.	CHERRY:	Yes.
5		MS.	KELLEY:	Larry?
6		DR.	CASALINO:	Yes.
7		MS.	KELLEY:	Lynn?
8		MS.	BARR: Ye	es.
9		MS.	KELLEY:	Amol?
10		DR.	NAVATHE:	Yes.
11		MS.	KELLEY:	Mike?
12		DR.	CHERNEW:	Yes.
13		MS.	KELLEY:	Okay. Moving to Recommendation 2
14		DR.	CHERNEW:	And we'll do it in alphabetical
15	order.			
16		MS.	KELLEY:	Okay.
17		[Lau	ghter.]	
18		DR.	CHERNEW:	Okay. We'll do them all in
19	reverse.	Fine		
20		MS.	KELLEY:	Recommendation 2 reads: The
21	Congress s	shoul	d give th	ne Secretary the authority to
22	establish	a si	ngle aver	rage sales price-based payment rate

1 for drugs and biologics with similar health effects.

2 Scott?

3	DR. SARRAN: Yes.
4	MS. KELLEY: Dana?
5	DR. GELB SAFRAN: Yes.
6	MS. KELLEY: Jaewon?
7	DR. RYU: Yes.
8	MS. KELLEY: Wayne?
9	DR. RILEY: Yes.
10	MS. KELLEY: Betty?
11	DR. RAMBUR: Yes.
12	MS. KELLEY: Greg? Thumbs up from Greg.
13	Kenny?
13 14	Kenny? MR. KAN: Yes.
	-
14	MR. KAN: Yes.
14 15	MR. KAN: Yes. MS. KELLEY: Jonathan?
14 15 16	MR. KAN: Yes. MS. KELLEY: Jonathan? DR. JAFFERY: Yes.
14 15 16 17	MR. KAN: Yes. MS. KELLEY: Jonathan? DR. JAFFERY: Yes. MS. KELLEY: David?
14 15 16 17 18	MR. KAN: Yes. MS. KELLEY: Jonathan? DR. JAFFERY: Yes. MS. KELLEY: David? DR. GRABOWSKI: Yes.
14 15 16 17 18 19	MR. KAN: Yes. MS. KELLEY: Jonathan? DR. JAFFERY: Yes. MS. KELLEY: David? DR. GRABOWSKI: Yes. MS. KELLEY: Marge?

	24
1	MS. KELLEY: Cheryl?
2	DR. DAMBERG: Yes.
3	MS. KELLEY: Robert?
4	DR. CHERRY: Yes.
5	MS. KELLEY: Larry?
6	DR. CASALINO: Yes.
7	MS. KELLEY: Lynn?
8	MS. BARR: Yes.
9	MS. KELLEY: Amol?
10	DR. NAVATHE: Yes.
11	MS. KELLEY: Mike?
12	DR. CHERNEW: Yes.
13	MS. KELLEY: And, lastly, Recommendation 3, which
14	reads: The Congress should require the Secretary to:
15	Reduce add-on payments for costly Part B drugs
16	paid based on ASP in order to minimize the relationship
17	between ASP and add-on payments, and
18	Eliminate add-on payments for Part B drugs and
19	biologics paid based on wholesale acquisition cost.
20	Voting yes or no, Scott?
21	DR. SARRAN: Yes.
22	MS. KELLEY: Dana?

1	DR.	GELB SAFRAN: Yes.
2	MS.	KELLEY: Jaewon?
3	DR.	RYU: Yes.
4	MS.	KELLEY: Wayne?
5	DR.	RILEY: Yes.
6	MS.	KELLEY: Betty?
7	DR.	RAMBUR: Yes.
8	MS.	KELLEY: Greg? Thumbs up from Greg.
9	Kenr	ıy?
10	MR.	KAN: Yes.
11	MS.	KELLEY: Jonathan?
12	DR.	JAFFERY: Yes.
13	MS.	KELLEY: David?
14	DR.	GRABOWSKI: Yes.
15	MS.	KELLEY: Marge?
16	MS.	GINSBURG: Yes.
17	MS.	KELLEY: Stacie?
18	DR.	DUSETZINA: Yes?
19	MS.	KELLEY: Cheryl?
20	DR.	DAMBERG: Yes.
21	MS.	KELLEY: Robert?
22	DR.	CHERRY: Yes.

1	MS.	KELLEY:	Larry?
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2 DR. CASALINO: Yes.

3 MS. KELLEY: Lynn?

4 MS. BARR: Yes.

5 MS. KELLEY: Amol?

6 DR. NAVATHE: Yes.

7 MS. KELLEY: Mike?

8 DR. CHERNEW: Yes.

9 MS. KELLEY: All right.

10 [Pause.]

DR. CHERNEW: Sorry. My power went out because the cord was off and I got distracted.

To Nancy and Kim, thank you both so much. To the Commissioners, thank you. Again, I'm glad that we got to have that discussion. Great job, everybody. And we're going to take a five-minute break, and then we're going to come back and talk about the wage index.

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18 [Recess.]
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DR. CHERNEW: Welcome back, everybody. We are now going to move on to our second quick session on recommendations, and this one is on the Medicare wage index. And am I turning it over to you, Alison? Take it

1 away.

21

MS. BINKOWSKI: Thanks, Mike, and good morning. 2 Today's presentation builds off the Commission's 3 4 work on wage index reform that began in 2007, has been 5 reiterated in numerous comment letters, and updated this cycle, as presented in September 2022 and March 2023. 6 7 At the March meeting, staff presented on 8 reforming Medicare's wage index systems and Commissioners 9 were in broad agreement to move forward with a draft 10 recommendation. 11 As summarized in the cover page to the April wage 12 index paper, the paper has been updated in response to Commissioner questions and suggestions during the March 13 meeting. Today I will provide a brief summary of the 14 15 information presented in March, and then present the draft 16 recommendation. 17 As a reminder, Medicare's wage indexes adjust 18 national base payment rates for geographic differences in 19 labor costs. The current wage indexes are based on data 20 from IPPS hospitals' aggregate labor costs; are calculated

for each labor market area, defined as metropolitan 22 statistical areas and statewide rural areas; and include

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numerous and often non-empirical exceptions for IPPS
 hospitals and none for most other types of providers.

Medicare uses these IPPS hospital-based wage indexes in each prospective payment system, including those for IPPS hospitals and post-acute care providers. The physician and other Medicare fee schedules have different geographic adjustments, which are beyond the scope of this presentation.

9 Consistent with MedPAC's 2007 report, the 10 Commission's key concern with current Medicare wage indexes 11 is that they fail to accurately reflect differences in 12 labor costs across geographic areas and create inequities 13 across providers. These inaccuracies and inequities stem 14 from the data source, definition of labor market areas, and 15 wage index exceptions.

In particular, basing Medicare wage indexes on IPPS hospital cost report data is circular for IPPS hospitals and can deviate from the market-wide labor costs faced by all employers of health-industry occupations, potentially disadvantaging other providers competing for labor in that market; the current definition of labor market areas masks differences in labor costs within areas

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and creates large differences in wage index values across
 some adjacent areas; and the numerous IPPS hospital wage
 index exceptions can exacerbate inaccuracies and
 inequities, be manipulated, and add administrative burden.

5 To avoid these concerns and more accurately 6 measure geographic differences in labor costs faced by 7 different types of providers, the Commission has identified 8 an approach for improving Medicare's wage indexes.

9 First, Medicare's wage indexes should use all-10 employer, occupation-level wage data with different 11 occupation weights for the wage index of each type of 12 provider; second, they should reflect local area differences in wages between and within metropolitan 13 14 statistical areas and statewide rural areas; and third, 15 they should smooth wage index differences across adjacent 16 local areas.

To develop illustrative alternative wage indexes consistent with this approach, we used all-employer data from the Bureau of Labor Statistics and the United States Census Bureau; developed a wage index value for each county by using a blend of the MSA/statewide rural area wage index value and a county-level adjustment, and capped wage index

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1 cliffs between adjacent counties.

2 More details on the illustrative alternative 3 method is in the mailing materials.

4 As we discussed at length in prior reports and meetings, the alternative wage indexes would have several 5 benefits. First, the use of all-employer data decreases 6 circularity and more accurately reflects relative labor 7 8 market costs. Second, the use of provider type specific 9 occupation weights more accurately reflects relative labor 10 market costs for each provider type, such as IPPS hospitals 11 and SNFs. Third, calculating a wage index value at a local 12 area level, such as counties, more accurate reflects variation in in labor costs within broader labor market 13 14 areas. Fourth, smoothing wage index cliffs across adjacent 15 counties decreases inequities between providers in adjacent 16 areas. Fifth, removing wage index exceptions increases 17 accuracy and equity, removes opportunities for wage index 18 manipulation, and decreases administrative burden.

Because of substantial inaccuracies in the current wage index, the redistribution effects of the alternative wage index would be material for many providers. More details are described in the March

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presentation and are in your paper, but for example, we estimate that IPPS payments would decrease by more than 10 percent for about 2 percent of IPPS hospitals, including some hospitals with very high current wage index values or very large current wage index exceptions.

6 Therefore, there would need to be a transitionary 7 period to the alternative wage indexes. For example, the 8 transition could be phased in over a fixed period of time, 9 or managed through a stop-loss policy so that no provider 10 experiences changes in Medicare payments of more than a 11 specified percent in any one year due to the transition.

In addition, to the extent that policymakers are concerned about certain providers, in particular, to those that are important for access and vulnerable to closure, any additional support should be targeted specifically to those providers to achieve defined and relevant policy goals, and not made inefficiently through unrelated policies such as the wage index.

19 The draft recommendation reads:

The Congress should repeal the existing Medicare wage index statutes, including current exceptions, and require the Secretary to phase-in a new Medicare wage index

1 system for hospitals and other types of providers that:

Uses all-employer, occupation-level wage data with different occupation weights for each provider type; reflects local area level differences in wages between and within metropolitan statistical areas and statewide rural areas; and smooths wage index differences across adjacent local areas.

8 As the alternative wage indexes would be budget-9 neutral to the current wage indexes, we expect the draft 10 recommendation would have no direct effect on federal 11 program spending relative to current law.

12 The draft recommendation will materially 13 redistribute Medicare payments across providers. However, 14 we do not expect the draft recommendation to materially 15 impact beneficiaries' access to services or providers' 16 willingness to treat Medicare beneficiaries.

17 Transitioning to wage indexes that better reflect 18 geographic differences in labor costs would make Medicare 19 payments more accurate and equitable.

And with that I turn it back to Mike.
DR. CHERNEW: Great. Alison, thank you. You
know, wage index is one of these topics that we have been

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focused on for a long time. It's really important, and I 1 think if you read the chapter, you realize how the system 2 has been subject to forces for a long, long time. It is 3 4 actually a really important part of the Medicare program, 5 and so again, to Alison and Jeff, thank you for this. Robert, I think you have a comment. 6 7 DR. CHERRY: First of all I want to thank the 8 staff for what is really a heavy lift, so congratulations

9 on that.

I just have, I think, a relatively minor comment. You know, past iterations of the chapter at times has been a little bit confusing for several Commissioners, including myself, in terms of what constitutes a hospital's labor costs and how to adjudicate those costs within the same market.

I briefly mentioned, and staff has clarified, that the chapter excludes, from the analysis, employed physicians such as hospitalists, intensivists, and primary care docs, as well as specialists including neurosurgeons, orthopedic surgeons, and contracted services such as podiatry, dentistry, and on-call pay, as well as other providers such as nurse practitioners and physician

assistants. And I realize that there are separate policies
 dealing with those employment models.

Nevertheless, the wage index, as titled, is counterintuitive for those managing integrated health systems and probably the general public. I realize that we are not making changes right now. However, future iterations probably requires a more clear title, such as wage index systems for occupations not included under the Medicare physician fee schedule.

10 Otherwise the proposal is much better than the 11 current model, and I am supportive of the recommendations. 12 Thank you.

DR. CHERNEW: Okay. If I'm following correctlythat is the only comment we had. Oh, Betty.

DR. RAMBUR: Very brief comment following up on that. This would not be for now but hopefully as we think about workforce in the future we think in a new and more complex way about labor costs, what labor is, and generating value, et cetera. I know that's beyond this conversation but I had to throw that out there.

21 DR. CASALINO: Yeah, I just want to say this is 22 really elegant work, Alison and Jeff. It's laid out so

1 clearly and it's so rational, it's hard to see how any 2 rational arguments could be made against it. It's really 3 nice. And the staff always does good, but this really 4 stands out, I think.

5 DR. CHERNEW: That seems like a reasonably good 6 lead-in for a vote. I don't know. I've seen the queue 7 just empty out. Anyway, I'm joking.

8 Okay, so Dana, do you want to --

9 MS. KELLEY: Okay.

10 Voting on the draft recommendation which reads:
11 The Congress should repeal the existing Medicare
12 wage index statutes, including current exceptions, and
13 require the Secretary to phase-in a new Medicare wage index
14 system for hospitals and other types of providers that:

Uses all-employer, occupation-level wage data with different occupation weights for each provider type; reflects local area level differences in wages between and within metropolitan statistical areas and statewide rural areas; and smooths wage index differences across adjacent local areas.

21 Voting yes or no. Amol?

22 DR. NAVATHE: Yes.

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1		MS.	KELLEY:	Lynn?
2		MS.	BARR: Y	es.
3		MS.	KELLEY:	Larry?
4		DR.	CASALINO	: Yes.
5		MS.	KELLEY:	Robert?
6		DR.	CHERRY:	Yes.
7		MS.	KELLEY:	Cheryl?
8		DR.	DAMBERG:	Yes.
9		MS.	KELLEY:	Stacie?
10		DR.	DUSETZIN	A: Yes.
11		MS.	KELLEY:	Marge?
12		MS.	GINSBURG	: Yes.
13		MS.	KELLEY:	David?
14		DR.	GRABOWSK	I: Yes.
15		MS.	KELLEY:	Jonathan?
16		DR.	JAFFERY:	Yes.
17		MS.	KELLEY:	Kenny?
18		MR.	KAN: Ye	s.
19		MS.	KELLEY:	Greg? A thumbs-up from Greg.
20	Betty?			
21		DR.	RAMBUR:	Yes.
22		MS.	KELLEY:	Wayne?

1 1	DR.	RILEY:	Yes.
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2 MS. KELLEY: Jaewon?

3 DR. RYU: Yes.

4 MS. KELLEY: Dana?

5 DR. GELB SAFRAN: Yes.

6 MS. KELLEY: Scott?

7 DR. SARRAN: Yes.

8 MS. KELLEY: And Mike?

9 DR. CHERNEW: Yes.

10 MS. KELLEY: Okay.

11 DR. CHERNEW: All right. So we are adjourned.

12 Jim, do you want to come back at the time on the agenda or

13 just come back in 10 minutes?

14 DR. MATHEWS: In 10 minutes.

15 DR. CHERNEW: Okay. We're going to take 10

16 minutes, so we'll be back at 11:45.

17 [Recess.]

DR. CHERNEW: Okay. Welcome back, everybody. We are going to our third session now. This is going to be on site-neutral payments, and I'm going to turn it over to Dan.

22 DR. ZABINSKI: Thank you. The audience can

1 download a PDF version of the slides for this presentation
2 in the Handouts section that is in the control panel on the
3 right side of your screen.

From 2012 to 2014, the Commission evaluated the effects of aligning payment rates for services provided in hospital outpatient departments with payment rates for services provided in physician offices. This work included recommendations in 2012 and 2014.

9 In the June 2022 Report to the Congress, we 10 published an analysis that built on previous Commission 11 work in which we evaluated the effects of aligning payment 12 rates across all ambulatory settings.

Today, we are moving forward from the June 2022 analysis and presenting a draft recommendation on aligning payment rates across ambulatory settings.

At the heart our analysis about site-neutral payments is the fact that fee-for-service Medicare has distinct payment systems for three ambulatory settings: physician offices, hospitals outpatient departments, or HOPDs, and ambulatory surgical centers, or ASCs.

21 For most services, the outpatient prospective 22 payment system, the OPPS, which is the payment system for

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1 most HOPD services, has higher payment rates than the 2 physician fee schedule and the ASC payment system.

These payment rate differences between settings have resulted in the higher-cost hospitals acquiring the lower-cost freestanding physician practices, then billing at the higher OPPS rates.

7 When this billing shift from the physician fee 8 schedule to the OPPS occurs, Medicare program outlays and 9 beneficiary cost-sharing obligations increase with no 10 change in the setting or the service provided.

11 To identify the services for which it is 12 reasonable to align payment rates across settings, we 13 collected services into ambulatory payment classifications, 14 or APCs, which is the payment classification system in the 15 OPPS. If offices had the highest volume for an APC, we 16 aligned OPPS and ASC rates with physician fee schedule 17 rates. But if ASCs had the highest volume for an APC, we 18 aligned the OPPS payment rates with the ASC payment rates, 19 but we kept the physician fee schedule rates unchanged. 20 Finally, if HOPDs had the highest volume for an APC, we did 21 not believe it was reasonable to align payment rates for 22 those APCs, so payment rates were unchanged in each setting

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1 for those services.

The OPPS has 169 APCs for services. We've 2 determined that it is appropriate to align the payment 3 rates for 66 of those APCs. Specifically, we identified 57 4 5 APCs for which we aligned OPPS and ASC rates with the PFS rates, and 9 more APCs for which we aligned OPPS rates with 6 7 ASC rates and left the physician fee schedule rates 8 unchanged. And then we did not align payment rates for the 9 remaining 103 APCs.

10 These are the aligned services from our approach, 11 but at the March meeting we made a point that CMS could 12 take a different approach, which could result in CMS 13 identifying different services for payment rate alignment. 14 In response to the discussion at the March meeting, we 15 incorporated this point in your paper.

16 Under current law, CMS would respond to the lower 17 payment rates from the payment rate alignment policy with a 18 budget neutrality adjustment to the other services covered 19 under the OPPS. So what happened is that for the 66 APCs 20 for which we more closely aligned the OPPS and ASC payment 21 rates with the physician fee schedule rates, beneficiary 22 cost sharing and program outlays would be lower for the

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services in those APCs. And for the 103 APCs for which we
 did not align payment rates CMS would apply a budget
 neutrality adjustment by increasing the OPPS payment rates
 for those services to fully offset the lower payment rates
 in the 66 aligned APCs.

6 However, over time there could be an indirect 7 budgetary effect because payment rate alignment could slow 8 the shift of services from the physician fee schedule to 9 the OPPS because incentives for hospitals to acquire 10 physician practices would be reduced. And to the extent 11 this occurs, savings for beneficiaries and Medicare would 12 result.

13 On this slide, we cover the key points of the 14 financial effects of payment rate alignment coupled with 15 the budget neutrality adjustment.

In the OPPS, these two policies together would move \$7.5 billion in program spending and beneficiary cost sharing from the 66 APCs for which we aligned payment rates to the 103 APCs for which we have not aligned payment rates, which includes the APCs for ED visits and trauma care.

22

In the ASC payment system, payment rate alignment

would move \$250 million from the services in the aligned
 APCs to the non-aligned APCs.

Even though the payment rate alignment policy 3 4 would initially have no effect on aggregate Medicare spending, some hospital categories would see a net gain in 5 total Medicare revenue, while other hospital categories 6 would see a net loss, including rural and government-owned 7 8 hospitals. This policy, however, should not adversely 9 affect rural beneficiaries because 10 It excludes critical access hospitals as they are paid 11 under a system distinct from the OPPS, and other policies 12 exist that support rural providers, such as the program for rural emergency hospitals and rural health clinics. 13 14 In addition, concerns about specific providers 15 should be addressed with policies targeted to those 16 providers rather than inefficiently supporting them by 17 maintaining higher payment rates for all hospitals. 18 For the Commission's consideration today we have this draft recommendation: 19 20 The Congress should more closely align payment 21 rates across ambulatory settings for selected services that are safe to provide in all settings and when doing so does 22

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1 not pose a risk to access.

In terms of implications, there would be no 2 direct effect on Medicare program spending. However, there 3 could be an indirect budgetary effect through reduced 4 5 incentive for hospital consolidation with physician practices, which would reduce the shift of billing of 6 7 services from the physician fee schedule to the OPPS. This 8 would lower Medicare program spending. We cannot be 9 certain, however, of how much the shift of services would 10 slow, so we cannot place a dollar figure on that effect. 11 For beneficiaries, they will have lower cost 12 sharing on the services for which payment rates are aligned and higher cost sharing for other services. We expect that 13 the under the draft recommendation beneficiaries would 14 15 maintain access to the services in the aligned APCs. 16 For providers, as mentioned earlier, the payment 17 alignment policy would have differing effects on the Medicare revenue of different hospital categories. And to 18 the extent there is concern about the effect of this 19 20 recommendation on specific providers, we emphasize that 21 these concerns should be addressed through policies 22 targeted to those providers.

1 Overall, however, this draft recommendation is 2 not expected to affect providers' willingness or ability to 3 furnish ambulatory services.

4 That concludes the presentation and I turn it 5 back to Mike.

DR. CHERNEW: Dan, thank you very much. Now we 6 7 will have a brief comment period, and I think, if I've got 8 this right, Lynn was the first one in the queue. So Lynn. 9 MS. BARR: Thank you. Dan, you know, this is a 10 very, very good work, and I think it is an elegant approach 11 to solving the problem. But I do disagree with your comments about access in rural. I don't think that there's 12 evidence to support that reducing payment to rural 13 providers will not affect access. I think maternal health 14 15 is a great example of where Medicaid paid so little for 16 maternal services that we've lost maternal services over 17 much of rural today. So we have evidence that by reducing 18 payment it will affect access.

19 So I feel like there are a lot of statements in 20 this chapter that access will not be affected without 21 evidence to support it, and I would recommend a softening 22 of that language and also in the presentation as well.

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1 Thank you.

2

MS. KELLEY: Larry?

3 DR. CASALINO: Yeah. This isn't what I was going 4 to comment on but I'll just mention that I share Lynn's 5 concern.

But the comment I wanted to make, Dan, I think at 6 the last meeting we talked a bit about, we emphasize volume 7 8 as a criterion for determining where it's safe to do 9 something, and I strongly agree with that. But I think 10 that when the assessment is made, if indeed CMS was to try 11 to change payment rates in a site-neutral way that we're 12 recommending, I think when that is done matters. And they could keep changing over time. 13

The example we used last time was transthoracic echocardiograms. That is a procedure that you can do it in your living room. It is completely safe. It is safer than drawing blood because there is no risk to it at all. And right now, as far as I can tell, a kind of a bare majority are done in cardiologists' offices.

20 So if the assessment was done now, transthoracic 21 echoes would be paid at the rate they're paid in physician 22 offices. But there is a good chance that in five years

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from now so many cardiologists will be employed by hospitals that then the majority of transthoracic echoes would be done in hospital outpatient departments. So looking purely at volume, in five years instead of now, it would look like that's a dangerous enough procedure that it has to be done in an HOPD and should be paid at that rate.

7 So this doesn't change the recommendation at all, 8 in my mind, but I think there should be a paragraph or so 9 about this in the chapter, because otherwise it could be 10 overlooked, and in fact, I just gave one example but I'm 11 sure there are others, and it could be quite a significant 12 thing.

13 MS. KELLEY: Jonathan?

14 DR. JAFFERY: Thanks, Dana, and thanks, Dan. Ι 15 really appreciate the way that this chapter has evolved and 16 the way that, including the draft recommendation, that does 17 point out that a lot of the work you've done is illustrative and that CMS and others would need to think 18 19 through a number of options and specific situations here. 20 I also really appreciate how you brought in some of the 21 other points we talked about in previous meetings around modifiers when there is geographic variability for 22

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1 ambulatory surgical centers, for example.

That said, and the flexibility that a recommendation has in it, there are clearly things that, because we put them in the chapters do jump out. And so I think it's important to speak to a couple of those, just because that's true and it's sort of groundwork for maybe future discussions.

8 There are a couple of places in the text. So 9 page 2, you say, quote, "If freestanding offices had the 10 highest volume for service, arguably it would be safe to 11 provide that service in freestanding offices for most 12 beneficiaries," unquote. And then on page 13, quote, "The effects of patient severity on payment rates is not 13 significant as the services we selected for alignment were 14 generally low complexity," unquote. 15

So I guess what I'm getting at is some of the notions around where a service can be provided safely. And certainly like Larry said there are some examples of things like transthoracic echo that we could do in the hallway.

But I'm not convinced that volume necessarily speaks to that all the time, and I'm also particularly concerned that the services and patients aren't the same,

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1 so patient severity and service complexity doesn't

2 necessarily correlate in the way that I think is implied in 3 the chapter. And there may be services that are safe for 4 most patients to get in a certain place, but not for 5 everybody.

And unlike a DRG, where everyone is going to the 6 7 hospital and there are some averages going on, there is a 8 great risk for adverse selection here, for some 9 institutions to then get the patients that are more 10 complex. And that could be for lots of reasons. That 11 could be because a patient is has morbid obesity or is not 12 ambulatory, in ways that are not easily modifiable on the system as it's laid out. 13

And then I think some other things that can be difficult to capture like patient and provider preference, that may not totally be based in medical need but nonetheless are very much realities of how the system works.

19 So I'll just throw out one example. You know, 20 you might have a patient who had a simple injection for 21 pain that can be handled in an outpatient office, and they 22 had a reaction. They had a vagal reaction so they passed

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out, and they were rushed to the hospital because of it.
There's no chance that person or the providers are going to
say, "Okay, we can just do it in the office again. That
was a one-off thing."

5 So there are those kinds of things that are more 6 common than I think you'd think and leave me with a little 7 bit of pause on basing it just on the volume and equating 8 the patient severity to the complexity of the service. 9 Thanks.

MS. KELLEY: Okay. I have a comment from Greg that I'll read. He sent some brief suggested edits to Mike and Jim regarding the text, explaining the recommendation, not an edit of the recommendation itself. His goal was to enhance the clarity regarding procedures that should be included in site-neutral versus those that should not, and he is grateful for consideration of those clarifying edits.

An example in the chapter is illustrative. On page 10, the discussion of an epidural injection could be used as an example of how the same technical procedure can be very different depending on the circumstances. A scheduled injection will require very different resources than a procedure for someone writhing in pain, often unable

1 to walk, being treated emergently, very possibly in the 2 middle of the night or on a weekend.

A 2015 study showed that such an urgent injection 3 4 can dramatically reduce hospital admissions and emergency 5 care, saving many thousands of dollars. Many of these procedures are provided in hospitals without an ER 6 admission as a direct treatment ordered by a physician in a 7 8 nursing home, an urgent care center, or a physician office. 9 These emergent treatments are very seldom, approaching 10 never, provided in freestanding settings. 11 In his view, this is an example of a procedure 12 that deserves to be paid differently in a 24/7, take-allcomers facility than in an 8-to-5 freestanding setting. 13 14 Providing clear insight on how CMS should identify services 15 that should be paid consistently versus differentially 16 between sites is incredibly important in this chapter. 17 And then I had Dana with a comment. DR. GELB SAFRAN: Yeah, thank you, and Dan, 18 19 thanks for this really superb work. 20 I had three comments that I'll make. One, really 21 in line with Greg's excellent points and other

22 Commissioners' comments too. To me that's where it comes

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down to the idea of what can be considered a commodity in Medicare services, and it brings me back to experiences I had when I was in my role at Blue Cross Massachusetts. We thought there were services that could be considered commodities, and as we dug more deeply, even things that seemed that way, you know, for example, an MRI, turned out to be much more complicated.

8 So I say this only to kind of underscore, even 9 without the clinical specificity that other Commissioners 10 have offered, the importance of feeling really clear and 11 confident when we are making pricing equivalent because we 12 are saying the service is equivalent. There are so many 13 considerations there.

14 The second comment has to do with the suggestion 15 I have that we ensure that -- and I think this builds on 16 some of the things Jonathan was saying -- that if this is 17 put into place it should have a companion set of 18 measurement approaches that are put in place to really 19 evaluate as we go the impact -- positive, negative, or none 20 -- on access, on safety, on outcomes for patients. I know 21 we're at the point where there's not a lot that can be 22 added, but I do think specifying the importance of

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1 measurement alongside of an initiative like this is going 2 to be very important.

And then finally, the last idea I'll put on the 3 4 table is something that came to my mind just listening to 5 what Linn was saying, and not really pertinent to this chapter but pertinent to next year's work on rate 6 adjustments. It did strike me that the really exciting, 7 important work that we did with respect to rate adjustments 8 9 for clinicians serving lower income or socioeconomically 10 vulnerable populations is something we should also consider 11 for rural providers. So I just wanted to add that in since 12 I won't be here next cycle, to offer that suggestion. 13 Thanks.

14 MS. KELLEY: Amol?

DR. NAVATHE: Thanks. Dan, great work. I'm really happy to see this moving forward.

I think a couple of quick comments. One, I think is probably like a poster child policy of let's not let the perfect be the enemy of the good. We all know, and I think you've outlined it in the chapter, but there are a lot of distortionary effects of not having site-neutral payments, in terms of consolidation and physician acquisition, et

1 cetera. And getting to a perfect policy was going to be 2 impossible. I think we also kind of know that that's most 3 likely true.

4 I think there are some nice elements of how this policy has been developed over time in terms of the budget 5 neutrality as an important element, that this is not 6 necessarily trying to take money out of the system per se. 7 8 In this particular context, the way that we've constructed 9 it, I think noting that there are aspects of the 10 illustrative policy in terms of the specific codes that are 11 at play here, they need to be married with clinical context 12 and some of the other elements around measurement, that fellow Commissioners have commented on. That's all very 13 important in context here. 14

15 I think it's also important for us to take a step 16 back and realize that oftentimes if we think about very specific examples of procedures, you know, whether they're 17 18 in the context of lumbar puncture, injection, spinal injection, something like Greg was commenting, or 19 20 otherwise, many times emergency departments in these cases, 21 they don't have a staff member who is just there for this 22 one procedure, or they don't have particular equipment that

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is just there for this one procedure. And so the payment
 is not being eliminated. It's being adjusted.

And I think if we take some of those elements 3 4 into context, I think it can make sense again why this policy is so important to address on the distortionary 5 effects, again, with recognizing that it's not perfect. 6 There is no perfect policy here. So I think it's just 7 8 important context for us to keep in mind, and I think it's 9 great to see this work move forward in that setting. 10 Thanks.

11 MS. KELLEY: Jaewon.

DR. RYU: Yeah, I have two comments, mostly sort of along the lines of plus 1's. I'll start by saying I'm supportive of the recommendation. I think this is exactly the right direction. We've spoken about this on the Commission for a number of years, and I think this is a really positive development and step.

I do think there are a couple ways that maybe I'd love to see if there's just one click more that we can do in terms of capturing some of the nuance. So one is on Lynn's point around rural. Yes, critical access hospitals, rural emergency, rural health clinic policies can be good

channels to target and replenish and ensure that, you know, 1 a good chunk of those rural hospitals are still protected. 2 But there are an awful lot of rural hospitals, rural 3 4 facilities, that don't fall into any of those programs. And so I think it's one of tempering where I don't think we 5 should presuppose and assume that those programs and the 6 7 existence of those programs, you know, buffers the effects 8 across the board, because I don't think they do.

9 And then the second is around the selection of 10 the procedures. I just think we've got to be a little 11 careful here. I totally agree with Amol; it's impossible 12 to get to perfection. But I think there's an awful lot of 13 nuance and complexity. And hanging your hat on volume 14 alone I think is really, really tricky and maybe even 15 dangerous.

You know, within any given procedure, I think it really is about the considerations of what's going on with that particular patient. And I think there is a lot of variability. You know, volume for a variety of reasons, I just think it's one determinant but not the sole. So I think Larry made a good point. You know, it may not reflect the setting where you want the care to happen

today, so that's one flaw. And then Greg and Jonathan I think raised some other flaws with just volume alone. There's clinical considerations and disease burden, frankly, that would make some procedures riskier to do in certain settings. It's sort of in the realm of what could happen that may not reflect on the claim of, you know, where a procedure actually took place.

8 I think this is especially true with vulnerable, 9 sicker populations, which is where I think in particular 10 you run this risk a little bit higher. So, you know, if 11 there's some way to temper or acknowledge that there are 12 other considerations at play, understanding that there's 13 probably no perfect way to get at that, I think that would 14 make it a little bit better in terms of tone and approach.

15 MS. KELLEY: Okay. Robert?

DR. CHERRY: Thank you, and I do appreciate all the work that the staff has done. I continue to struggle with the draft language. I was hoping that, you know, the term "safe and appropriate" could actually be utilized. Several Commissioners have expressed -- you know, the issue with site neutrality as it's currently constructed in the chapter is that it may lead to unintended consequences,

specifically with respect to the clinical safety of 1 individual patients who may benefit from a more -- least 2 worse intense setting such as a hospital outpatient 3 4 department. If you had something like safe and appropriate, that language was ultimately adopted by 5 Congress, then the term "appropriate" allows CMS to 6 consider a couple of approaches. One is appropriateness 7 8 criteria, in other words, clinical criteria that may drive 9 an individual patient to one setting or another based on 10 clinical condition and acuity.

11 Second, the term also allows CMS to consider 12 modifiers to establish billing codes when patient acuity 13 requires greater resource intensity compared to healthier 14 patients.

15 So I'm still, for reasons that have already been 16 mentioned, struggling with this recommendation without some 17 nuance like "safe and appropriate."

MS. KELLEY: Larry, I think you wanted to say something.

20 DR. CASALINO: I think we still have a few 21 minutes. Just very briefly, you know, the current policy 22 is really bad, the non-site-neutral policy, and it has a

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lot of extremely pernicious effects, I think. And I think 1 many Commissioners feel that way. So I don't want to throw 2 the -- I'm kind of echoing Amol here. I don't want to 3 4 throw the baby out with the bath water. I think that 5 whether it's volume, volume plus clinical input, some way of listing things that are going to be paid at the lowest -6 - at the appropriate site rate, I think that should be 7 8 done. And there can be -- and this could -- there could be 9 a paragraph or two about this in the paper.

10 It is true that individual circumstances can make 11 it unsafe to do something, or infeasible to do an epidural 12 injection, say, in a physician office on a morbidly obese 13 patient perhaps or someone in a lot of pain. But to me, 14 the way to deal with that is not to alter the policy, but 15 to try to have -- and not to say, okay, epidural 16 injections, if they're done in an HOPD, should be paid at 17 the HOPD rate. That's just wrong, I think.

18 So what would be preferable, I think, would be 19 epidural injections be paid at the physician office rate. 20 But an opportunity for fairly clearly defined modifiers, 21 which would say, okay, yeah, this is an epidural injection 22 but this is the reason why it had to be done in an HOPD and

1 can be paid at an HOPD rate.

22

I recognize that could be fairly complicated, but 2 I think enough people have brought up enough good reasons 3 4 to think about something along those lines, not having to 5 change the recommendation but discussion of that in the chapter. 6 7 MS. KELLEY: Betty? 8 DR. RAMBUR: Very briefly, I just want to say 9 that I really support this recommendation and really align 10 with Amol's thoughts and what Larry has just stated, as 11 well as others. The current policy has so many problems 12 and so many consequences that are really not okay. 13 I hear what you're saying, Lynn, and others, 14 about the rural piece, and I really also am concerned about 15 that. I would just comment though that frontier areas have 16 so many other challenges in the way that I think we can't 17 let that piece take away from what needs to be done here, 18 so I really support this recommendation and appreciate the hard work. Thanks. 19 20 DR. CHERNEW: Okay. That was a very rich 21 discussion. I'll just add a few very quick points, and

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then we're going to go to a vote.

1 Point number one is we heard the comment that volume is certainly not the best indicator for picking 2 services. There's been a bunch of stuff in the chapter to 3 4 change out a bunch of stuff even in the rec to understand 5 This is not a mechanical this is the volume; this is it. therefore what you should do. The policy is illustrative, 6 and that's easy for us to do given the resources that we 7 8 have. I think we think about these as candidate services 9 in a range of ways, and I think that's fine.

10 The second point is there's been a lot of concern 11 and a lot of discussion here about access, and, in fact, 12 relative to where we were before, the access is now emphasized in the recommendation and is guidance to CMS to 13 14 make sure that they take access into account, and several 15 of the comments here have explicitly said that. I think 16 it's important to understand that we understand that access 17 is an important issue when making the specific decisions.

The only other thing I'll say which hasn't come up here which I think is important is I understand much of the discussion, but what strikes me is sometimes just the sheer magnitude of the differences across site-neutral. It's not simply that you're paying more if something is

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1 happening in one site versus another. In some cases, 2 you're paying close to double. Dan may want to comment on what the average is. I don't know what it is offhand, but 3 some of the examples we have, it's like 194 percent shows 4 5 up in the chapter. I don't know if that's --DR. ZABINSKI: [Off microphone.] 6 7 DR. CHERNEW: Oh, is that -- right, exactly. So 8 I don't know what the overall -- Dan, you don't need to 9 answer now, by the way. Okay, Dan, why don't you go 10 answer? 11 DR. ZABINSKI: It's about 2.5 times. 12 DR. CHERNEW: Yeah, so this is not -- this is not sort of like, well, okay, we're going to pay a little bit 13 14 more because the patients are more expensive, which, by the 15 way, if there was an access problem, we would. We're 16 talking 2.5 times payment differentials, and if you look 17 through the chapter, it's clear that a lot of what has 18 happened, per Larry's comment, is this consolidation has 19 moved -- it's not like the patients are moving in varying 20 The consolidation of the number of patients that are ways. 21 moving up the 2.5 percent price increase is really a significant increase for a lot of the services. 22

1 So I want to emphasize it has been an important thing for me, I think an important thing for this 2 Commission, to understand that we need to support the 3 4 providers that need support. We've moved that in a safety 5 net way. We can think through that specifically in rural. I've talked with you, Lynn, about how to do that in rural. 6 But the idea in my mind, you're going to pay 2.5 times on 7 8 average more for a set of services that are shifting simply 9 because of the acquisition that's going on seems like a 10 problem that the Commission should undertake, which, 11 fortunately, the Commission did undertake it. And, in 12 fact, in this particular case, Dan.

13 So I didn't mean to rant. I do tend to do that 14 sometimes. But I think the conversation and where we've 15 moved on this chapter really has been valuable, and I hope, 16 since I've spoken to most of you, at least at a minimum you 17 feel like you were heard. But in any case, we are now at 18 the point where we're going to take a vote, so Dana?

MS. KELLEY: Okay, voting on the recommendation, which reads: The Congress should more closely align payment rates across ambulatory settings for selected services that are safe to provide in all settings and when

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1	doing sc	does not pose a risk to access.
2		Voting yes or no, Scott?
3		DR. SARRAN: Yes.
4		MS. KELLEY: Dana?
5		DR. GELB SAFRAN: Yes.
6		MS. KELLEY: Jaewon?
7		DR. RYU: Yes.
8		MS. KELLEY: Wayne?
9		DR. RILEY: Yes.
10		MS. KELLEY: Betty?
11		DR. RAMBUR: Yes.
12		MS. KELLEY: Greg? Greg has a thumbs up. Thank
12 13	you. Ke	
	you. Ke	
13	you. Ke	enny?
13 14	you. Ke	mny? MR. KAN: Yes.
13 14 15	you. Ke	enny? MR. KAN: Yes. MS. KELLEY: Jonathan?
13 14 15 16	you. Ke	enny? MR. KAN: Yes. MS. KELLEY: Jonathan? DR. JAFFERY: Yes.
13 14 15 16 17	you. Ke	mny? MR. KAN: Yes. MS. KELLEY: Jonathan? DR. JAFFERY: Yes. MS. KELLEY: David?
13 14 15 16 17 18	you. Ke	enny? MR. KAN: Yes. MS. KELLEY: Jonathan? DR. JAFFERY: Yes. MS. KELLEY: David? DR. GRABOWSKI: Yes.
13 14 15 16 17 18 19	you. Ke	enny? MR. KAN: Yes. MS. KELLEY: Jonathan? DR. JAFFERY: Yes. MS. KELLEY: David? DR. GRABOWSKI: Yes. MS. KELLEY: Marge?

1	MS. KELLEY: Cheryl?
2	DR. DAMBERG: Yes.
3	MS. KELLEY: Robert?
4	DR. CHERRY: Abstain.
5	MS. KELLEY: All right. Larry?
6	DR. CASALINO: Yes.
7	MS. KELLEY: Lynn?
8	MS. BARR: Yes.
9	MS. KELLEY: Amol?
10	DR. NAVATHE: Yes.
11	MS. KELLEY: Mike?
12	DR. CHERNEW: Yes.
13	MS. KELLEY: Okay.
14	DR. CHERNEW: Okay. We are now adjourned for
15	this session. We will come back I think, roughly speaking,
16	at 12:30, and we will talk about post-acute.
17	[Recess.]
18	DR. CHERNEW: Welcome back, everybody. We have a
19	somewhat dramatic and unprecedented situation it might
20	not be that dramatic. It probably is unprecedented
21	about the vote that we just took on site neutral. So just
22	so the folks at home understand, the recommendation

1 language in the chapter was different than the

2 recommendation language that we actually voted on, which 3 was an inadvertent shift. And so what we are going to do 4 is put up the recommendation language that was from the 5 chapter, which had been discussed with a lot of people, and 6 we are going to then redo the vote on the slightly revised 7 wording on the recommendation. Then we're going to jump in 8 and get back to our post-acute care.

9 So Dana, if we could, if we're ready to go. The 10 new recommendation, Dana, I think you need to read it, and 11 then we'll do the vote.

MS. KELLEY: Okay. So voting on the recommendation, the amended recommendation, which reads: The Congress should more closely align payment rates across ambulatory settings for selected services that are safe and appropriate to provide in all settings and when doing so does not pose a risk to access.

18 Voting yes or no. Scott?

19 DR. CASALINO: Mike, I'm sorry. What is "in all 20 settings" mean?

21 DR. CHERNEW: That should have been the same as 22 it was before, across the settings.

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1	MS. KELLEY: That is the same as it was before.
2	DR. CHERNEW: Yeah. We're just going with the
3	language that was in the chapter, and this is the language
4	that was in the chapter, for better or worse.
5	MS. KELLEY: Okay. Voting yes or no. Scott?
6	DR. SARRAN: Yes.
7	MS. KELLEY: Dana?
8	DR. GELB SAFRAN: Yes.
9	MS. KELLEY: Jaewon?
10	DR. RYU: Yes.
11	MS. KELLEY: Wayne?
12	DR. RILEY: Yes.
13	MS. KELLEY: Betty?
14	DR. RAMBUR: Yes.
15	MS. KELLEY: Greg? A thumbs-up from Greg.
16	Kenny?
17	MR. KAN: Yes.
18	MS. KELLEY: Jonathan?
19	DR. JAFFERY: Yes.
20	MS. KELLEY: David?
21	DR. GRABOWSKI: Yes.
22	MS. KELLEY: Marge?

1	MS. GINSBURG: Yes.
2	MS. KELLEY: Stacie?
3	DR. DUSETZINA: Yes.
4	MS. KELLEY: Cheryl?
5	DR. DAMBERG: Yes.
6	MS. KELLEY: Robert?
7	DR. CHERRY: Yes.
8	MS. KELLEY: Larry?
9	DR. CASALINO: Yes.
10	MS. KELLEY: Lynn?
11	MS. BARR: Yes.
12	MS. KELLEY: Amol?
13	DR. NAVATHE: Yes.
14	MS. KELLEY: Mike?
15	DR. CHERNEW: Yes.
16	MS. KELLEY: Okay.
17	DR. CHERNEW: All right. With that behind us we
18	are now going to talk about the unified post-acute work.
19	So Carol, you're up.
20	DR. CARTER: Okay. Hello, everybody. Before I
21	get started, I want to thank Kathryn Linehan for her help
22	on this project, and I want to remind the audience that

1 they can download a PDF version of these slides in the 2 handout section of the control panel on the right hand of 3 the screen.

Today's presentation is the last in a series to prepare a mandated report on a prospective payment system for post-acute care. We discussed the draft report and recommendation at the March meeting, so I will present only a high-level summary.

9 The IMPACT Act of 2014 mandated three reports on 10 a prospective payment system for post-acute care, or a PAC 11 The first report was completed by the Commission in PPS. 12 2016. The Secretary submitted his report to the Congress 13 in July 2022. This report includes a prototype design. 14 The last report is to be completed by the Commission and is due on June 30, 2023. The PAC PPS design must span the 15 16 four settings and base payments on patient characteristics, 17 not the setting.

18 The Act does not require that a PAC PPS be 19 implemented.

There were a couple of reasons why policymakers were interested in a unified payment system for post-acute care. Our work and that done by others had found that

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beneficiaries who look similar in terms of their condition
and comorbidities can be treated in different settings.
But because Medicare uses separate payment systems for each
setting, payments can differ substantially. A unified
payment system would change that, creating site-neutral
payments based on patient and stay characteristics.

7 Another concern was that there were shortcomings 8 in the payment systems in place at the time. The home 9 health and SNF PPSs encouraged providers to furnish 10 unnecessary rehabilitation therapy, while the LTCH payment 11 system encouraged LTCHs to admit low-acuity patients. 12 Since the IMPACT Act, CMS has made substantial changes to 13 these payment systems.

We identified key features that should be included in a design if development work proceeds, and those are summarized on the left side of the slide.

Our work and that done by CMS and ASPE concluded that a PAC PPS was feasible. It could establish accurate payments and result in uniform profitability across different types of cases that would dampen incentives to selectively admit or avoid certain types of patients. The CMS/ASPE prototype is consistent with most of

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the recommended design features, and would be a good starting point for a design. However, the design includes adjusters for each setting that would undermine the uniformity of a payment system. If CMS proceeds with a PAC PPS, this feature should be phased out over time.

6 While designing a unified payment system is 7 feasible, developing the necessary companion policies would 8 be especially challenging.

9 On the left, you see that aligning benefits and 10 cost sharing would involve tradeoffs that are likely to be 11 controversial.

At the bottom, a value incentive program would require CMS to conduct additional development work on measures of performance, such as a measure of patient experience, and a measure of the social risk of a provider's patient population.

On the right, a common set of Conditions of Participation would impose new requirements for providers. Some of these would be relatively easy to align but others would be more complicated.

21 Based our work and that done by CMS and ASPE, we 22 concluded that designing a PAC PPS would be relatively

straightforward. However, implementing the companion
 policies would not be. Each policy is likely to be
 controversial, require considerable resources to develop,
 and take many years to implement.

5 The changes CMS has already implemented to the 6 SNF, home health, and LTCH payment systems are substantial 7 and greatly improved these payment systems. Given the 8 considerable agency resources that would be required to 9 implement a unified payment system, CMS could instead 10 consider smaller-scale, site-neutral policies that would be 11 simpler to implement.

Over the coming years, the Commission will look for such opportunities. In the meanwhile, given the high level of payments relative to the cost of care, the Congress should implement the Commission's standing recommendations to lower the level of payments to home health agencies, SNFs, and IRFs.

18 At the March meeting you reviewed the draft 19 recommendation. It reads:

The Commission forwards to the Congress the report on the unified post-acute care payment system mandated by the Improving Medicare Post-Acute Care

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1 Transformation Act of 2014.

The recommendation has no spending implications.
And with that, I'll turn the discussion back to
Mike for your voting.

5 DR. CHERNEW: Great. Carol, thank you so much. 6 I think we have a comment from David, if I'm right, Dana? 7 MS. KELLEY: Yes.

8 DR. GRABOWSKI: Surprise, surprise. I want to 9 speak on post-acute care. First, Carol, thank you so much 10 for this work. Your leadership has just been tremendous on 11 this. This work started -- so this is my sixth and final 12 year on the Commission. This work started back in, I think, the 2016-2017 cycle, so you've been at this, what, 13 14 seven cycles, focusing on this. Oh wow, even earlier, 15 geez. Yeah, tremendous. It's just been phenomenal.

I wanted to say a couple of words. You know, you noted it well during your comments. The world has definitely changed since we started this unified PAC work, and I agree with the argument in the chapter that the need for this policy today is lower than when we started, but I don't think it's zero. And we just had a session on siteneutral payment. Amol pointed out the distortionary

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effects that are present in the system. I think we still have those same distortionary effects here in post-acute care. A lot of the discussion that we just had with siteneutral could be certainly carried over and applied to post-acute care.

6 Once again, the distortionary effects may not be 7 as large and when you started, but they're still there, and 8 I hope the Commission doesn't abandon this line of work to 9 try to kind of align payments across settings, to try to 10 match patients with the safest and most appropriate 11 setting.

12 Two areas where I think there is real potential. 13 The first would be just thinking about home health and 14 skilled nursing facility care. That is where the vast 15 majority of patients are going. Are there opportunities 16 along that margin, especially with the adoption of the 17 patient-driven models in both home health and skilled 18 nursing facility care.

19 The second example would just be in terms of 20 skilled nursing facility care and inpatient rehab facility 21 care. On that margin, MedPAC has been on this for a long 22 time. There is a lot of commonality in the patients across

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1 those two settings. I think there is tremendous potential 2 there as well.

3 So I look forward to following MedPAC work. This 4 may be the end of one body of work but I hope you'll 5 continue to focus on site-neutral type issues in the post-6 acute care setting. Thanks.

7 DR. CHERNEW: Okay. Robert did you -- yeah,
8 Robert has a comment.

9 DR. CHERRY: Yeah, I think I sent that out wrong 10 but yes, I wanted to comment. Thank you.

I just wanted to actually -- it is great work --I just wanted to underscore one line in the report that I totally agree with, which is, you know, regular updating and recalibration of the PAC PPS would keep payments aligned with the cost of care.

16 The reason why I wanted to emphasize that is 17 because this idea of regular recalibration I think will 18 require models that also define equitable care so that we 19 can track and trend and really ensure that socially high-20 risk patients are not adversely impacted by these models, 21 models that do align with an approach to site neutrality. 22 So equitable care, which still needs to be, I

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think, defined by this Commission, should evaluate access
 to service, cost, as well as clinical outcomes.

3 So I am very supportive of the language here. I 4 just wanted to put in a plug there for equitable access and 5 equitable care.

6 DR. CHERNEW: Thank you. I think we have Scott. 7 DR. SARRAN: Yeah. Very impressive work. I just 8 want to reinforce David's comments about the need for 9 ongoing work in this space, and maybe, Jim and Carol, we 10 can tee that up. But there is an important body of work 11 that needs to continue.

12 I would highlight that work needs to occur in at least the following areas. One is that we move ahead at a 13 14 faster and better pace around ensuring that decisions made 15 for the individual beneficiary are really driven primarily 16 by the beneficiary's specific clinical circumstances as 17 well as by the realities of their caregiver capabilities 18 when contemplating sending that person home from the 19 hospital.

20 So it's not just the clinical, such as in the 21 last discussion about site-neutral, when we said there are 22 certain times where you could do an MRI safely here or you

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need to do an MRI there. This is not just about the clinical circumstances of the beneficiary but it's around the setting that they're going to be discharged to, when that setting is contemplated as being home. And second is ensuring again that decisions are beneficiary and caregiver driven primarily, and not financially driven.

7 And second is, to the extent possible, we need to 8 incorporate MA into the post-acute work. You know, a lot 9 of concerns about what's going on in MA, a different set of 10 incentives, and different implications. It's a long 11 discussion, but I think the short take on this is we really 12 need to include MA in this.

13 And the third body of work that I think is 14 important is to understand the unique issues around 15 beneficiaries sort of living long-term in a nursing 16 facility and what happens with them and the perverse 17 incentives that exist in fee-for-service Medicare that 18 result in a lot of unnecessary hospitalizations following 19 by the person coming back but to a Medicare-paid bed. So those three bodies of work I'd like to see us 20

21

22 DR. CHERNEW: Okay. Thank you.

tee up as part of next-generation work.

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1 DR. RAMBUR: Just one very brief comment. I just 2 want to say I really support the comments of David and Scott, and to just add one more piece to your criteria, 3 4 also patient and family values, because that's often just 5 obliterated in kind of this storm to treat and overtreat, 6 et cetera. 7 So thank you. Great work, and very much 8 appreciated. 9 DR. CHERNEW: All right. So I think now we're 10 going to move to the vote. Dana. 11 MS. KELLEY: All right. Voting on the 12 recommendation, which is to forward to the Congress the 13 report on a unified post-acute care payment system, 14 mandated by the Improving Medicare Post-Acute Care 15 Transformation Act of 2014. 16 Voting yes or no. Amol? 17 DR. NAVATHE: Yes. 18 MS. KELLEY: Lynn? MS. BARR: Yes. 19 20 MS. KELLEY: Larry? 21 DR. CASALINO: Yes. 22 MS. KELLEY: Robert?

1	DR.	CHERRY: Yes.
2	MS.	KELLEY: Cheryl?
3	DR.	DAMBERG: Yes.
4	MS.	KELLEY: Stacie?
5	DR.	DUSETZINA: Yes.
6	MS.	KELLEY: Marge?
7	MS.	GINSBURG: Yes.
8	MS.	KELLEY: David?
9	DR.	GRABOWSKI: Yes.
10	MS.	KELLEY: Jonathan?
11	DR.	JAFFERY: Yes.
12	MS.	KELLEY: Kenny?
13	MR.	KAN: Yes.
14	MS.	KELLEY: Greg? Okay, yes, that was a thumbs-
15	up. Betty?	
16	DR.	RAMBUR: Yes.
17	MS.	KELLEY: Wayne?
18	DR.	RILEY: Yes.
19	MS.	KELLEY: Jaewon?
20	DR.	RYU: Yes.
21	MS.	KELLEY: Dana?
22	DR.	GELB SAFRAN: Yes.

1	MS. KELLEY: Scott?
2	DR. SARRAN: Yes.
3	MS. KELLEY: Mike?
4	DR. CHERNEW: Yes.
5	MS. KELLEY: All right.
6	DR. CHERNEW: Okay. With that our morning
7	session is adjourned. Thank you all for your time. I
8	thank the staff for your work and your presentations. And
9	we will come back. We're going to talk about prescription
10	drug rebates when we get back after lunch, and that is
11	going to be at 2:15.
12	Oh, if you have any comments at home, please send
13	your comments to meetingcomments@medpac.gov, or go on the
14	website and you can otherwise reach out to us. We do want
15	to hear comments from folks at home about the work that we
16	do.
17	So again, with that we are now adjourned, and we
18	will be back at 2:15 to talk about drug rebates. Thanks,
19	everybody.
20	[Whereupon, at 12:52 p.m., the meeting was

22 day.]

21

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recessed for lunch, to reconvene at 2:15 p.m., this same

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1

2 [2:17 p.m.] Hello, everybody. Welcome back to 3 DR. CHERNEW: 4 our afternoon session. We have gone through the portion of 5 the meeting that involved votes, and now we're going to talk about four broadly important topics, the first two 6 7 this afternoon, and we're going to start with rebates for 8 prescription drugs. And, with that, I'm going to turn it 9 over to Rachel. Rachel, take it away. 10 DR. SCHMIDT: Good afternoon. In this session, 11 we'll describe our team's continued work looking at 12 proprietary pricing data on Part D drug rebates and discounts that Congress made available to the Commission. 13 This is a continuation of work we've done over the past two 14 15 years and will become part of a chapter in the Commission's 16 June 2023 report to the Congress. 17 As a reminder to the audience, you can download a PDF version of these slides in the handouts section of the 18 19 control panel at the right-hand side of your screen. 20 Before we dig into what we've found, we want to 21 acknowledge that the landscape is changing. In the years ahead, the drug pricing provisions of the Inflation 22

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Reduction Act may affect rebate negotiations between drug manufacturers and Part D plan sponsors. The law included a redesign of the Part D benefit, established mandatory rebates where drug manufacturers must pay Medicare for any growth in prices faster than inflation, and provided new authority for the Secretary of Health and Human Services to negotiate prices for some drugs.

8 Each of these changes is likely to affect 9 manufacturers' pricing decisions and may affect the 10 availability and size of rebates. Our analysis of direct 11 and indirect remuneration data (which include post-sale 12 manufacturer rebates and fees from pharmacies to Part D 13 plans) will provide a baseline for evaluating some of the 14 effects of these major policy changes.

Let's walk through a pharmacy transaction using a numeric example. Here a beneficiary fills a prescription for her diabetes medicine, which has a price of \$200 at the pharmacy. She pays the pharmacy her plan's required 25 percent coinsurance, or \$50, and her plan pays the pharmacy the plan's share of an amount agreed upon under their network contract -- in this example, \$150.

22 Claims data for this prescription would show a

\$200 point-of-sale transaction, \$50 from the beneficiary and \$150 from the plan. However, the plan negotiated a rebate of \$25 from the drug's manufacturer and a post-sale fee of \$5 from the pharmacy. So the plan's net cost is \$120: its \$150 payment to the pharmacy minus the \$25 rebate and the \$5 from the pharmacy.

If we focus on the beneficiary's \$50 in cost sharing, it makes up 25 percent of the price on the claim, or \$50 divided by \$200. However, her cost sharing makes up about 29 percent of the prescription's cost after rebates and discounts, or \$50 divided by \$170, which is the sum of \$50 plus \$120.

There are some inherent tradeoffs to bear in mind 13 about how plan sponsors use direct and indirect 14 15 remuneration, or DIR. First, CMS keeps a portion so that 16 Medicare's reinsurance payments to plans reflect net rather than gross costs. Plans typically use the remaining DIR to 17 18 keep their premiums lower than they'd otherwise be. Lower 19 premiums benefit every enrollee in the plan, as well as 20 Medicare because the Medicare program subsidizes premiums 21 for all enrollees.

22 However, there are tradeoffs. Part D plans

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charge coinsurance for prescriptions in certain phases of 1 the benefit and for specialty-tier drugs. As we saw on the 2 previous slide, because that coinsurance is a percentage of 3 4 the price at the pharmacy before rebates and fees, it's a higher amount of cost sharing that the beneficiary has to 5 pay, or that Medicare pays on behalf of low-income 6 7 enrollees. Sometimes that amount can be greater than 8 plans' net ingredient cost for the drug. Further, higher 9 cost-sharing moves beneficiaries more quickly into the 10 catastrophic phase of the benefit where Medicare currently 11 pays 80 percent of the costs. Remember, though, that after 12 Part D's new benefit design begins in 2025, enrollee cost sharing will be capped at \$2,000, and Medicare will pay a 13 14 much lower percentage in reinsurance.

15 In the aggregate, DIR ballooned from \$8.7 billion 16 in 2010, or about 11 percent of gross Part D drug spending, to \$62.7 billion in 2021, or 29 percent. So, over time, 17 18 growth in rebates and fees has widened the gap between prices at the pharmacy and benefit costs net of DIR. 19 20 Manufacturer rebates, shown in light blue, made 21 up the vast majority of DIR and grew dramatically. However, rebates' share of total DIR declined over time 22

because pharmacy fees, which are shown in darker blue, grew
 more rapidly. In 2021, manufacturer rebates totaled \$50
 billion, or 23 percent of gross Part D spending, and
 pharmacy DIR totaled \$12.6 billion, or 6 percent.

5 Over the rest of the presentation, we're going to walk you through three main factors that have contributed 6 to the enormous growth in DIR. First, there are design 7 8 features of Part D, particularly its benefit structure and 9 the program's emphasis on premium competition. Second, in 10 certain drug classes, price competition among brand-name 11 products played out using rebates. Third, consolidation 12 among plan sponsors and vertical integration of the largest sponsors with pharmacy benefit managers have given those 13 14 organizations bargaining leverage to negotiate more DIR 15 from drug manufacturers and pharmacies.

MS. O'NEILL HAYES: So, first, let's discuss the benefit structure. Part D's current benefit structure and plans' emphasis on premium competition has created incentives to maximize rebates and use those rebates to keep premiums low.

21 Today, the structure of Part D's benefit has plan
22 sponsors bearing relatively little financial risk in

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certain phases of the benefit. There are two standard 1 benefits -- one for enrollees without low-income subsidies 2 (on the left) and another for those with the LIS (on the 3 4 right). Focus if you will on the darker blue parts on the right side of each graphic, showing plan sponsors' 5 financial risk. You can see in both cases plans do not 6 bear much risk in the coverage gap or in the catastrophic 7 8 phase where Medicare pays 80 percent of costs. Relatively 9 low plan liability in the later phases of the benefit 10 undermines plans' incentives to manage spending, and the ability of plan sponsors and their PBMs to collect rebates 11 12 from drug manufacturers can incentivize the use of high-13 cost, high-rebate drugs.

Also note the significant costs borne by Medicare for LIS enrollees, who tend to more frequently use brandname drugs with higher cost-sharing and are more likely to reach the catastrophic phase.

18 The IRA's redesigned benefit will apply uniform 19 structure to both LIS and non-LIS enrollees, provide 20 beneficiaries with a \$2000 annual out-of-pocket cap, 21 eliminate the coverage gap, and increase plan liability 22 while decreasing Medicare's reinsurance. There will also

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be a new manufacturer discount shown in gray -- 10 percent in the initial coverage phase and 20 percent in the catastrophic phase.

The new design would rely less on cost-based payments and restore plans' incentive to manage the benefit. Higher plan liability would provide better formulary incentives and would ensure that plans no longer benefit financially from high-priced drugs with rebates.

9 The next main factor we observed to be related to 10 DIR was competition among brand products within a 11 therapeutic class. These next three slides show the top 12 seven drug classes by gross spending in Part D, along with the average rebates for each class and their subsequent 13 14 rank on a net spending basis after accounting for those 15 rebates. 2015 data are currently grayed out since we won't 16 focus on growth over time until the third slide.

First, we highlight classes that have substantially higher average rebates than other classes, including antidiabetics, anticoagulants, and asthma/COPD therapies. These classes have strong, brand-to-brand rivalry but few generics, at least as of 2021, as you may remember from our last discussion on DIR. Note that

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diabetic therapies rank first based on gross spending, but
after accounting for rebates of greater than 50 percent,
they fall to second on a net spending basis.

4 Next, we have the same drug classes as in the previous slide, but this time we highlight three of the 5 protected classes for which Part D plans are required to 6 cover substantially all drugs. There are six total, and 7 8 three rank among the top seven by gross spending in 2021. 9 The mandatory coverage of these products limits 10 manufacturers' need to constrain prices and plans' ability 11 to negotiate rebates, as you can see from the substantially 12 lower average rebates for these classes relative to other 13 classes.

Antineoplastics, for instance, have rebates of less than 10 percent and move into first on a net spending basis despite their gross spending being roughly 27 percent less than that of diabetic therapies.

Now, one more time with a look at how rebates have changed over time, or not. Looking across the columns at 2015, you can see that rebates have grown for most classes, but again, the protected classes stand out, with some exception for antipsychotics. This exception seems to

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fit with our first point that rebates tend to grow when 1 there is strong brand-to-brand rivalry, and several new 2 antipsychotic medicines specifically for schizophrenia were 3 4 approved during this period. Antiretrovirals, on the other hand, continue to be dominated by a single manufacturer, so 5 there is little competition. As for antineoplastics, 6 despite there being many brand-name cancer drugs within 7 8 most sub-classes, these products tend to be less likely to 9 directly compete with one another because treatment 10 regimens are often highly personalized and involve numerous 11 medications.

So what are the implications of these rebates?
For some products with particularly high rebates,
enrollees' cost sharing sometimes exceeded plans' net drug
ingredient costs, as Rachel mentioned earlier.

This graph, which you saw in October last year but has since been updated with 2021 data, shows, for the six largest plan sponsors, enrollee cost sharing for an asthma product as a share of plans' costs net of manufacturer rebates. Plan sponsors A through F are arrayed in no particular order. Each vertical line reflects the distribution of cost sharing across all plans

1 offered by each sponsor.

For example, median cost sharing across plans operated by Sponsor A was 34 percent of plans' net costs for the drug (denoted by the red square), compared with 45 percent of net costs for enrollees in a plan at the 90th percentile of the distribution.

7 For every other sponsor shown here, median cost 8 sharing was greater than 50 percent of the plan's net 9 costs. The dotted line shows where cost sharing exceeds 10 100 percent. As you can see, many sponsors had some plans 11 with cost sharing above 100 percent. For example, plan 12 Sponsor D had plans with cost sharing that was 184 percent of its net cost of the drug. In these instances, plans 13 would bear no cost for that product aside from 14 15 administrative costs. We found similar patterns for other 16 products from one year to the next.

In 2021, the share of cases in which aggregate cost sharing was greater than plans' aggregate drug ingredient cost net of rebates accounted for 8 percent of gross Part D spending. A vast majority of such prescriptions were filled by LIS enrollees, compared with just under half of all brand prescriptions. Thus, because

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of the low-income cost-sharing subsidy, the Medicare program endured most of these costs. Further, because higher cost-sharing pushes enrollees into the catastrophic phase more quickly, Medicare also incurs greater reinsurance costs. For beneficiaries without the LIS, high cost sharing may affect their decision to fill a prescription.

8 MS. SUZUKI: The third factor contributing to the 9 enormous growth in Part D DIR is the consolidation of plan 10 sponsors over time and their vertical integration with PBMs 11 and pharmacies. Sponsors use PBMs for a number of 12 functions, but a key role is to negotiate with drug manufacturers and pharmacies for post-sale rebates and 13 14 fees. By combining purchasing leverage across payers, PBMs 15 create stronger competition among drug therapies and can 16 counter drug manufacturers' pricing power.

The chart on the right compares concentration in enrollment with concentration in the amount of DIR received by large plan sponsors. Larger sponsors typically own their own PBM, mail-order, and specialty pharmacies. The blue bars show the share of all Part D enrollees in plans operated by each year's top five Part D plan sponsors

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ranked by enrollment. You can see that between 2010 and
 2021, enrollment became more concentrated. The gray bars
 show the share of all DIR that those sponsors received,
 which was even more concentrated than enrollment. In other
 words, the largest plan sponsors received a
 disproportionate share of all Part D DIR.

7 In our presentation on this topic last fall, we 8 described wide variation in rebate amounts for the largest 9 plan sponsors. At that point, we had examined 2020 DIR 10 data in detail for 10 drug classes. Subsequently, we also 11 examined data for 2015 and 2021. We focused on the average 12 rebate amount per standardized prescription.

The widest variation we observed was across the large plan sponsors. This makes sense because the largest sponsors have differing portfolios of Part D plans. Large sponsors typically use multiple formularies that are tailored for different plan segments.

Between 2015 and 2021, the magnitude of average rebates for the largest sponsors increased, but we also observed that there was smaller variation across those sponsors in two out of three classes we examined. This could, in part, reflect maturing of competition among

brands for the drug classes we examined, and the increased awareness among payers about the magnitude of rebates negotiated by others.

In general, we saw more variation across sponsors than within, but for some sponsors there was still a lot of variation, even among plans that used the same formulary.

7 As you just saw, the Part D market has become 8 more concentrated, served increasingly by large plan 9 sponsors. Now we are focusing on their PBMs and vertically 10 integrated, or VI, pharmacies. Between 2015 and 2021, VI 11 pharmacies' share of Part D prescriptions had risen from 12 just over a quarter to about a third. All four major PBMs 13 operate mail and specialty pharmacies and, in some cases, 14 retail pharmacies.

Among the four PBMs, three serve both VI plans and other non-VI plans. Because Part D regulations limit the ability of plans and PBMs to use narrow pharmacy networks, in-network pharmacies include both VI and non-VI pharmacies.

I wanted to focus on the four types of planpharmacy transactions shown in the figure -- namely, that there are four distinct transactions that may provide us

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with insights about how vertical integration may affect
 Part D costs. There are transactions between vertically
 integrated plans and VI pharmacies, VI plans and other,
 non-VI pharmacies, non-VI plans and VI pharmacies, and non VI plans and non-VI pharmacies.

6 In the case of a vertically integrated entity, 7 there could be conflicting incentives, for example, between 8 a PBM that contracts with a payer to lower pharmacy benefit 9 costs and the pharmacy that faces financial incentives to 10 increase its revenue through higher payments or 11 prescription volume.

12 We evaluated several categories of drugs and found that vertical integration may have resulted in higher 13 costs to Part D and plan enrollees. Across the four 14 15 possible combinations of plan-pharmacy transactions, gross 16 payments to pharmacies and net-of-rebate costs were more 17 likely to be highest for VI pharmacies filling 18 prescriptions for VI plans and lowest for non-VI 19 pharmacies.

These findings are directionally consistent with the hypothesis that vertically integrated organizations may financially benefit from higher payments to their own

1 vertically integrated pharmacies.

2 This could be an issue for CMS because it has no 3 visibility into prices between upstream and downstream 4 entities of a combined company.

5 To summarize, while rebates varied widely, we found some patterns that provide insight into factors that 6 contribute to higher rebates. Through case studies, we 7 8 found that therapeutic competition and regulatory policies 9 can affect drug pricing, and that larger rebates are 10 offered in classes with strong brand-brand competition but 11 no generics or biosimilars. From our examination of 12 protected class drugs, we found that mandating coverage weakened price competition and hindered plans' ability to 13 14 negotiate rebates.

There are tradeoffs associated with using rebates to reduce enrollee premiums. As our analysis has shown, in some cases, cost sharing for beneficiaries may exceed a drug's cost net of rebates. While this situation is concerning, going forward we expect the Inflation Reduction Act's out-of-pocket cap and other changes in plans' incentives will help address this issue.

22 Our examination of payments and costs at

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vertically integrated entities suggests that continued 1 growth in the market share of VI plans and pharmacies may 2 pose a particular challenge for Part D. Our findings were 3 4 directionally consistent with the conflicting interests 5 faced by VI entities which could increase costs for Part D and its enrollees. But, in those cases, CMS may have less 6 7 insight into the actual benefit costs because prices 8 between upstream and downstream companies are less 9 transparent.

10 This material will be included in the June 2023 11 report.

12 Our findings provide insights into current rebate 13 practices and, going forward, will serve as a baseline for 14 evaluating changes in pricing and rebates as the provisions 15 of the Inflation Reduction Act are implemented.

16 With that, we'll turn it back over to Mike. 17 DR. CHERNEW: Thank you so much. It's just 18 wonderful to see this insight on data that we actually 19 heretofore had not seen, so this is just a real privilege 20 to be able to read. In any case, we will go through 21 questions. We're going to start with Round 1. Dana, I'll 22 let you do the queue, but I'll just kick it off first, and

1 I believe Larry is number one. Now it's up to you. Larry.

2 DR. CASALINO: I have an extremely naïve question, which I am actually embarrassed about asking now, 3 4 we have had so many sessions about that. But you've both 5 directly stated and implied some drawbacks to rebates, from a patient and public policy and CMS, their perspective. 6 Why are they legal? And I'm asking this as a question, not 7 8 as an argument, really. But now have competition be about 9 negotiating prices directly? Is it because then 10 competitors would be able to see the prices their 11 competitors are getting? Is that the justification for rebates? Because the lack of transparency that they 12 introduce seems undesirable. 13

14 DR. SCHMIDT: So first of all we should say that 15 this kind of, the economists refer to it as price 16 discrimination. I know that sounds like something bad but 17 it's actually pretty widespread. It's not only used in 18 this circumstance. It's widely used in many other sectors of the economy. Any time you purchase an airline ticket, 19 20 for example. And it's used to try and get at what each 21 buyer is willing to pay for a certain thing is.

22 So the argument is that if it were completely

transparent, if it were very visible, then probably the overall amount of discount that one might get, or the net prices one might get would be actually a little bit higher in the aggregate than if you allow less transparency to those negotiations.

6 DR. CHERNEW: So price is higher.

7 DR. SCHMIDT: Right.

8 DR. CHERNEW: Not the rebate would be higher.

9 DR. SCHMIDT: Correct. The net cost. I'm sorry.

10 DR. CASALINO: Everybody would want the best

11 price.

12 DR. SCHMIDT: Right. And, you know, some organizations are better at traps, you know, having a 13 14 relationship with prescribers so that they can direct 15 market share to a particular drug. So they can assure a 16 manufacturer that they're going to have this revenue stream 17 coming forward. And so those organizations might be able 18 to get a very deep discount, but others maybe less so. Maybe they have a smaller risk pool, a smaller population 19 20 they're covering, and less control over prescribers, and 21 maybe less utilization management tools, that sort of 22 thing.

1 So the argument is that you get a better overall average net price that is lower using these sorts of 2 negotiations. But there are drawbacks, as we see. 3 4 DR. RAMBUR: Can I ask a guestion? 5 MS. KELLEY: Betty, did you have something on this point? 6 7 DR. RAMBUR: Yeah. Thank you for asking that 8 question, Larry, because it's confusing to me as well, or 9 not obvious. I just have one quick question. Is there 10 empirical evidence that the price would be higher without 11 rebates or is that the conjecture or the assumption? MS. SUZUKI: I don't know whether it's considered 12 empirical findings, but the theory does predict that the 13 prices, on average, would be higher, and I think 14 15 Congressional Budget Office had a report showing that the 16 distribution of rebates would be compressed once its 17 publicly known how much everyone was getting, and that on 18 average that amount would be lower.

DR. SCHMIDT: We've certainly heard from organizations that, for example, do control the prescribing behavior of folks much more closely, and they routinely complain when things are a little more transparent.

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1 DR. RAMBUR: Thank you.

2 MS. KELLEY: Amol.

3 DR. NAVATHE: Thanks. I have three questions,4 hopefully two of which will be very short.

5 One question is in Table 6 of the reading materials, which I think is page 51 or 52 of the PDF file, 6 in the last column, this is where we're denoting the 7 8 highest average costs or the lowest average cost for the VI 9 and non-VI different combinations, and in the last column 10 the non-VI/non-VI is denoted as being the lowest average 11 cost, whereas numerically the VI-to-VI would be the lowest 12 numerical cost. I was curious if I'm missing something 13 there or is that a typo?

14 MS. SUZUKI: It is a typo.

15 DR. NAVATHE: Okay. Good. Easily rectifiable.

16 Second question -- so this is on the topic of 17 vertically integrated plans and PBMs -- so this is kind of 18 a conceptual question. But we note in the slides, we note 19 in the reading materials the conflicting incentives, and I 20 was wondering if you could just kind of recap for us how 21 you see the conflicting incentives. As I see it there's 22 kind of two different aspects. One part is the co-

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insurance part, which is basically what share the beneficiary pays or the Medicare program pays, based on LIS or non-LIS. And then there's the interaction with the benefit design, which is whether the plan sponsors have liability or not.

6 So, one, I wanted to see if I got that right, 7 because that's generally true, but then that's just 8 specifically going to interact with the VI element. And I 9 was curious if you could then, in the context of the 10 vertical integration, comment on how we think the new 11 benefit design starting in 2025, from the IRA, how that is 12 going to impact those conflicting incentives.

MS. SUZUKI: So the two conflicting incentives that we were focused on is primarily that PBMs have an incentive to lower benefit costs, or at least they contract with their plan sponsors to lower benefit costs, so the bids are lower, payments are lower, and you can track enrollees. So that's one incentive.

But we also know that PBMs and PBMs that own their own pharmacies, the vertically integrated pharmacies, they also make money when the payments to pharmacies and the spread of the pharmacy is higher. And they could make

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more money through higher prices or higher volume, and we thought that would be a conflicting incentive for the PBM that owns the pharmacy. So that was the primary sort of focus of this analysis, comparing the different plan pharmacy setting.

I think the other PBM incentive that we had been 6 7 concerned about related to what you were talking about with 8 the benefit design and not having liability. And so PBM in 9 the plan benefitted sometimes from having a higher-priced 10 product when there were high rebates. And that incentive 11 we believe would be better under the 2025 fee structure, 12 where plans will have significant liability in all phases of the benefit. 13

DR. NAVATHE: So if I repeat that back to you, in essence then, as you think about the new plan benefit design, we're not expecting the particular conflicting incentive on the VI side of the spread. That's not necessarily going to be modulated or moderated.

MS. SUZUKI: So I don't -- well, we don't think that is going to substantially change, and our concern is that if these vertically integrated entities' market share grew, is there a wider effect on what prices are

1 going to be available to the vertically integrated plan
2 pharmacies and non-vertically integrated plans that are
3 contracting with those PBMs that are integrated with other
4 plans.

5 So there are anti-competitive concerns that we 6 discussed a little bit in the mailing material. Our 7 analysis is very narrow in the sense that we're looking at 8 specifically payment for certain categories of drugs and 9 looking at the payments and cost patterns.

10 DR. NAVATHE: Okay. So the last follow-up 11 question to this point, and I will stop. But I quess 12 partly what I'm trying to get a handle on for the vertical integration side is that -- so economic theory-wise we 13 14 would say vertical integration essentially removes a layer 15 of marginalization, and so in theory it should be good, 16 unless there is some sort of distortionary aspect to the 17 policy. That's what I was kind of picking on the co-18 insurance part of it, if you will, or kind of highlighting 19 that part and/or the plan liability pieces relative to the 20 spread.

21 That's why I was picking on those, in a sense,22 because I thought is that the place where we're seeing some

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distortionary incentives that would change VI plan behavior
 even more so than general plan behavior.

And so what I'm trying to understand here is does 3 4 the element of the spread itself actually add any sort of 5 distortionary effect on VI plan behavior that would be different than for non-VI plans. 6 7 DR. SCHMIDT: I'm sorry. Which spread are you 8 referring to? 9 DR. NAVATHE: I'm referring to the spread that's 10 at the pharmacy, essentially, I think. 11 DR. SCHMIDT: Okay. 12 DR. CHERNEW: He's confused even himself. 13 DR. SCHMIDT: I think we're going to have to go think about your question a bit more. So the redesign, as 14 15 Shinobu was saying, is putting a whole lot more of the 16 benefit liability on the back of the plan sponsor. So the 17 current problem is that there are gaping holes in the 18 benefit structure where a rebate that you could get on any 19 single prescription might be far larger than what the plan 20 is liable for. And so the formulary incentives are messed 21 up there. So we are hoping the redesign will address all 22 of that.

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1 Now thinking that through into incentives about vertical integration, I'm not convinced necessarily that 2 that redesign is going to solve those issues there. I 3 4 mean, I think the vertical integration has been part of a larger transformation of what's been going on in the drug 5 supply chain and the PBMs and plan sponsors and pharmacies, 6 and it seems like the PBMs' sources of revenues have been 7 8 changing over time from maybe holding onto some of the 9 rebates to some administrative fees, and now perhaps more 10 profitability associated with specialty dispensing. And I 11 think we just need to think about that more, whether the 12 redesign itself would affect that much.

DR. NAVATHE: Okay. Thank you. I will alsothink about my question a little bit more.

15 MS. KELLEY: Dana.

DR. GELB SAFRAN: Thanks. I think my question is a pretty simple one. If you think about the four categories that you defined, and you illustrated them on Slide 16, on the right side where you have the non-VI plans contracting with the VI pharmacies, I just wanted to understand, I presume it's the case that what you mean by those VI pharmacies is the ones that are vertically

1 integrated with other plans.

2 MS. SUZUKI: So you're talking about the VI plan, 3 VI pharmacy relationship?

4 DR. GELB SAFRAN: I'm talking about the non-VI 5 plans and VI pharmacy relationship.

6 MS. SUZUKI: Right. So this could be a plan that 7 is not affiliated with the parent organization that runs 8 the PBM.

9 DR. GELB SAFRAN: Yes. Okay. That's what I 10 thought you mean. And so then if we go to the other side, 11 where you have the VI plan and the VI pharmacy, are you 12 presuming that they're only relating to their own pharmacy, or would they too -- so on the right side that could be any 13 14 number of VI pharmacies that the non-VI plan is working 15 with, and so the data points there are going to be some 16 kind of averaging, I think. Whereas over on the other 17 side, is the presumption that the vertically integrated 18 plan, when it's doing business with a vertically integrated 19 pharmacy, it's only doing business with its own, or might 20 it be a whole range? Do you understand my question? 21 DR. SCHMIDT: I think her analysis was just for 22 those owned by that particular pharmacy.

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DR. GELB SAFRAN: Okay. Thank you.
 MS. KELLEY: Cheryl, did you have a Round 1
 question?

4 DR. DAMBERG: Yeah, thanks. I noticed in the chapter there was reference to the fact that currently we 5 are not able to see into manufacturer discounts or fees 6 7 retained by pharmacies. And I'm curious if that's 8 something in the future could be captured? Because I feel 9 like part of what we're trying to do is follow the money 10 flow and figure out whether the incentives are right. So 11 is that something that could be requested, and then we 12 would be able to have some insights into it in the future? 13 DR. SCHMIDT: Are you referring to the pharmacy 14 DIR fees, that side?

15 DR. DAMBERG: Yes.

DR. SCHMIDT: So we do get some data on that, and as one of the early slides shows it's ballooned quite a bit. It was \$12.6 billion in 2021, that number. And what we don't have is a whole lot of detail about which pharmacies those came from, in particular. And so it's kind of hard to use that in the sort of analysis that we were just doing, for example.

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1 However, there's about to be a policy change that CMS has put into place, starting next year, in which the 2 Part D plans are supposed to use at the pharmacy their 3 4 expectation of what some pejoratively called clawbacks from pharmacies, these pharmacy DIR fees, what those are when 5 trying to figure out what the cost-sharing is at the 6 pharmacy. And so they're supposed to use that as a 7 8 negotiated price, so that the claims for Part D 9 prescriptions are going to start to look different. It's 10 going to use an anticipated amount of those clawbacks. 11 And when they are doing negotiations with 12 pharmacy networks to set up agreements, the thought from 13 CMS is then to give bonuses rather than clawback payments. 14 This was a provision that CMS put in place last year, 15 effective the coming year. 16 MS. HAYES: And that is what the beneficiary's 17 co-insurance will be based on, is that lower amount where 18 that's accounted for.

19 MS. KELLEY: Scott.

DR. SARRAN: Is there any information out there as to what effective prices the big there PBMs are paying versus what Medicaid or the VA pays for a comparable list

of drugs? I'm just trying to understand what the effective 1 rates are for brand drugs in Medicare versus the two payers 2 that I understand, in the U.S., get the lowest prices. 3 4 DR. SCHMIDT: Is that net of rebates or not? 5 DR. SARRAN: Net. MS. SUZUKI: So CBO has done a study comparing 6 7 the net prices for Medicare and Medicaid for brand-name 8 drugs, so we can certainly find that information for you. 9 DR. SARRAN: It seems to me, from a conceptual 10 level, that, in essence, if Medicare via the Part D 11 program, is delegating the operationalization of purchasing 12 for 60 million beneficiaries, we should get pretty close to 13 the same prices as Medicaid or the VA, given the overall 14 market size. And we're not splitting this up among dozens 15 of PBMs. It's just three big ones. 16 I think just understanding that orders of 17 magnitude and how much, I'm not sure if "fat in the system" 18 is the right phrase, but slack maybe in the system exists, 19 might be helpful. 20 DR. SCHMIDT: So we can certainly provide that 21 document that CBO put together. Those are mandated 22 rebates, for the most part, right. Medicaid has some

1 negotiated ones too. But those are mandated by law, and so 2 the counterargument is that maybe other payers might be 3 having to pay more.

MS. HAYES: There are also differences in coverage requirements with different formularies, so you don't have exactly the same drugs covered under Medicaid and the VA as under Medicare.

8 DR. SARRAN: All sort of non-apples to non-9 apples.

10 MS. HAYES: Sure.

DR. SARRAN: But it might be worth just understanding kind of the magnitude.

MS. KELLEY: Mike, do you have a Round 1 question?

DR. CHERNEW: I do have a Round 1 question. Can you put up the slide that has the little pictures of the PBMs and the plans and pharmacy one? I figure if I get the Round 1 rules wrong, I'm in trouble.

19 So I'm going to use some names of actual 20 organizations. I think one reason why this is so confusing 21 is just we talk about vertically integrated or not, so let 22 me ask it this way.

If one is thinking about CVS Aetna, there is the PBM, Caremark; the plan, Aetna; and the pharmacy, CVS, and it fits into this picture. If you were talking about Cigna, there's Express Scripts, the PBM; and there's the plan, Cigna; but they don't have a pharmacy as far as I know. At least certainly they don't have a CVS-type pharmacy.

8 DR. SCHMIDT: They have a mail order. 9 DR. CHERNEW: Oh, they have a mail order 10 pharmacy. And if you were doing United, they have Optum 11 RX; and the have the plan, United; but again they may also 12 have a mail order pharmacy, but they don't have a pharmacy -- again, I apologize for my limited interaction with 13 14 pharmacies, but my view of pharmacies is basically I'm 15 driving around, there's a CVS, there's a Walgreen's, 16 there's a Rite Aid, there are some independents. So there 17 are mail order pharmacies, which is a very limited thing. 18 So this is depicted as if it's a vertical 19 integration, and a lot of the text is the vertical 20 integration soup to nuts, which really seems fundamentally 21 like a CVS-Aetna kind of thing. Does the whole discussion 22 analysis flip out for organizations that are only partly

1 integrated here? In other words, they don't have, say, the 2 bottom row, or the bottom row in the same sense?

MS. SUZUKI: So one thing we did is to select drug categories that are more likely to be dispensed at specialty pharmacies. So these were expensive drugs like multiple sclerosis treatment, that are less likely to be provided at retail locations, and cancer drugs.

8 So one table in the paper was comparing what 9 kinds of drugs and therapeutic classes were dispensed at 10 vertically integrated versus non-vertically integrated. 11 And we were trying to compare what are the differences. 12 And then we picked the ones that were particularly likely to be mail order or specialty pharmacy. And when you say 13 "mail order," I think now there is not a clear difference 14 15 between specialty and mail. A lot of mail order pharmacies 16 are also providing specialty pharmaceuticals.

DR. CHERNEW: For the most part there is a pharmacy line for these organizations, because you're focusing on specialty pharmacy. But if a person just wants to go their corner pharmacy there is less of that integration here, and so we can have a separate conversation. But at least now I understand.

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1 MS. HAYES: And Mike, we would just point out 2 also that mail and specialty pharmacies, that's a growing share of prescriptions going to Part D benes. 3 DR. SCHMIDT: And spending. 4 5 MS. HAYES: Yeah, spending in particular, yeah. MS. KELLEY: Jaewon. 6 7 DR. RYU: That was actually going to be my 8 question, is do you have any sense of what the share is of 9 the spend between mail, retail, specialty, and I don't know 10 if this belongs in a separate bucket, but in-home infusion 11 I think is another big one that's growing. I'd just be 12 curious, because my understanding is that the actual retail 13 is a fairly small piece and a dwindling piece of the 14 overall spend. But I think it would be helpful just to see 15 the relative amounts. 16 DR. SCHMIDT: So I don't think we have the 17 numbers off the top of our head now, but we can look at 18 that to add to the paper. 19 You know, I think in Part D beneficiaries have 20 been less likely to use mail order maybe than in the 21 commercial sector, but it is growing, and specialty 22 spending is getting huge.

1 MS. KELLEY: So I think that's all we had for 2 Round 1, unless anyone wants to jump in.

3 DR. CHERNEW: We can guess as to who is going to 4 talk next, so we should jump to Round 2, and I think that's 5 going to be Stacie.

DR. DUSETZINA: Thank you. Great chapter andexcellent work.

8 I will say reading this was fantastic. I feel 9 like it really did help to start to shed some light on some 10 things that we think we know but it's nice to have some 11 confirmation that the things we think we know are happening 12 actually look like they're happening.

13 I will say there were a few things that struck me 14 as kind of the elephant in the room or missing information 15 or things I really wish we knew. One of those things, 16 especially when I was reading the piece on the vertically 17 integrated plans' pharmacies, PBMs, was about the DIR fees 18 that the pharmacy adds. So it's like it doesn't surprise 19 me that they're kind of paying themselves better at their 20 pharmacies. And are the DIR fees also lower or are they 21 higher? Like, if there were some way to figure that out, even at that higher-level category of vertically integrated 22

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1 or not, since you can't kind of tease it apart too much, 2 that would be really useful. I don't know if that's even a 3 possibility.

4 MS. SUZUKI: So it's complicated because the pharmacy DIR fees, as with the rebates, are reported at the 5 NDC level and not specific to individual pharmacies. So 6 you could not compare the DIR amount for vertically 7 8 integrated versus non-vertically integrated. However, we 9 did try to look at the market shares of vertically 10 integrated pharmacies for particular categories to see if they was a correlation between the average amount of 11 12 pharmacy DIR. We did not find a systematic relationship for the categories that we looked at, but that may not be 13 true in all cases. 14

15 DR. DUSETZINA: And I think one other thing that 16 strikes me as the missing piece -- and you all did a nice 17 job highlighting this, of like the fees, like what else is 18 happening with the payments that are being made for 19 covering pharmacy benefit manager services? And that feels 20 like just a giant missing piece of information. And I 21 think as there's more and more interest in this, especially 22 by congressional committees and others, it wouldn't

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surprise me if then the things we're looking at start to
 look better, and then suddenly the things we can't see look
 worse.

So I think that knowing more about those fees and how they look, because it wouldn't surprise me if, you know, for example, the PBM that's vertically integrated gets a higher fee, you know? So it's like just moving money around.

9 DR. CASALINO: You're talking about the fees that 10 the plans pay the PBMs?

DR. DUSETZINA: Right, so there's the pharmacy 11 12 DIR fees that they take back. There's the rebate that's coming from the manufacturer. And then there's the fee 13 that you pay for PBM services. So it's -- all of those 14 15 entities have different transactions, and since they have 16 kind of a parent company and there's vertically integrated, 17 it's like they could just kind of move money around versus 18 having it be really competitive. So those are maybe just 19 two things for the long-term wish list.

I think the other thing that I would really love for future exploration is thinking about kind of the two opposite ends of the spectrum on the drugs that we're

thinking about. One is thinking about specialty pharmacy, 1 2 as you all were just emphasizing how much of the spending that is, how small the rebates are for some of those 3 4 classes, and how we know that there's more ability to restrict where you get your drugs through those networks. 5 So the limited distribution drugs and the specialty 6 pharmacy drugs, having additional exploration there would 7 8 be great.

9 On the other side of that spectrum, I really want 10 to know what's going on with generic drugs. It's a huge 11 amount of the spending. We know rebates are less likely to 12 be in play, but that's where fees would really come in 13 handy to understand how those are being paid for, because I think there is now kind of this consistent flow of 14 15 information that Medicare is overpaying relative to if you looked up cash pay prices, that Medicare's price is way out 16 17 of bounds in some cases, and that's really concerning. 18 Another thing, just a small point around the 19 finding you had on the low-income subsidy beneficiaries and 20 the dramatic kind of overcharging -- overpayment basically 21 for those people on those plans. That was incredibly

22 concerning because we know Medicare is picking up that tab,

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but it just seems like that is another place to really dig and try to understand like why is this happening on these particular plans. It just seems that the outlier of those payments was high.

5 Okay, and I want to take one small stab at -well, Larry triggered a thought to me, Rachel's response to 6 Larry triggered a thought that it might be nice when you 7 8 were talking about having the ability to steer the 9 providers more to a specific drug and having more control 10 over the formulary, it made me think we should be 11 stratifying by MA and stand-alone, to think about that 12 because there are maybe additional tools or communications or something, maybe not, but that might be --13

DR. SCHMIDT: We actually started to try to look at that, and thus far we haven't really found systematic differences. It looked like the rebates are roughly similar.

18 DR. DUSETZINA: Okay.

DR. SCHMIDT: But there may be differences forindividual plan sponsors.

21 DR. DUSETZINA: Yeah, it just struck me when you 22 were explaining that potential, like where that could fall,

1 it was like, oh, that might be good. But it's good to know
2 that so far nothing is pinging.

And maybe I'll take one tiny stab at Amol's 3 4 question, because thinking about the redesign and how it will affect incentives, I think one of the nice things 5 about the chapter that you all highlight throughout, and 6 especially on those two front parts about the coinsurance 7 8 for the beneficiaries and how that leads to overpayments of 9 their percentage and then also how little responsibility 10 plans have under the current benefit. It does strike me 11 that that might help to improve things, even for -- if you think about the vertical integration, the plan, the 12 pharmacy, and the PBM all might be making quite a bit of 13 money under sales today. So if Medicare and the 14 15 beneficiary are dramatically overpaying, then in some cases 16 the -- you know, every time the drug is filled, the plan 17 might actually be making money, and the PBM's making money 18 and the pharmacy's making money.

19 So I think with the redesign of the benefit, it 20 basically will shift much more responsibility to plans for 21 the whole benefit, and that will kind of avoid this very 22 weird set of incentives that, thanks to this wonderful team

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1 and prior teammates, will be corrected.

2	DR. NAVATHE: That being said, to some extent
3	that correction, if I understand it correctly, will be
4	modulated or moderated because some of the spread that's
5	being earned, if you will, off the internal transaction
6	price is actually related to the price of that in the VI
7	context, that internal piece, as well as the
8	anticompetitive piece. I just want to make sure that we
9	get these different pieces right.
10	DR. CASALINO: It won't be fully corrected.
11	DR. NAVATHE: I think that
12	DR. CHERNEW: Let me try and take a stab, and
13	then maybe this might be complicated enough that we [off
14	microphone] otherwise you might go a little crazy.
15	I think big picture, per your question, there's
16	this issue about how much money comes from the outside into
17	an organization and how does that relate to the integration
18	of the organization, and so one question is: If you take
19	price in a much simpler world and move it from, say, the
20	parent to the acquired organization, it's not that big of a
21	deal. One is more profitable; one is less profitable. It
22	just gets offset.

But here, because of the way revenues are flowing, Medicare money goes out through a complicated process to plans with benchmarks and bids and it goes to drug payments in a separate way to the plans, it's conceivable that where you put the cost can influence the total amount of money coming into the system.

7 It is also the case, because of the way that 8 benefit design works, where the beneficiary is paying a 9 percent of gross and not a percent of net, you can actually 10 bring more money into the system if for any given net you 11 accomplish that with a high gross, because you're 12 essentially taxing the beneficiary who needs the drug. And, of course, you don't get to keep all of that. Some 13 you're passing along in terms of lower premium so we don't 14 15 think all of it. So some of it is -- so part of this is 16 about figuring out -- not figuring out. Part of this is 17 about where you put your price, even though it's a cost to 18 one part of your organization and a revenue to the other, it doesn't completely offset because the payment models 19 20 could pull more revenue, and that is clearly true in the 21 cost-sharing part. It may also be true in the Medicare 22 payment part, because Medicare pays the different people in

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1 the tiers of the picture.

So I think that's --2 DR. NAVATHE: Well, and then there's -- so I 3 4 think that's right, but then there's also the dimension to 5 your point of this sort of internal transfer price in terms of how much they can charge in terms of the internal fees, 6 like that creates the spread. So -- because that, how much 7 8 they can keep basically off of this is in part marginally 9 the right price. In a very bad analogy, in some sense it's 10 like if you have how much comes into the system as well as 11 how much then you can keep within the system is dependent 12 on the price, the gross price, those elements are really important. I agree that they're partially offset by the 13 2025 benefit redesign, but I think there's elements of this 14 15 that are not -- that are mitigating that offset in some 16 sense. And so I quess -- this is more a Round 2 comment. 17 I would say if we can spend a little bit of effort to 18 actually outline where we have this gross price dependency 19 both on Mike's point of what comes into the system, like 20 where the beneficiary pays more or where Medicare pays 21 more, as well as what's allowed for essentially what is margin or profit to be kept, I think that -- in terms of 22

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1 the spread, that will be really helpful because that will 2 help us understand exactly what's happening.

DR. CHERNEW: I think another way of saying what 3 4 Amol's saying, and then I do want to move on, is -- I'm 5 just trying to make it more concrete. Imagine -- and I'm not sure this is true, so I'm just -- I really mean 6 imagine, although it might be true, is the -- there's rules 7 8 on profitability in the auditing of the Part D plans in a 9 range of ways, and if you could shift some of your profits 10 to, say, your pharmacy and away from your Part D plan, you 11 can benefit even in the -- even if the revenue's exactly 12 the same, you can accomplish things you otherwise wouldn't 13 be able to accomplish because now you've moved your profits to a less constrained place by, at some simple level, as I 14 15 said before, the higher payment to the pharmacy is a cost 16 to the plan at some level, so that seems like what does it 17 matter to you? But it might matter to you if there's 18 regulations going on or other limits as to how much profit 19 you can have in different buckets. If there's limits on 20 your profits, you want to move your profits to the place 21 where there's not limits.

DR. SCHMIDT: Sure, and that's what Shinobu was

22

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referring to in these lack of transparency into upstream
 and downstream entities.

3 DR. CHERNEW: Yeah, right. So I'm just trying -4 again -- I saw a hand signal.

DR. NAVATHE: I'm just saying yes, that's exactly right, I think that's what we want to try to make less ambiguous and make clear what these different incentives are. And I think the most important mention of this is how is it linked to gross price.

10 DR. CHERNEW: Yeah.

DR. NAVATHE: Because that is ultimately, I think, what a lot of this is about, is why are gross prices going up and net prices aren't. But there's an incentive to drive that gross price up, try to offset it with using a rebate to get the net price down perhaps, but there's this distortionary effect on bringing the gross price up. That's why that's the dimension we care about.

DR. CHERNEW: This seems to be the most hand-signaled chapter.

20 [Laughter.]

21 DR. CHERNEW: But in any case, we can continue as 22 we work through the chapter on getting some of this right.

1 But let's move on to the next person in the queue.

MS. KELLEY: Okay, that person is Cheryl. 2 DR. DAMBERG: First, this was a real tour de 3 4 force and such a great chapter, so thank you for all the 5 work in that space. But I just kind of want to -- I want to underscore what has just been discussed and just that 6 complexity of what we're trying to understand here and 7 8 determine sort of what's the impact on Medicare spending, 9 what beneficiaries pay. And I think throughout this, it 10 just feels to me like, okay, we're trying to make sure we 11 get the incentives right, but there's so many different 12 layers in this equation, if you will, and is there any 13 opportunity, say, as this work progresses in the future, 14 for trying to think about opportunities for simplifying 15 this process? Because it just feels to me like there's 16 probably a significant amount of waste happening through 17 all these various transaction costs that are getting baked 18 into the system, and I feel like we haven't talked about 19 that or thought it through.

20 Do you want to say something back?

21 DR. CHERNEW: I do, but I think I should really 22 let Rachel, Tara, and Shinobu have the first crack. I'm

1 going to save my response to your question until after we 2 get to Round 2. I do have a particular comment related to 3 that.

DR. DAMBERG: Okay, and then I just want to double down on more transparency about all of these fees and who's getting paid what.

7 MS. KELLEY: Okay. Greg has a Round 2 question, 8 comment, but with a hint of a Round 1 question. He says: 9 Great chapter and brings clarity to a very complex 10 situation. Do we believe that net of all the rebate and 11 fee complexities there is a net value increase for Medicare 12 and beneficiaries based on this entire process? Or does it 13 add complexity without net value?

More specifically, if the government took on the role of negotiating prices for the entire Medicare spend and all plans could purchase at that price and no rebates entered the picture, would we anticipate being better or worse off? Under that scenario, plans and potentially PBMs would take on the role of assisting in optimal drug selection and use rather than negotiating price.

In general, since larger purchasers have greater negotiating power, the greatest impact would be if a single

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entity, such as the U.S. government, negotiated for the
 entire purchase. Of course, this has proved to be powerful
 in other countries that negotiate as a unitary entity, but
 has not yet been successful in the U.S.

5 What is clear, I think -- or he thinks -- is that 6 as a country, what we get today is a very complex, 7 nontransparent system that ends up paying much more than 8 the international market.

9 I think we have Dana next for the Round 2 10 comment.

11 DR. GELB SAFRAN: Thanks. The points that Greq 12 just made and that Cheryl made just reminded me of some work I was involved with a number of years ago, and it was 13 14 working with purchasers who did indeed find that at every 15 intermediary along the way that somebody was pocketing 16 margins. And there were disrupters who were coming into play, who were going to allow at least private sector 17 18 purchasers to unbundle what PBMs have bundled. And I'm 19 just curious, because I've been away from that work for 20 some time, in your research have you come across some of 21 those kind of disrupters? And is there any possibility of 22 their playing a role, even on a pilot basis, in the

1 Medicare program?

DR. SCHMIDT: So we've talked to a few of them, 2 but, you know, PBMs do a lot of different functions, right? 3 4 And the one that we think about the most is rebate negotiation and, you know, pharmacy networks and that sort 5 of thing, but there's also claims processing and setting up 6 7 the networks themselves and all sorts of things, running 8 utilization management. And a lot of these disrupters thus 9 far have not gotten into rebate negotiating, and they're 10 very efficient, you know, a lot of investment into putting 11 in place very efficient systems in claims processing, you 12 know, some of those other functions, but thus far not 13 rebate negotiation.

DR. CHERNEW: I know, Robert, you're next in the queue. I just want to say something because it picks up on where this conversation spins, so this is a little bit about on this point, and then I think we'll go to you, Robert, if that's okay.

In the chapter, there's a section on the relationship between profits and innovation, which you can read the literature on that point. The reason why this is so complex is there's absolutely no doubt, at least in my

mind, that if our only goal was to lower what we spend on drugs or get what we spend on drugs to mimic what's spent on drugs in other countries, we could do that much better with a centralized price-setting sort of system. The challenge there is in many ways what do we give up in terms of innovation in the drug industry and a whole series of things?

8 We can have that core debate, but in general, we 9 have -- it is typically the case that we worry, some people 10 worry -- I don't know who "we" is -- that in a government -11 - in a more government-oriented system where all you focus 12 on is spending less for the set of drugs you have that you end up having less drugs going forward for a range of 13 14 reasons, which is the core debate here, and we can discuss 15 a whole bunch of -- and there's stuff in the chapter on 16 that debate, so I won't sort of weigh that now.

What seems to be true is of the money we spend on drugs per this whole discussion, a nontrivial share of that is being siphoned off by the people that aren't doing the innovation. So we are getting less innovation than we otherwise would for a given spend because we are siphoning the money away from the innovators towards the people that

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1 are trying to be counterweights to the obviously monopoly 2 power that we give to the innovators that allows them to 3 charge the high prices in the first place.

4 And so the big question, which is, I think, true in what Cheryl said, it's true in what Greq wrote, is: 5 Is the tradeoff we make between the risk of, say, the 6 government setting too low of a price and not having enough 7 8 innovation or whatever it happens to be, how do we feel 9 about that relative to -- we have a system that is not --10 it seems to be working for virtually no one in a range of ways. I can't think of any -- you know, a lot of people 11 12 like parts of -- well, maybe that's not true, but I'm not going to say who it's right for. But, anyhow, patients are 13 14 very frustrated, purchasers are very frustrated. It's 15 really hard to understand what's going on. Physicians are 16 very frustrated. We've put in place a ton of 17 administrative costs that make it hard for people to get 18 access to their drugs. A whole bunch of things happen 19 because we're trying to counterweight essentially the 20 price-setting power that we have when we give innovators a 21 monopoly. And it's not clear we do that in the most 22 efficient way.

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1 I'm going to look to Jim and then I'm going to make this next comment, and then I feel like I should run. 2 But solving the broad inefficiencies of America's drug-3 4 pricing problem, which extend well beyond Medicare, is 5 probably beyond what we're going to be able to do. It's particular probably beyond what we're going to be able to 6 7 do because there was an attempt to do that which led to the 8 IRA, which, of course, had many things that we contributed 9 to, much more modest things, like there's problems with the 10 Part D benefit design, let's change it. Big issues like 11 government-involved price setting of all drugs or 12 reimportation or a whole bunch of things like that. That's pretty much going to be outside of where we're going to go. 13 14 That's sort of an expectation-setting comment, and I am 15 perfectly happy to be proven wrong, but --16 [Pause.] 17 DR. CHERNEW: That was Jim saying all good. 18 I apologize for that speech, and now let's just 19 qo to Robert. 20 21 DR. CHERRY: Thank you. You've really made a 22 complex topic and you've simplified it I think as best as

possible, given the nature of the topic. I also think that the graphics do a good job in terms of formulating the questions that we have as well. And I've been spending some time trying to think about my question so I can ask it in an intelligent way.

6 It centers around specialty pharmacies, you know, 7 which do a lot of compounding. So they could be part of a 8 big-box retail shop or they could be independent specialty 9 pharmacies, or they might belong to large, integrated 10 health systems. And each of those buckets have varying 11 degrees of vertical integration, I would imagine.

I think what I'm trying to understand, in that particular sector, what are the challenges relative to what you pointed out, and does this proposal close those gaps in terms of aligning the incentives appropriately.

16 DR. SCHMIDT: You mean the redesigned benefits?
17 Could you just elaborate more?

DR. CHERRY: Yeah, for specialty pharmacies inparticular.

DR. SCHMIDT: Yeah. Can you take another crack at asking your question? I think we're still a little bit confused.

DR. CHERRY: Well, I think it has to do with the 1 fact that some of these specialty pharmacies may be 2 vertically aligned and some are not, and therefore if 3 4 they're part of one bucket or the other, are the incentives 5 behaving differently, and does this proposal actually work to the beneficiary's advantage? 6 7 MS. SUZUKI: When you say "proposal," can you say 8 a little bit more? The redesign proposal?

9 DR. CHERRY: Yeah, right.

10 MS. SUZUKI: So it sounds a little bit similar to 11 what maybe Amol was asking, whether redesign affects how 12 these vertically integrated entities' incentives work.

DR. CHERRY: Yeah, I guess because some of these specialty pharmacies are involved in compounding and --

DR. SCHMIDT: Not just compounding. I think there's just so much of the spending for pharmaceutical is moving towards biologics, in particular.

18 DR. CHERRY: Right, yeah.

DR. SCHMIDT: That's been such a big part of the drug pipeline and so much of the spend that you've got all kinds of players jumping in. And so you're seeing growth in hospital dispensing of it, and in some cases big box

maybe. But a lot of it is mail order-type or home delivery-type services. So that whole industry is changing, especially biosimilars are on the cusp of entering into Part D, so you're going to see a big sexplosion of that over the next few years when more of those come into the market.

7 So there's a lot of entry and I'm not sure how to 8 tie it back yet because we still need to go think about how 9 the redesign affects incentives. But I'd say that there's 10 so much profitability, and that's why you've seen a lot of entry. But our concern is in the vertically integrated 11 12 cases, you know, we don't have visibility into at what 13 price are these vertically integrated specialty pharmacies 14 able to acquire drugs versus what is charged to plans, both 15 of their own and to other Part D plans that they serve. 16 And that's our concern at the moment, that vertical 17 integration. I'm not sure if that addresses your question. 18 DR. CHERRY: No, I think that does, and it'll 19 still continue to be a black box, if you will, in the short 20 term, is what you're saying. Yeah, okay. That clarifies. 21 Thank you.

22 MS. KELLEY: Scott.

1 DR. SARRAN: Yeah. So to Mike's point around isn't it fair that we pay for innovation via paying more 2 for drugs here than much of the rest of the world, you 3 4 know, my sense is everyone agrees that yeah, there's a 5 certain appropriateness to that. I think the challenge is that the complexity and the opacity of the current system 6 7 preclude us from reasonably understanding how much we're 8 paying for innovation and how that payment is structured.

9 That's where I think many of us are jumping to 10 saying, well, can we fix the complexity and opacity of the 11 system by changing the system, and to some extent that's 12 what the IRA has done. But I wonder if a preceding important step is to clarify the complexity and the opacity 13 14 and give us and other policymakers better information 15 about, again, how much is being paid and how it's being 16 paid. If you look at a delta between what the U.S. pays 17 and what the rest of the Western world pays, and you can 18 simplify a market basket kind of thing, then clarifying what that delta is, and where that money goes. 19

20 So I would love to see, Jim and staff, if there's 21 a way, over the next at least several cycles, where the 22 data allows, among other things, a fairly simple visual

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where you could see from a market basket -- let's say a separate market basket for brand names, a separate market basket for generics -- what does the rest of the Western world pay? What are we paying in Medicare today via Part D program? What's Medicaid paying? What's the VA paying? And what the profit margins are, collectively, of the big three PBMs and the big three or four MA plans?

8 I just think if there were a way to lay that out 9 visually it would help us and other policymakers understand 10 how well the current system is, in fact, subsidizing a 11 societal good, which is innovation, versus how much the 12 system currently is just subsidizing the inefficiencies of the market that are not going to the makers of innovation. 13 DR. CHERNEW: Although I couldn't give you a 14 15 specific site, my guess is -- and maybe one of you three 16 know -- that there has been work that would tell you like

17 of a dollar you spend on drugs how much is going to, say, 18 the innovator, and how much is going to other points in the 19 supply chain. I saw some shaking heads.

20 DR. SCHMIDT: There's a study out of USC that's 21 kind of how much goes to which part of --

22 DR. CHERNEW: So we can incorporate some of that.

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1 The problem with comparing to other countries is 2 sort of the notion that they are paying the right amount, 3 and I think what's probably the case is that they are 4 getting innovation that we are financing. And if we were 5 to pay their rates we would spend less, and we would have 6 less innovation. And, of course, in some policies they 7 would just end up paying more.

8 So there's a separate question of whether the 9 goal is to pay the same as them or the goal is to get the 10 right innovation. But for now the easiest way to address 11 your question is we can put in information about how much 12 of the money, the word I used was "siphoned away" from 13 supporting the actual innovation and moving to the system 14 of getting any given payer to pay less for it.

15 MS. KELLEY: Betty.

DR. RAMBUR: Thank you. Well, I have to pile on a bit on here. Nearing the end of my third year, I have to say that this is one of the most complex and convoluted and difficult to understand black box, and the rebates and the whole thing.

21 So my sense is that the nation has allowed a 22 situation that deliberately obscures things, and we should

be able to shed some light without squelching meaningful innovation that creates value. I can't find the reference now, but there was something out not too long ago that talked about innovation does not necessarily always mean clinical value.

So I would really welcome more clarity on at 6 least understanding that any reasonably intelligent person 7 8 could understand this, and it's very, very difficult to do 9 And you guys have done a fabulous job. So I want to so. 10 make it really, really clear that this is a fabulous 11 report, and so I feel like I'm almost on first grade with 12 understanding it. But I would really welcome more work in really understanding what are the cost inputs and the value 13 14 that's created. Thanks.

15 DR. CASALINO: I have a quick question point. So 16 if one wants to accept that rebates are useful and that 17 keeping them secret is useful, is there any way -- I'm not 18 talking about necessarily for this chapter, but if there's 19 work going forward -- given those constraints, you know, 20 secret rebates, is there a way to make this process more 21 transparent so that (a) more people could understand it, and (b) there would be less opportunity to siphon off money 22

in the non-transparent points in the process without people being aware of it or being able to do anything about it. Or if we accepted current kind of secret rebates, is this about as transparent as it can get?

5 DR. SCHMIDT: I don't think we have an answer to 6 that, unfortunately.

7 DR. CASALINO: And I'm not asking you for an 8 answer on the spot, although if you had one that would be 9 great. But if we do more work in this area -- and I have 10 to say, whenever this comes on the agenda, Stacie is like, 11 oh goodie, and I feel like putting a revolver to my head. 12 [Laughter.]

DR. CASALINO: But even after all these years, you know, I gradually learn a little more, a little more. I understand a little more. But if we do more work going forward, I think that would be a fairly important thing to give some thought to, because otherwise, really, what's the point?

MS. GINSBURG: All this discussion brings to mind previous discussions not too many years ago, of trying to engage the public in some of these difficult discussions, and I'm sure many, maybe most of you remember incredible

pushback from the public. Because all they need to hear is that innovation will be squelched. And that's all the drug companies or any of the other medical providers need to say, and the public is convinced.

5 And regardless of what this means as to what they're going to be paying at the drug store for their 6 meds, that scares the daylights out of them. And they're 7 8 so easily influenced by the thought that innovation will 9 come to a halt. All the other foreign countries of the 10 world take advantage. Everybody's going to take advantage 11 of the work we do. But that doesn't mean we should be like 12 every other First World country.

13 So I throw that in now not because in any way 14 would I want to discourage at all this work. I think it's critical. It's just that it makes me rather pessimistic, 15 16 if that's the nicest word I can come up with, on how far 17 we're going to get on this in terms of really practical 18 moving forward. And maybe there's a way around it. I don't know what it is. But I felt like this issue about 19 20 how the public views innovation has been, in the past, so 21 strong -- I don't know what research has been done. I 22 don't know whether we've done focus groups on this

1 particular issue. Wow, that would be great if MedPAC could 2 focus some of their focus group work on this whole issue of 3 innovation and the impact that has on them.

Fabulous work, it's exciting, I'm all for it, and5 it worries me. That's all. Thank you.

MS. KELLEY: I have another comment from Greg. He very much agrees with Scott's comment. He is of the opinion that innovation is optimized when the constraints are known, including both capability and cost. Computer chips are innovated within cost constraints. Historically Moore's Law is an example.

12 He is deeply troubled with the idea that only the 13 U.S. can trigger innovation. In every other sector of the economy that he can think of innovation is constrained by 14 15 cost as well as capability, and is generally driven by 16 global competitive factors. We don't get a new iPhone 17 iteration 10 years ahead of the rest of the world. 18 He is troubled that what works for high tech, 19 consumer products, commodity production, and on and on, is 20 for some reason not appropriate for pharma.

21 And Stacie, I think you had a comment?22 DR. DUSETZINA: Yeah. Maybe just bring us back.

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Marge, I understand the frustrations and concerns. But I think one of the things that's really promising about this work is that for so long we haven't had any concrete answers. We've had a lot of like suggestions about how things probably work, or why they work one way, or we can't know rebates because there is a huge different in what different companies get.

And I think this work allows us to start to actually answer some of those questions and have a better sense of how the market is functioning. It also helps us to learn where the other pieces of information that are still missing that would help us piece the puzzle together, because we've got just part of it and we can start to see a little bit better what we're missing.

15 So I think this work so far has been just 16 incredibly valuable for that. It confirms a lot of things 17 again that I think we know, like protected classes don't 18 get rebates. High competition within classes where a plan 19 can exclude drugs do get rebates, and sometimes they're 20 very large and they've grown over time. You know, the 21 spread of rebates across different plan sponsors. Does 22 vertical integration actually get you better prices? No,

1 not so much.

So I think that answering these questions is really getting us on the path and helps basically with other momentum that is going on now. I mean, other groups are looking at this. There is a lot of interest in Congress at this particular issue. But there's so little transparency that people don't even know what to ask.

8 And so I think that this type of work helps to at 9 least clarify as much as we can in the Part D program, and 10 I think that's why it's so important to be thinking hard 11 about like where are the places we're still concerned. And 12 that's why I think the specialty drugs and the generics and thinking about the payments for those would be a really 13 helpful space to go next, because it kind of starts to 14 15 highlight, you know, maybe going back to Greg's question, 16 are we actually doing the right thing with this system?

And I think a lot of people are starting to think maybe we're not. Maybe it's not really working as well as it was initially intended to work. And I think vertical integration is part of why that's the case.

21 So I'm incredibly enthusiastic about this work, 22 and I'm glad you're all doing it, and I'm looking forward

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1 to future iterations.

2 MS. KELLEY: I believe that is the end of Round 3 2.

4 DR. CHERNEW: So let me try and summarize. One, great. Two, better measures of important things. That 5 matters. Three, some beginning understandings of 6 behaviors. So, you know, it's been very hard to know very 7 8 basic questions, like how does competition affect price 9 when all you observe is gross price, not net price? Now 10 you can just ask a whole lot of questions that could be 11 done. And three, baseline for what is going to happen as 12 we move into IRA Part D, and for that matter, Part B stuff, I think it will be useful to have. Now that's the 13 14 baseline. It's going to take a while to actually get to, 15 but we can see that.

I think those are the types of things that for now we're going to have to focus on with this sort of body of work. We will continue to, as always, and as we did this morning, think about ways to change the Part B and the Part D system to serve the beneficiaries better within the set of things that we control.

22 So that's where we are. I could not be happier

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we have this information. It's clear that there's a lot of both passion around this topic generally and appreciation for the work that was done. But with that I will say a particular thank-you for all of the stuff that MedPAC has done on drugs over the course of the years, and the people who have done it.

And we are going to take a five-minute break and come back at 3:45, when we will talk about safety net for skilled nursing facilities and home health.

10 So again, thank you. Back soon.

11 [Recess.]

DR. CHERNEW: All right. Welcome back, 12 everybody. For our last show of the day we're going to 13 14 talk about a topic that I think, broadly speaking, has been 15 very important. And just for those at home and to recap, 16 it's been a longstanding concern of the Commission and it's 17 been a longstanding concern of mine that we make sure that 18 Medicare payments are adequate to support care for a range 19 of vulnerable or other populations. And in that spirit, we 20 completed a bunch of what I consider to be outstanding work 21 that is in the hospital and physician update chapters related to safety net recommendations. We have related 22

recommendations in both of those chapters about supporting
 the safety net for hospitals and physicians.

Now we're going to think about doing this for skilled nursing facilities and home health agencies. And am I turning it over to you, Kathryn? To Evan. Okay. Evan.

7 MR. CHRISTMAN: Good afternoon. As a reminder, a
8 PDF version of these slides is available in the control
9 panel.

We are here to present our assessment of the need for Medicare safety net payments for skilled nursing facilities and home health agencies. This continues the application of the safety net framework we published in our June 2022 Report to the Congress. The paper will not become a standalone written product, but will be incorporated into future work.

In today's presentation, we will review the Commission's approach to identify and support safety net providers that serve low-income Medicare beneficiaries, apply our safety net frameworks to consider the need for a Medicare safety net policy for skilled nursing facilities and home health agencies, and present next steps for your

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1 discussion.

Recall that our Medicare safety net framework has 2 two parts. In the first part, our goal is to identify 3 4 safety net providers that serve high shares of low-income 5 beneficiaries. The second part is deciding whether new Medicare funding is warranted to support the safety net 6 providers identified in the first step. The goal of having 7 8 a two-step framework is to allow us to broadly identify 9 safety net providers while recognizing that new Medicare 10 funding is not warranted in all situations. 11 Our focus is Medicare centric by design. It 12 balances support for Medicare safety net providers with the 13 reality that the program has limited financial resources. 14 Safety net definitions used by Medicaid and other payers 15 likely will differ. 16 We applied this framework in our March 2023 17 Report to Congress to inpatient hospitals and clinicians 18 and made recommendations for payments to support safety net 19 providers in these sectors.

20 Before we consider the need for a Medicare safety 21 net policy for SNFs and home health agencies, let's first 22 review a few relevant facts about the prospective payment

1 systems for these sectors.

2	SNF and home health care are paid under case-mix
3	adjusted prospective payment systems. SNFs are paid on a
4	per-day basis, while home health care is paid for in 30-day
5	periods. A payment adjustment for serving low-income
6	beneficiaries is not a feature of either PPS. SNF has a
7	per-day cost-sharing that begins after the 20th day, while
8	home health care has no cost-sharing requirements.
9	We identify safety net providers as those who
10	treat a high share of fee-for-service Medicare
11	beneficiaries that receive the Part D low-income subsidy.
12	This category includes Medicare beneficiaries who are also
13	full or partial Medicaid enrollees.
14	For SNFs, we computed the share of each
15	facility's total Medicare fee-for-service stays that were
16	provided to LIS beneficiaries. For HHAs, we computed the
17	share of each agency's total Medicare fee-for-service 30-
18	day periods that were provided to LIS beneficiaries. For
19	the remainder of the presentation we will refer to these as
20	"LIS share" as shorthand.
21	To examine the association between SNFs' and

22 HHAs' LIS shares and financial performance, we put

providers within each sector into five groups based on 1 providers' LIS shares. This slide shows the distribution 2 LIS share for SNFs on the left in blue and for HHAs on the 3 4 right, in red. On the left, in blue, you can see that 64 percent of SNFs had a caseload that was 40 percent or more 5 LIS beneficiaries, while the same share for home health 6 agencies was only 35 percent. While both sectors had 7 8 providers that delivered a high share of services to LIS 9 beneficiaries, there were relatively more high share SNFs 10 than high share home health agencies.

MS. LINEHAN: Before discussing the relationship between providers' share of volume attributable to LIS beneficiaries and financial performance, we want to touch on important context for the discussion of Medicare safety net policy in the SNF and home health sectors.

Fee-for-service Medicare is a profitable and preferred payer in these sectors. Aggregate Medicare margins for freestanding providers have exceeded 10 percent in both sectors for more than two decades. In 2021, the Medicare fee-for-service margin for freestanding SNFs was 17.2 percent, and the margin for home health agencies was 24.9 percent. Based on this and our other indicators, we

recommended payment reductions for both sector in our March
 2023 Report to Congress.

Second, total, all-payer margins are lower for 3 4 both sectors, reflecting that caring for other patients, 5 such as those covered by Medicaid and Medicare Advantage are less profitable. The impact of Medicaid on total 6 margins is particularly significant for SNFs, but the 7 8 Commission has long held that Medicare's payments should 9 not subsidize lower rates by Medicaid or other payers. 10 This principle is reflected in our framework, which is 11 concerned with ensuring access to Medicare-covered services for Medicare beneficiaries. 12

13 This figure takes those five groups of SNFs 14 grouped by their LIS share, and arrays them along the x-15 axis. The y-axis shows the median margin for SNFs in each 16 cohort along with the interquartile range. What we see 17 here is that freestanding SNFs with higher LIS shares had 18 higher median Medicare margins than freestanding SNFs with 19 lower LIS shares, on average.

This slide has the same x and y axis as the previous slide, but shows the results for home health agencies. Home health agencies with the highest share of

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LIS periods had lower median Medicare margins than home health agencies with lower LIS shares, but the highest LIS share agencies' median Medicare margin was 18 percent, still well above the cost of care.

5 The higher average Medicare margins among higher LIS- share SNFs is driven, in part, by their lower average 6 standardized Medicare costs per day compared to providers 7 8 with lower LIS shares. Higher LIS-beneficiary share SNFs 9 have less overall Medicare volume and higher Medicaid 10 volume. Facilities with a higher Medicaid facility mix may 11 keep their costs lower, in part through lower staffing, 12 contributing to their higher Medicare margins.

Higher LIS share SNFs also have higher total facility volume than lower LIS-beneficiary share SNFs, so they may achieve economies of scale that could lower their costs per day.

Home health agencies with an LIS share greater than 80 percent tended to be smaller in Medicare volume and total volume. In prior work, MedPAC has found that lower volume agencies, regardless of LIS share, tend to have higher cost per visit, so the lower cost for this group may reflect, in part, the smaller size of the agencies.

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So applying our Medicare safety net framework we find that many SNFs and home health agencies care for large shares of LIS beneficiaries, but the need for additional Medicare safety net payments to supplement Medicare's rates to ensure access to Medicare-covered services is not indicated by our findings.

7 SNFs with higher shares of LIS beneficiary stay 8 volume have, on average, have higher, not lower Medicare 9 margins than other SNFs. For home health care, providers 10 with the highest share of LIS share, they had lower 11 Medicare margins than other home health agencies, but their 12 Medicare margins nevertheless reflected payments well above 13 the cost of care.

14 The relationship we observe between LIS 15 beneficiary share and Medicare margins, as well as the 16 variation in margins within the SNF and home health 17 sectors, raise questions about the care the program is 18 buying. To better understand the variation in financial 19 performance in the SNF and home health sectors and the high 20 Medicare margins for providers that care for low-income 21 beneficiaries, we plan to further examine the relationship 22 between financial performance and size, costs per unit, and

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1 the amount and mix of care provided to low-income and other
2 beneficiaries.

Relatedly, we will also continue to examine the 3 4 quality of care provided in SNFs and home health agencies, including the quality of care furnished by providers who 5 care for large shares of low-income beneficiaries. 6 7 Research has shown economic and racial disparities in 8 access to high-quality providers in both sectors. 9 We will also examine how staffing in SNFs varies 10 for facilities with low and high shares of LIS 11 beneficiaries. Researchers have found that dual-eligible 12 beneficiaries were more likely to be discharged to SNFs with lower nurse staffing levels that treat patients for a 13 14 longer time and were more likely than Medicare-only 15 beneficiaries to become long-stay nursing home resident if 16 treated in SNFs with low staffing ratios. 17 If future analysis reveals systematic quality or utilization differences for low-income or other vulnerable 18 19 populations, we will assess potential policy remedies. The 20 high margins in the SNF and home health sectors suggest

21 that funding for any new policies could be provided through 22 redistributing payments within the sector, rather than

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through increases in a sector's Medicare payment rates. 1 2 We'll wrap up there and take your questions and feedback on additional analysis to examine access and 3 4 quality of care for low-income Medicare beneficiaries. 5 DR. CHERNEW: Kathryn, thank you. Evan, thank 6 you. 7 I think we're going to go straight to Round 2. 8 Is that right, Dana? 9 MS. KELLEY: I think that's right. 10 DR. CHERNEW: Oh, okay. Late breaking. 11 DR. CASALINO: Late breaking with the very last 12 statement. Kathryn, the last statement in the chapter, and 13 the one you just said, talks about if future work 14 identifies the need to increase payments to improve access 15 or quality for vulnerable populations could be accomplished 16 through redistributing payments within the sector, and so 17 on, rather than just raising the rates for everybody. Βv 18 that are you really referring to what we've called on in 19 work on hospitals and clinicians and MedPAC safety net 20 index, by redistributing payments within the sector? Is 21 the idea that that could be done by creating, you know, if such a time arrives, that that could be done through a 22

1 safety net index? Or am I wrong about that?

2 MS. LINEHAN: I think we are potentially ruling 3 that out here as sort of like an add-on to a fee-for-4 service payment, given the rates as they are now.

5 DR. CASALINO: Ruling it out now.

MS. LINEHAN: Right. But I think we're considering potential mechanisms like quality payment, or are there characteristics that the case mix adjustment is not picking up. So there are other policies that we could use that aren't just an add-on payment to the base rate.

11 DR. CASALINO: Right.

DR. CHERNEW: Can I try and give an answer, whichI think will help? I'm sorry.

14 DR. CASALINO: Yeah.

DR. CHERNEW: In the safety net index work we did there was sort of a very explicit formula that was based on LIS beneficiaries, Medicare volume, and things like that, which we then funneled money through in a particular case. And I think -- but again, we're about to have a discussion in Round 2 -- the analysis did really support that.

21 That being said, that doesn't mean we're saying 22 the payment is greater and everybody has access. So there

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can be other -- again, Kathryn, I don't mean to put words 1 in your mouth -- non-safety net index policy modifications 2 that might support continued access to care for -- for 3 4 important care. So quality metrics is one that Kathryn 5 mentioned. There could be a bunch of other things we do, but the idea of a safety net index, the way we did in the 6 other areas, is probably not what this data supports. 7 8 That's what I took from the chapter.

9 DR. CASALINO: Okay. I think this is a Round 1 10 point, and I'm not trying to squeeze into Round 2. But I 11 think it is an important one. We start the chapter off by 12 talking about the safety net index. We do that for other 13 things and should we do it here. And we say no, we shouldn't do it here. But then when we talk about well, in 14 15 the future, I guess in the future you're talking about 16 future work, not necessarily a reduction in future margins 17 ___

18 MS. LINEHAN: Correct.

DR. CASALINO: -- which is kind of what I was actually thinking about.

21 MS. LINEHAN: Yeah. I think this analysis is 22 very proscribed, and we're not saying that everything is

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1 hunky-dory and we need to move on. I think we think we
2 need to look at there is a lot of evidence that there are
3 quality disparities, and so we want to look at those kinds
4 of issues. And there might be other payment mechanisms
5 that are not a safety net index.

6 DR. CASALINO: Okay. I think it might be -- I'm 7 not arguing about that, but I would say that a safety net 8 index that was budget neutral would redistribute money, 9 right? So that would be one way to target money without 10 getting into quality measurements and things like that.

11 But whether or not that's something that you want 12 to recommend in the future, I just think that in this chapter just to make it understandable if we're explicitly 13 14 not thinking about it, just not now but not going forward, 15 a safety net index, budget neutral, is a way to 16 redistribute money, but some other things, as you were just 17 mentioning. It might be good to make that explicit, I 18 think. Because otherwise, when I read this, I wasn't sure, 19 this last paragraph, are you guys talking about safety net 20 index and budget neutral without using those terms, or are 21 you talking about something more different. And it sounds 22 like it's the latter.

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1 DR. CHERNEW: Yeah, exactly. So just to clarify 2 -- and again I don't want to put -- in that last part we are not talking a safety net index. We are talking about 3 4 non-safety net index-type things that might achieve some of 5 the other goals. DR. CASALINO: I think that could just --6 7 DR. CHERNEW: Dana? MS. KELLEY: Just another clarification. This is 8 9 not intended as a chapter in the June report, this is 10 ongoing work and still an internal document. DR. CASALINO: It's helpful for me because I 11 actually did wonder whether these were just different words 12 for safety net index, budget neutral, or other things. So 13 14 it's helpful to know that. 15 DR. CHERNEW: Late breaking Round 1, if I 16 understand correctly, which is Cheryl. 17 DR. DAMBERG: So I'm staring at Slide 8 and trying to make sense of it, because it seems like the SNFs 18 19 that had high shares of LIS had the higher profit margins, 20 or Medicare margins. And are you saying that some of the 21 follow-on work would be to try to better characterize 22 what's happening in that environment?

1 MS. LINEHAN: Yes, exactly. And we've started doing some of that work with the staffing data. Just 2 didn't roll it out today. And, I mean, on the next slide, 3 4 or two slides after, I think, we talk about some of the 5 drivers of that, and the lower costs per day of those facilities suggests they have lower staffing, which we also 6 found and reported in the update chapter, that the high-7 8 margin SNFs had lower costs per day. So it's consistent 9 with that.

10 MS. KELLEY: Okay. Are we ready to move to Round 11 2? Then I have David first.

DR. GRABOWSKI: Great. Thanks, Dana, and thanks,Kathryn and Evan. This was great work.

I think if I had to give my high-level summary of this -- I was going to call it a chapter but I guess it's not yet a chapter -- of this paper, it's that we're a Medicare payment commission trying to solve what's largely a Medicaid payment issue, and there's some real disconnect in that.

I'm going to focus my remarks on nursing homes,
but I think everything I say will also apply to home
health.

1 I would assert there are safety net nursing homes 2 or resource-poor nursing homes out there. They just aren't the ones caring for greater numbers of LIS short-stay 3 4 Medicare patients. All of the analyses you did had all Medicare patients as the denominator, LIS in the numerator. 5 I think if you looked at all patient days in the 6 7 denominator and Medicaid in the numerator you would find a 8 relationship there.

9 And indeed, my colleagues at Brown, Vince Mor and 10 others, have a great sort of really important paper called 11 "Driven to Tiers," T-i-e-r-s. It's one of the best-titled 12 papers in health services research. But they show this 13 kind of multi-tiered or two-tiered nursing home system.

14 And I'll just read from their abstract, because I 15 think it's really important, that nearly 15 percent of U.S. 16 non-hospital-based nursing homes that serve predominantly 17 Medicaid residents have fewer nurses -- that's to Cheryl's 18 point; they didn't write that in their abstract about 19 Cheryl -- lower occupancy rates, and more health-related 20 deficiency. They are more likely to be terminated from the 21 Medicare/Medicaid programs, or disproportionately located in the poorest counties, are more likely to serve African 22

1 American residents that other facilities.

2	So we have this group of nursing homes. They
3	fill an important point. I do think they often have fewer
4	staff, and I think that maybe explains, and I'll be really
5	interested to see what your work teases out with those kind
6	of most profitable SNFs having the greatest share of LIS
7	patients. That's kind of counterintuitive, and I think
8	it's probably something about staff there.

9 Three quick points. The first would be, you 10 know, I think, and Amol's made this point in the past, but 11 I really think we need to be careful with language here. 12 This is a Medicare payment safety net, not a safety net payment, and I think just being very careful here because I 13 think a lot of audiences are going to read this and be 14 15 somewhat confused by that we're really talking about 16 Medicare short stay in the denominator, not all care.

The second point is maybe a broader philosophical one that comes up at this Commission a lot. Is this a Medicare beneficiary problem? I would say yes, although a lot of these individuals who are long-stay nursing home residents, although their nursing home care is covered by Medicaid, they are duals, and all their health care is

1 covered by the Medicare program. So how we think about
2 them and how we think about access for that population and
3 quality of care is really important.

Once again, as a body, I don't know that this has always been a MedPAC issue, but I would assert it's a Medicare issue and one we should be concerned with.

And as a final point on that, I think until we come up with models that are more integrated across Medicare and Medicaid that really account for this type of fragmentation, we're never really going to address these issues of access and quality.

Final point on future work, and this may have 12 been queued up in the studies you're thinking about, we did 13 14 a paper where we looked at duals and where they were 15 discharged, within markets. So coming from the same, you 16 know, hospitals. And we found that duals relative to non-17 duals were discharged to SNFs with a higher share of 18 Medicaid patients and fewer nurses. And this comes back to 19 staffing there.

But I do think some of our beneficiaries face access issues. And so I'll send you the reference for that paper. But I do think depending how you set up this model,

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like looking across, you know, as you look at those five
 tiers that you have, it looks like they're more profitable.
 But there's something going on in those more profitable
 facilities and it could be fewer staff, and we've seen that
 in our work. So I'd really encourage you to push on that
 issue. Thanks.

7 MS. KELLEY: Lynn.

8 MS. BARR: Kathryn and Evan, thank you so much 9 for this work. I'm really looking forward to how this 10 develops over time.

I'm going to really talk about home health because that's something that continues to concern me, particularly as it relates to rural access.

One of the things I was thinking about when I was reading this was wouldn't it be interesting if you did that same analysis that you did for LIS based on the rurality of the beneficiary, and would you see anything different

18 related to home health?

I saw an article in the last week, that was published in, I think, Home Health News -- I can send it to you -- and it talked about the high rate of how patients are not accepted by home health agencies. And they had

some really startling data. Now we don't normally have
access to that data, but it was using a software program
called CarePort, that tracks transitions. And so they
would call an agency and then they'd get rejected, and that
would be recorded in the software.

And they were talking about rejection rates that 6 7 are approaching 50 percent, and actually they thought were 8 increasing. And it really made me think about the 9 economics of running a home health agency and why their 10 margins are so high. And does this allow them to cherrypick more profitable patients? So 97 percent of all 11 12 counties have a Home Health Agency. Therefore, it is deemed that we have adequate access to home health in rural 13 areas. Yet I hear, anecdotally, quite a bit from our rural 14 15 hospitals that the home health agencies routinely reject 16 their requests, and so they don't truly have the access to 17 care that we think.

And I was just wondering, as we are looking at trying to understand is there an underserved population in here, is there some way to look at the data to better understand -- and I know, and Jim said, it's complicated because there's a lot of fraud, and you might have to throw

1 certain states or certain counties out as outliers, and 2 things like that because they don't make sense. But is 3 there something out there that's truly happening?

4 You know, the areas of the country I hear this most from are like Michigan, Iowa, sort of those kind of 5 Midwest states that have reported the biggest problems, and 6 I don't think are on the naughty list for fraud. So maybe 7 there's a way to look at those states specifically and try 8 9 to understand, is the margin because they're only accepting 10 patients that are less expensive, and therefore, you know, 11 they're not having to drive an extra hour because it's a 12 rural patient.

13 And I would also wonder about, it seems like 14 there's a concentration of home health agencies that are 15 taking care of these low-income beneficiaries. Does that 16 mean that everybody else isn't taking them? And I don't 17 know if this maybe leads to some sort of EMTALA kind of 18 recommendation, where home health agencies aren't allowed 19 to disallow patients based on their economic status or 20 their geographic status.

21 That was a long comment. Thank you.22 MS. KELLEY: Scott.

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1 DR. SARRAN: Yeah, a SNF comment, and building off David's. I think it really is important that we, in 2 order to understand what's going on and look for reasonable 3 4 opportunities for improvement, we look through the lens of 5 the beneficiary as well as the setting. And that's just crucial. We get really locked into an inappropriately 6 7 small box from which we can't find our way out, when we 8 continue to look only through the setting specific, you 9 know, the provider, rather than the beneficiary.

10 And so to the extent that we can further gather 11 data on quality, utilization, and costs for beneficiaries 12 living long-term in a facility, and industry-wide it's a little over a million of our most frail beneficiaries, and 13 14 we just do not have very good data on what's going on in 15 quality, utilization, and costs. And that needs to be 16 done, and to the extent possible across MA as well as 17 traditional Medicare, because there's all sorts of 18 problematic outcomes in MA as well as traditional Medicare. 19 And the last point I'll make is if we get further 20 into the work that that data will tee up, it will become

21 apparent that we do not need to solve for Medicaid's 22 shortfalls or problems in order to significantly improve

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outcome for our beneficiaries. The solutions are largely,
 if not entirely within the scope of how nursing facilities
 today are being paid by Medicare. So that's a teaser.

4 MS. KELLEY: Betty.

5 DR. RAMBUR: Thank you so much for this important 6 work. I really appreciate it, and I am piling on, I guess, 7 what a lot have said. But briefly, I'm really excited to 8 be looking at the staffing in the skilled nursing 9 facilities, home health too, and a few points of additional 10 nuance for that.

11 Obviously, race issues are important, but so is the staffing mix on the RNs, LPNs, nursing assistants. But 12 13 also to the extent that turnover can be captured, it's really important. For the low-wage direct care workers who 14 are disproportionately women of color and immigrants, that 15 16 is a very stressful situation to the organization when there is high turnover, but also to the beneficiaries. 17 18 Like Scott said, this is often their home, these are the 19 people they know, and it's very stressful.

And turnover, I think, is tricky. At least in some of the things I've looked at it's been as high as 300 percent, maybe higher. David would know. But I always

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wonder if those that are low, is it because they are doing so well or because people are economic hostages, and if there's any way to sort some of that out with quality measures, I think it's important. But I think it's really an issue of justice in so many ways, not only to the residents but also to the workers, particularly the lowwage, direct care workers. So thank you.

8 MS. LINEHAN: I mean, we can look at all of those 9 aspects of staffing turnover mix.

10 DR. RAMBUR: Excellent. Thank you.

11 MS. KELLEY: Amol.

DR. NAVATHE: Great. Thank you. I also echo fellow Commissioners in saying that I'm very thankful for this work. I agree with many of the comments that have been made. David made a number of comments that I won't repeat.

17 I'll highlight a couple of points, which is I 18 think that we have to be careful in our interpretation and 19 in really being very, I think, forthcoming about this as a 20 Medicare program view, particularly in the context of short 21 stays. And I think that does impact the interpretation 22 quite a bit in terms of differentiating between, as I think

the title of the presentation was, you know, assessing the need for Medicare safety net payments versus are there safety net skilled nursing facilities or other safety net home health agencies, or something of that nature.

5 And there are a number of different factors here. We've talked about staffing. We've talked about the fact 6 that Medicaid beneficiaries are really the primary revenue 7 8 source and, therefore, since Medicaid rates are lower it's 9 not surprising, to some extent, that the staffing ratios 10 might be different, and therefore you end up with this 11 situation almost by, quote/unquote, "design," that Medicare 12 profitability looks high.

But that doesn't necessarily mean that the 13 14 financial health of these organizations is fine, and we 15 don't incorporate financial health metrics very generally 16 into our work, nor should we, so I'm not advocating for 17 I'm just mainly pointing out that there are, I that. 18 think, some important dimensions and contours here that are worth, probably, honestly, kind of going overboard in 19 20 trying to be sure that we are clear about.

I would say, anecdotally, I have certainly found that there are a number of organizations and individuals

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who have interpreted our work, broadly speaking, in different ways than we probably intend it to be, and so I think taking some extra steps to try to really be clear about what we mean and how the programmatic view, if you will, of Medicare is different than the societal view, or of the cross-payor view, or something to that effect I think would be really important.

8 That being said, I very much support the 9 direction, which is not to pursue Medicare safety net 10 payments for these two sectors, and instead to think much 11 more about the context of equity and quality and staffing 12 and the number of dimensions that others have highlighted.

13 So I'm very strongly in support. I just think we 14 should really double or triple down on making sure that 15 we're very clear about what we mean when we say we're not 16 going to pursue Medicare safety net payments in terms of 17 differentiating that. Thanks.

18 MS. KELLEY: Larry.

DR. CASALINO: I had a question and then a comment. The question is, and another very basic question. So home health agencies are paid on a 30-day episode basis. Is that correct? So they are paid the same amount if

1 someone gets a week of services as opposed to a month?

MR. CHRISTMAN: The qualification for the full 30-day bundled payment is based on the numb er of visits. 4 So if, in a 30-day period -- and it varies a little bit --5 but if it is more than the low payment threshold, which 6 varies from two to six visits, depending on the patient 7 characteristics, but once you get over that threshold of 8 visits you get the full 30-day payment.

9 DR. CASALINO: So there is some opportunity to 10 cherry-pick on that basis, looking for people who are 11 likely to need enough days to get the 30 days but not 12 really 30 days. And that could explain some of the 13 profitability margins we're looking at. Go ahead. I'm 14 sorry.

MR. CHRISTMAN: Yeah, sure. I mean, it's like every PPS system. It's built around a system of averages, and the notion is that ideally a provider gets a mix of cases above and below the mean. But yes, if they targeted the low end of the spectrum, it would be more profitable. DR. CASALINO: Yep, unlike hospitals, for example, they can cherry-pick. They probably have a pretty

22 good sense of who is going to need a lot and who isn't.

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1 Okay. That was my question.

The comment is, and this is just, again, a 2 framing comment, looking at the last section of the 3 4 chapter, or this document, and thinking about future work. 5 I think it's pretty clear from the discussion today, and also what you presented, that simply if we did recommend a 6 7 social safety net index it would funnel more money into 8 high-LIS facilities, especially the SNFs, that are already 9 making more money. So that's one reason not to do it. 10 But the corollary of that is that we think that 11 those SNFs, say, or HHAs, may not be providing the quality, 12 the staffing, whatever that we want. So in your last paragraph you talk about for future work we're going to 13 look into those specific things. It would be just great to 14 15 see a connecting paragraph, I think, somewhere in there, 16 which basically says what I just said, right, that doing 17 the same thing would not work under present circumstances. 18 Instead we need to look at these specific things and see 19 how to do something about that, whether it be rewards or 20 penalties or whatever. I think that would help a lot, just 21 to frame. Because I should have gotten that very clearly 22 when I first read the manuscript, and I actually didn't.

That's why I asked the question originally -- are you just
 using other words for a safety net index here.

3 So I may be dumb but there are other dumb people 4 out there, so making it as clear as possible would help, I 5 think.

6 MS. KELLEY: Robert.

7 DR. CHERRY: Yeah, thank you for a great 8 analysis. Unlike our last discussion, very clear, and the 9 conclusion is also appropriate relative to the data 10 analysis. And of course, always an opportunity to do 11 further sub-analysis, like on rural areas, for example.

I think also in the future what I would also like to see is the safety net model also applied to other areas as well, such as psychiatric facilities, dialysis units, LTCHs, rehab. There are probably opportunities beyond just hospitals and providers to be able to close some of the gaps.

So I really like the work and thank you.
MS. KELLEY: I think that's all we have.
DR. CHERNEW: Yes. So let me summarize for a
second. First, as with all the safety net work we've been
doing, it's really an input, in many ways, into the update

1 recommendations -- not into the recommendations. Into to 2 the chapter, so that's where we put the other work. And what is clear in all of those other discussions related to 3 these sectors is we face this conundrum that David mentions 4 at every meeting, which is nowhere more than here is it 5 harder to stay in our Medicare lane. It came up when we 6 were dealing with aspects of the DSH reallocation, when we 7 8 did the other safety net work, which was really a 9 challenging thing to sort of think through. And that is a 10 problem. It's a problem that transcends what goes on at 11 MedPAC, given sort of where our mission is. It's something 12 that I think gives a lot of people pause when one separates out Medicare services from Medicare people in a whole bunch 13 14 So it's very clear. of ways.

15 The sort of direct work here, in some ways, is 16 other sectors' safety net work was complicated but it kind of played out the way you thought it did, and it didn't 17 18 involve those issues. Here it plays out in a way that's 19 not particularly satisfying, because on one hand I think we 20 understand everything that David said, that there are a lot 21 of places where Medicare beneficiaries -- and I will 22 emphasize that, Medicare beneficiaries -- are not

necessarily getting the quality of care, the access to care that we want them to get. The problem is a lot of that is for services and other things that is not really in the Medicare set of things. So figuring out how to manage that will continue to be a challenge.

So just to reiterate, I think, what was an answer 6 I gave to Larry's question at the very beginning, which I 7 8 think was the right question, is the safety net stuff that 9 we have done follows those two very big charts in the 10 chapter that people will get to read. There's a 11 complicated flowchart thing. I feel like it's a computer 12 language sort of thing going on there. If yes, do this, if no, do that, and blah-blah-blah. 13

14 When you work through that cascade of decision-15 making you don't end up with something that is similar to 16 what we got before, which is put \$2 billion into hospitals 17 that serve disadvantaged populations, or some version of 18 that. You don't see the result at the margins of 19 facilities that are serving a lot of Medicare patients that 20 are substantially worse than the Medicare payment policy. 21 You don't see that.

22 That being said, we will continue to grapple with

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how to make sure that Medicare beneficiaries get the care that they need to get, but do so within the confines of where we are. And that might take a little more work, a little more focus on things.

5 It is odd in some ways, last point, many of our 6 analyses of our value incentive programs involve trying to 7 make sure that organizations that provide better quality 8 get paid more. There's sometimes a tone here, which is if 9 quality is bad, we need to pay you more to bring it up. 10 And first of all it's not clear to me how it responds to 11 payment.

12 We will continue to work on our quality payment type analysis, which will fit into this, and we will 13 14 continue to work to think through the resources necessary 15 to provide good quality for the services that Medicare 16 covers, and we're going to have to grapple with how to deal 17 with this uncomfortable connection between the different 18 programs. And I think that's going to be harder to do 19 without David, but we will muddle along because we happen 20 to have Evan and Kathryn.

21 So in any case, that's where we are on this. I 22 really do appreciate the conversation, and again, this is

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not going to appear in a chapter. It will appear as a
 chapter. It will appear in varying ways in other things
 that we do. But I appreciate the discussion.

4 So what I'm going to do now, barring any other comments, is say thank you to the public and invite them to 5 submit comments to meetingcomments@medpac.gov -- it should 6 be on the screen -- or to reach out onto the website and 7 8 find ways to communicate to the staff or any other way you 9 can reach the many MedPAC forums for which you could give 10 comments -- website, send emails to me or to Jim, some 11 version of that. In any case, we do want to hear from the 12 public on these topics.

So again I will thank Kathryn and Evan. And we are going to reconvene tomorrow. For those who want to know what we're talking about tomorrow morning it is going to be telehealth and behavioral health. Both are really important.

So again, thank you all, and we'll see you in the morning.

20 [Whereupon, at 4:32 p.m., the meeting was 21 recessed, to reconvene at 9:00 a.m. on Friday, April 14, 22 2023.]

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MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

> Friday, April 14, 2023 9:00 a.m.

COMMISSIONERS PRESENT:

MICHAEL CHERNEW, PhD, Chair AMOL S. NAVATHE, MD, PhD, Vice Chair LYNN BARR, MPH LAWRENCE P. CASALINO, MD, PhD ROBERT CHERRY, MD, MS, FACS, FACHE CHERYL DAMBERG, PhD, MPH STACIE B. DUSETZINA, PhD MARJORIE E. GINSBURG, BSN, MPH DAVID GRABOWSKI, PhD JONATHAN B. JAFFERY, MD, MS, MMM, FACP KENNY KAN, CPA, CFA, MAAA GREGORY POULSON, MBA BETTY RAMBUR, PhD, RN, FAAN WAYNE J. RILEY, MD, MPH, MBA JAEWON RYU, MD, JD DANA GELB SAFRAN, ScD SCOTT SARRAN, MD

AGENDA

Mandated report: Telehealth in Medicare - Ledia Tabor, Corinna Cline, Brian O'Donnell3
Recess73
Congressional request: Behavioral health in Medicare - Betty Fout, Ledia Tabor, Jamila Torain, - Corinna Cline, Lauren Stubbs
Adjourn

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1 PROCEEDINGS 2 [9:00 a.m.] Hello, everybody. Welcome to our 3 DR. CHERNEW: 4 Friday morning session, which brings to us two of, I think, 5 the most challenging issues facing the Medicare program, and we're going to start with telehealth, and so I think 6 7 I'm turning it over to Corinna. 8 Corinna, go ahead. 9 MS. CLINE: Good morning. The audience can 10 download a PDF version of these slides in the handout 11 section of the control panel on the right-hand side of the 12 screen. 13 Today we will discuss Medicare telehealth policy 14 for the third time this meeting cycle with a focus on the 15 effect of expanded telehealth coverage on quality, access, 16 and cost. 17 First, we will review the requirements of our 18 mandated report on telehealth in Medicare. Then, we'll briefly review Medicare's temporary expansions of coverage 19 20 for telehealth services during and after the PHE, the 21 Commission's policy option for covering telehealth after 22 the PHE that was in our March 2021 report, and previous

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1 Commission discussions on telehealth this cycle.

Next, Ledia will present the results from our study using population-based measures to assess the effect of telehealth expansion on quality, access, and cost during the COVID-19 pandemic.

6 At this meeting, we would like to get your 7 feedback on the material.

8 In the Consolidated Appropriations Act, 2022, the 9 Congress mandated that MedPAC submit a report by June 2023, 10 which should include four elements:

11 First, the utilization of telehealth services; 12 And, second, Medicare program expenditures on 13 telehealth, both of which we discussed at the Commission 14 meeting in January;

Third, Medicare payment policy for telehealth services and alternative approaches to such payment policy, including for federally qualified health centers and rural health clinics, which we discussed at the Commission meeting in late September last year;

Fourth, the implications of expanded Medicare coverage of telehealth services on quality, access, and cost, which we will discuss today.

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Before the PHE, Medicare's coverage of telehealth was flexible in MA, two-sided ACOs, and other payment systems.

4 Under the fee schedule, Medicare paid for a 5 limited set of telehealth services provided to 6 beneficiaries in rural areas in certain settings, such as 7 physicians' offices and hospitals, with some exceptions.

8 As a result, use of telehealth was very low; it 9 accounted for less than 1 percent of fee schedule spending 10 in 2019. This low use was consistent with other payers.

11 As we have discussed before, Medicare temporarily 12 expanded coverage of telehealth under the fee schedule to allow beneficiaries to maintain access to care and help 13 limit community spread of COVID-19 during the public health 14 15 emergency. As noted in this table, many of these 16 flexibilities have been extended for temporary periods 17 after the PHE which is expected to end on May 11, 2023. 18 Some policies are set to expire at the end of 2024 and 19 others at the end of this calendar year, but may be 20 extended through upcoming rulemaking.

21 In our March 2021 report, we described a policy 22 option for covering telehealth after the PHE.

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1 Under this option, Medicare would continue certain telehealth expansions for a limited duration, such 2 as one to two years, after the PHE ends. This is 3 4 consistent with the action that Congress has taken to date by extending the telehealth expansions beyond the PHE. 5 Many stakeholders have urged Congress to make the 6 expansions permanent; however, continuing expansions for 7 8 limited periods of time would allow policymakers to gather 9 more evidence about the impact of telehealth on access, 10 quality, and cost. This evidence should inform any 11 permanent changes to Medicare's telehealth policies. Now we will discuss the telehealth mandate. 12 Initially part of our 2021 policy option, and 13 14 further discussed at the late September meeting, we 15 considered alternative approaches for paying for telehealth 16 services under the physician fee schedule and those billed 17 by FQHCs and RHCs. 18 For telehealth services paid under the physician fee schedule, Medicare should return to paying the lower 19 20 rate, the facility rate, for all telehealth services.

21 We expect the rates for telehealth to be lower 22 than for in-person services because services delivered via

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1 telehealth likely do not require the same practice costs as 2 services provided in a physical office.

Medicare should also collect data from practices,
particularly direct-to-consumer telehealth vendors, to
determine future payment rates for telehealth services.
Additionally, Medicare should pay rates

7 comparable to the physician fee schedule for telehealth 8 services provided by FQHCs and RHCs, which is the PHE 9 policy. This approach balances the dual goals of ensuring 10 beneficiary access and prudent fiscal stewardship. 11 Medicare would likely need legislative authority to 12 implement this policy.

As an alternative payment option, the Commission discussed a policy of bundling telehealth services into larger units of payment under the fee schedule. However, this approach would have many implementation challenges, so this approach was not pursued further.

In January, we discussed the results of our analysis of trends in use and spending for telehealth services. More information is included in your mailing materials, but as a reminder, here are some of the key findings.

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1 We found that both telehealth use and spending 2 peaked in the second quarter of 2020 and leveled off by the 3 end of 2021.

Forty percent of all Part B fee-for-service
beneficiaries received at least one telehealth service in
2020 compared to 29 percent in 2021.

Annual fee-for-service telehealth spending was
\$4.8 billion in 2020 and decreased to \$4.1 billion in 2021.
E&M services accounted for almost all telehealth
spending.

11 Spending for tele-behavioral health services 12 delivered by telehealth grew in 2021, which highlights the 13 growing significance of tele-behavioral health services. 14 Congress has required the Secretary to conduct a 15 study on Medicare program integrity related to telehealth 16 services.

Our analysis of claims data supports the need for more review on the length of telehealth visits. As shown in your meeting materials, the distribution of the levels of office visits was about the same for in-person and telehealth visits. However, in our focus groups, most clinicians said that telehealth visits take less time, so

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we could expect there to be a higher percentage of lower level telehealth visits compared to in-person visits.

Another area that could be analyzed in the future is the use of audio-only services. Starting in 2023, Clinicians will be required to indicate on Medicare claims when they provide an audio-only telehealth service.

7 I will now turn it over to Ledia to discuss the
8 effect of expanded telehealth coverage on quality, access,
9 and cost.

MS. TABOR: Our mandated report requires that we assess the impact of telehealth on quality, access, and cost, to the extent that data are available. Our analysis is limited by several factors.

First, before the PHE, coverage of telehealth in Medicare was limited to certain services and areas (for example, rural areas). Pre-pandemic literature and data are of limited use in understanding the impact of an expansion in telehealth.

Second, it is difficult to measure the quality of clinician care for many reasons, including calculating reliable measure results.

22 Third, Medicare lacks comprehensive data sources

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1 like lab results and patient-reported outcomes, so we are 2 limited to claims-based measures.

Fourth, because of the time lag in claims data, the time period of available fee-for-service claims data, 2021, overlaps with surges in COVID-19 cases which could influence the use of telehealth.

7 We posed a research question. Is greater use of 8 telehealth associated with changes in quality, access, and 9 costs?

10 To answer this question, we worked with a team from the American Institutes for Research to test a concept 11 12 aimed at assessing the feasibility of using populationbased measures to estimate the association between 13 telehealth use and outcomes measures. As we said on the 14 15 last slide, it is difficult to measure the quality of 16 clinician care, so we used population-based measures 17 calculated with fee-for-service claims data.

We used 2021 claims data because that is the most recent data available to us, and we wanted to meet our mandate. Per the Commission's policy option, policymakers need to continue to gather evidence after we have reached a steady state with COVID-19.

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We used fee-for-service administrative data to
 compare population-based outcomes across hospital service
 areas with different levels of telehealth use.

4 For each HSA nationwide, we examined four population-based measures. The first two are measures of 5 quality: ambulatory care sensitive hospitalizations and 6 ACS emergency department visits per 1,000 fee-for-service 7 Medicare beneficiaries. The third is for access: total 8 9 clinician encounters per beneficiary. Fourth, for costs, 10 total cost of care for Parts A and B services per 11 beneficiary.

We compared measures from the second half of 2019, which is a time period before telehealth expansion, with those from the second half of 2021, which is a time period during telehealth expansion.

HSAs were categorized as having low or high telehealth intensity based on the number of telehealth visits per 1,000 beneficiaries in the second half of 2021, with the bottom third of HSAs assigned to the lowertelehealth-intensity level and the top third of HSAs to the high level.

22

Our analysis aimed to estimate what effect

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greater telehealth use in market areas had on outcomes.
 Simply comparing outcomes before and after telehealth
 expansion does not account for factors other than
 telehealth that influence the outcomes over time.

5 We apply a difference-in-differences framework, 6 which measures the difference in an outcome in the high-7 telehealth-intensity HSAs across two time periods minus the 8 difference in outcome in the low-telehealth-intensity HSAs 9 across the same time periods.

10 DID approaches are frequently used to measure 11 associations between interventions and outcomes.

We also performed DID with several HSA-level covariates that could confound the association between telehealth and outcomes, for example, share of beneficiaries eligible for Medicare and Medicaid and average HCC scores.

Now that we have reviewed the study methods,let's move on to discussing the results.

To orient you to the tables that we will be reviewing, the first row includes results for the lowtelehealth-intensity HSAs, and the second row includes results for the high-telehealth-intensity HSAs.

1 Looking at the first two columns, we see that risk-adjusted ACS hospitalization rates were higher in low-2 telehealth-intensity HSAs compared to high-telehealth-3 4 intensity HSAs during both time periods. Risk-adjusted rates decreased for both groups, but the rate decreased 5 more slowly, on average, among high-telehealth-intensity 6 7 HSAs than among low-telehealth-intensity HSAs. I'll qo 8 over that more.

9 Looking at the first row, between the second half 10 of 2019 and second half of 2021, the risk-adjusted ACS 11 hospitalization rate for low-telehealth-intensity HSAs 12 decreased from 25.4 to 17.89, which is a difference of 13 7.51. Now looking at the second row, the high-telehealth-14 intensity HSA rates went from 23.54 to 17.42 or a 15 difference of 6.12.

16 The difference between these two differences is 17 1.39, meaning that ACS hospitalization rates decreased by 18 1.39 less in high-telehealth-intensity HSAs compared to 19 low-telehealth-intensity HSAs. When controlling for 20 covariates, the DID estimate increased to 1.63 ACS 21 hospitalizations. Both of these estimates are 22 statistically significant at 1 percent.

Now switching to the ACS ED visit rates.

1

Risk-adjusted ACS ED visit rates were higher in 2 low-telehealth-intensity HSA compared to high-telehealth-3 4 intensity HSAs during both of the time periods. Rates of 5 ED visits for the two periods decreased over time at about the same rate. Between the second half of 2019 and the 6 7 second half of 2021, the ED visit rate for low-telehealth-8 intensity HSAs decreased by 8.49 ED visits, while the high-9 telehealth-intensity HSAs decreased by the same amount or 10 8.31 ED visits. The difference in differences is 0.18 ED 11 visits, but it is not statistically significant. The DID 12 estimate when controlling for other factors decreased and remained statistically insignificant. 13

To summarize the findings from the last two slides, risk-adjusted rates of ACS hospitalizations decreased in both groups of HSAs, but the rate decreased more slowly among high-telehealth-intensity HSAs. There was no statistically significant

19 association between telehealth intensity and risk-adjusted
20 ED visit rates.

21 So HSAs with high telehealth intensity do not 22 appear to be associated with improved rates of ACS

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hospitalizations and ED visits relative to HSAs with lower
 telehealth intensity.

Moving to a measure of access, total clinician 3 4 encounters per beneficiary were higher in high-telehealth-5 intensity HSAs compared to low-telehealth-intensity HSAs both before and during telehealth expansion. Total 6 clinician encounters per beneficiary decreased slightly 7 8 across both HSA groups during the two periods; however, 9 total clinician encounters decreased more for low-10 telehealth-intensity HSAs than for high-telehealth-11 intensity HSAs.

12 Between the two time periods, the rate of total clinician encounters per beneficiary in low-telehealth-13 14 intensity HSAs decreased by 0.25 encounters. However, the 15 rates for high-telehealth-intensity HSAs decreased by about 16 0.16 encounters. The difference between these two 17 differences is 0.1 total encounters per clinician, meaning 18 that rates of total clinician encounters decreased by 0.1 19 less in high-telehealth-intensity HSAs compared to low-20 telehealth-intensity HSAs. After controlling for 21 additional factors, we estimate the DID to be 0.3. Both of 22 these results are statistically significant.

1 The interpretation for the results from the last 2 slide is that the rate of total clinician encounters per 3 beneficiary decreased in both groups of HSAs, but the rate 4 decreased at a slower rate, on average, among high-5 telehealth-intensity HSAs than among low-telehealth-6 intensity HSAs.

HSAs with high telehealth intensity appear to be associated with increased rates of total clinician encounters relative to HSAs with low telehealth intensity. The improved access could be due to the convenience of telehealth, not having to leave home if feeling sick, and decrease in "no show" rates for clinician visits.

Moving to a measure of total cost of care per beneficiary, total cost of care per beneficiary was higher in high-telehealth-intensity HSAs compared to lowtelehealth-intensity HSAs both before and during telehealth expansion. The increase over the two periods was slightly larger for the high-intensity HSAs.

Between the two time periods, total cost of care per beneficiary in low-telehealth-intensity HSAs increased by \$229. However, the total cost of care per beneficiary for high-telehealth-intensity HSAs increased by more at

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\$258. The difference between these two differences is \$30
 meaning that rates of total spending per beneficiary
 increased by \$30 more in high-telehealth-intensity HSAs
 compared to low-telehealth-intensity HSAs. However, the
 DID estimate is not statistically significant.

6 After controlling for additional factors, the DID 7 estimate increased to \$165 and was statistically 8 significant. The DID estimate likely changed in magnitude 9 and significance because the controls adjust for factors 10 that impact the accuracy of total cost per beneficiary 11 comparisons.

To summarize the findings from the previous slide, we found that total cost of care per beneficiary increased across all HSAs, but the rate of total cost of care per beneficiary increased more in high-telehealthintensity HSAs.

This means that high-telehealth-intensity HSAs could be associated with higher total costs. When looking at total costs by setting, we did find that clinician and hospitalization spending increased in the high-telehealth intensity HSAs, which is consistent with earlier findings regarding additional spending on clinician encounters and

1 ACS hospitalizations.

2	In summary, we have confidence in the approach to
3	assess the association of between telehealth and
4	population-based outcomes because the results were
5	consistent across multiple validity checks we performed.
6	It was a very difficult methodological analysis.
7	The underlying data is still confounded by COVID-
8	19, so we cannot make casual interpretation of our
9	findings. However, using currently available data, the
10	findings support the hypothesis that telehealth likely
11	improved access to care for some beneficiaries, but do not
12	support the hypothesis that telehealth improved outcomes or
13	lowered costs.
14	Consistent with the Commission's policy option,
15	more evidence is needed from time periods when COVID-19 has
16	reached a steady state before making any permanent
17	decisions. We plan to continue to monitor the impacts of
18	telehealth on quality, access, and cost.
19	I'll conclude with a reminder that this material
20	and mandated report will be a chapter in our June 2023
21	report to the Congress. For your discussion, we would like
22	your comments on these materials.

1 I'll turn it back over to Mike.

2 DR. CHERNEW: Thank you so much. That was a lot 3 of work and I appreciate you digging in on this subject. 4 Dana, we should probably start with Round 1. 5 MS. KELLEY: Okay. I have Lynn first.

MS. BARR: Thank you. This was a really great 6 7 report and I look forward to seeing the data once COVID is 8 through, because it is very confusing. And one of the 9 things that I think makes this really hard for us to 10 understand is COVID wasn't like the whole country got COVID 11 at once, you know, and it was fine. I mean, there was a 12 real difference in how COVID hit urban versus rural, and the timing of that, I think, really confounds a lot of 13 things, a lot of calculations. And as we saw in ACO data, 14 15 it's very, very complicated because it seems like COVID was 16 a 2020 disease in urban and a 2021 disease in rural. So as 17 we're looking at these things, I think there are some 18 things to pick apart.

But my main question is, we had seen data early on that suggested that rural beneficiaries were utilizing telehealth less than urban beneficiaries. And again, who knows what was the incidence of COVID and how all that

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1 confounded things, but anecdotally, we were battling with 2 those rural providers during COVID and they were refusing 3 to adopt telehealth because of the payment policy. So that 4 changed more in 2021, I think when the payment policy 5 changed, but it was too little, too late. So a lot of 6 providers couldn't deal with the billing issues around a 7 rural health clinic and just didn't offer it.

8 And so I think as we're looking at this data it's 9 going to be really important, because when we're looking at 10 HSAs, you know, you just kind of lump a lot of rural into 11 those HSAs. The question is for me, the biggest question 12 that comes out of this report is the question of access for rural beneficiaries. And I'll get to this in Round 2, 13 14 there are recommendations around payment policy for these 15 RHCs, and I'm very concerned these two things are related. 16 So without that data it's going to be very hard to evaluate 17 your recommendations around pricing.

So if it would be possible -- and I know obviously not for the June report -- we have very limited time and this is a great analysis, but I do think that we need to look at rural versus urban in this case. Thank you.

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1 MS. KELLEY: Jonathan.

2 DR. JAFFERY: Thanks. Thanks for a great report 3 and presentation, and I echo the others. This is a 4 phenomenal amount of work and a lot of important questions.

5 My question is, in some, if not all, of the difference-in-difference analysis we saw that there were 6 changes, pre and post 2019, 2021, and as you described it, 7 8 there weren't differences in the low intensity or high 9 intensity. So my question is, have you thought about it, 10 or did you look at the idea of maybe there is some sort of dose response? You know, could it be that telehealth 11 12 services did, in fact, improve one of the parameters you're looking at, and the fact that you're looking at a 13 14 difference-in-difference between the highest, the top one-15 third and the low one-third utilization areas meant that 16 there's a certain threshold, that telehealth services used, 17 in other words, does improve things but once you get over a certain amount it doesn't matter. 18

MS. TABOR: We did look at, it's not so much as this response -- which is an interesting question and one that we can think about for the future, for sure -- we did look at medium versus low as well, but the results were

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generally consistent with the high versus low, but there 1 were some differences. So that's a good question and let 2 me go back and think about it some more. 3 4 MS. KELLEY: Robert? 5 DR. CHERRY: Yes, thank you. The report is well done, and congratulations on this analysis. 6 7 I just had a question regarding total clinician 8 encounters. Is that in-person and telehealth when you 9 refer to total? 10 MS. TABOR: Yes. 11 DR. CHERRY: Okay, great. Thank you. 12 MS. KELLEY: Larry. DR. CASALINO: Yeah, two quick things. One is 13 14 just a wording thing. I totally agree with the idea of 15 paying facility fee going forward. But actually even in 16 the past sessions it took me a while to get my mind around 17 what that means. Because at first reading it sounded to 18 me, at least, like facility fee, oh, that's the fee that 19 gets paid to the hospital, and that's pretty high, right. 20 But I think what we really mean is the fee that 21 gets paid for professional services when the physician is 22 working in that hospital outpatient department. So it kind

of comes up repeatedly, and each time I have to tell myself, no, no, no, it's not the hospital facility fee, which is a lot. It's the physician professional fee when they're working in-institution.

5 So I think probably I'm not the only one who 6 would be confused by that, so I think trying to clarify 7 that. And you might even have to repeatedly clarify it, or 8 maybe just change the wording to something like, you know, 9 professional fee paid when a physician is working in a 10 facility, or whatever.

And the second point is just that in the section where you mention that the level of office visits that were being coded for telehealth visits were pretty much the same as for in-person visits, and that seems paradoxical, given what you found in focus groups, I agree, and I think that's a little bit troubling.

But for readers who aren't physicians it might be good to just spend a couple of sentences explaining when a visit is billed in-person or via telehealth, based on time spent, I think readers might want to know does time spent include time reviewing the chart and time charting as well as time with the patient. Because you wouldn't think that

time reviewing the chart or charting would really differ
between in-person and telehealth visits, and ideally that
could explain some of the lack of difference in coding the
visits. So just commenting on that a little bit I think
might be helpful.

6 MS. KELLEY: Betty.

DR. RAMBUR: Thank you. I thought this wasfabulous and very interesting.

9 I muddled on, of course, many things, but I'm 10 looking at Slide 17 when it shows the clinician encounters 11 per beneficiary, and it shows the statistical significance. 12 I'm just trying to understand what that would mean in terms 13 of clinical significance. I can't lace that through.

MS. TABOR: So I would say that we were able to look at associations and whether those associations were statistically significant. I think your question is a good one of clinical or economic significance and one that I don't think we can answer. So I would ask the Commission's opinion on that.

DR. RAMBUR: Just say that point one and point three do not seem particularly large in terms of clinical significance, if I'm reading it correctly. I could be

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1 wrong.

2 MS. TABOR: And I'm not a clinician so I don't 3 want to weigh in on that, but yes, I think you are raising 4 an interesting question.

5 MR. O'DONNELL: Yeah, I just want to note that when you think about the totality of encounters, all of 6 telehealth is actually quite small, so it's maybe 5 to 6 7 8 percent of total encounters. So when you say there's an 9 increase of 0.3, it's starting off from quite a small base. 10 So you wouldn't expect an increase in like one visit of 11 telehealth to increase total encounters, which is much, 12 much larger by a huge amount. So it kind of makes sense 13 when you go from a 30,000-foot view that telehealth is 14 actually guite small to start with.

15 DR. CHERNEW: So if I could jump in on this 16 point. As was said, this is a particularly challenging 17 analytic task given the period in which this was happening, 18 and to Lynn's point, the non-random distribution of COVID 19 across the country. So drawing conclusions strongly about 20 telehealth is good or telehealth is b ad is really hard to 21 do from this basic design, and that's just the way it's going to be. I think it was important to try and take this 22

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look to see what's going on. I think you could say if the 1 number were, you know, eight visits, or something like 2 that, you would have a different view. But then you would 3 4 ask, what type of visits? What patients? I think you're going to see something different in behavioral health than 5 other things. The rural effect might be different, if 6 7 there was an effect, might be different than somewhere 8 else.

9 So I'm not sure what the right framing is. I 10 think this is a reasonable assessment of what the data 11 looked like, for what it was, that you should take it for 12 what it is, and I wouldn't try and take it for more than what it is. And I will say that it is likely -- just a 13 guess -- that over the next period of time you will see a 14 15 bunch of other folks, academics and others, trying to think 16 through different ways of getting at this sort of 17 fundamental question about what telehealth does, and for 18 whom, under what circumstances, in ways that it's just good 19 granular for us to do, given that there was a report 20 requirement that we had to do. And I think that's sort of 21 giving you a sense of what the data is showing. But I 22 would take it just at face value for that. And if I've

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1 misinterpreted anything please --

2 MS. KELLEY: Okay. Amol. DR. NAVATHE: I had guick guestion on Slide 19. 3 4 I think it's kind of interesting and potentially notable 5 that without the controls the association is not significant, and then it becomes significant because of the 6 7 controls. And I was curious, you listed a number of 8 different controls that were used in the mailing materials, 9 and I was curious if you had a sense of which of those 10 covariates actually kind of led, or I don't know if you did 11 it in a kind of sequential fashion, but do you have a sense 12 of which of these is the most important in kind of seeing this effect emerge, if you will? 13

14 MS. TABOR: I don't have a sense for which of the 15 covariates for this DID with controls, but we did do a 16 separate analysis that is not included in your meeting 17 materials that looked at adding geographic adjustment 18 factors, so things like wage index and GPCIs. And that 19 also changed the statistical significance and the magnitude 20 very similar to this one, 6.5. So my quess is that it's 21 really kind of the geographic factors plus the HCCs, but we 22 didn't actually run that.

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But just to your point, trying kind of other ways of controlling for differences across the HSAs, we found similar results for this measure.

DR. NAVATHE: Got it. And do you have sense from just looking at the coefficients on the covariates which ones of them are from a magnitude perspective the most associated with these?

8 MS. TABOR: I have the data but I don't have it 9 at my fingertips, so I'll go back and look and we can add 10 it to the report.

11 DR. NAVATHE: Okay. Thanks.

12 MS. KELLEY: Okay. That's the end of Round 1 13 unless anyone wants to jump in.

14 DR. CHERNEW: Yeah. So I'm going to ask a 15 clarifying question just because I want to give the 16 opportunity to sort of say this, but I think it is 17 important for people to understand. The definition of 18 telehealth, the way we think about it and the way this is discussed, is a very particular definition in the sense 19 20 that it's an encounter. You know, you're thinking about 21 it. You would've gone to your doctor and now you go on a 22 telehealth visit.

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1 There are a bunch of other digital health services that are coming down the road. You mentioned a 2 few in the chapter. E-visits, which is a very technical 3 4 thing, as opposed to non-E-visit portal messages, remote patient monitoring, which sometimes is considered, 5 sometimes not, a telehealth visit. I'm not sure how you 6 treated remote patient monitoring type things. There are a 7 8 bunch of new digital codes. Betty mentioned them earlier 9 to me, around artificial intelligence type algorithms and 10 new types of services.

11 So could you just say, just briefly, so people 12 understand, what type of things were counted as a 13 telehealth visit and what type of new things that might be 14 digital weren't actually telehealth visits?

15 MS. TABOR: Yeah. That's a great question. So we 16 did, in our determination of telehealth intensity, we did 17 include physician fee schedule and outpatient telehealth 18 services, so coded with the appropriate modifiers, and we 19 did include codes for things like e-visits and remote 20 patient monitoring that Medicare does pay for. I don't 21 think there's any payment yet for kind of the AI chatbot discussion that we've had previously. But for what exists 22

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1 in Medicare payments that is tied to the digital health 2 world we did include.

DR. CHERNEW: So this is just so people 3 4 understand. When eventually we sort all of this out, in my 5 personal view there is reason to believe there will be heterogeneity. The question of what's the effect about 6 remote patient monitoring is different about what's the 7 8 impact of a remote scheduled visit, and that's different if 9 you're talking about that in a behavioral health sense, 10 which, since we're going to talk about behavioral health in 11 a little bit, it's an unbelievably important access point 12 but it might be very different if you're picking some other 13 type of service.

14 So I'm saying that now just so that people at 15 home and others can understand that we recognize that 16 heterogeneity, and this is just, you know, a stab at where 17 we needed to be at this point in time.

18 I didn't want that to go unsaid as people were 19 going through this.

20 So we can go to Round 2.

MS. KELLEY: Okay. And I have Kenny first.
MR. KAN: Sure. I'm very supportive and

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enthusiastic about this telehealth body of work. So as
 many have pointed out earlier, COVID-19 is confounding the
 data underlying the study. So two questions or
 observations.

5 Number one, a very strong plus one on what Mike 6 said about really, for future studies, assessing the impact 7 of AI and e-visits, remote monitoring, and what that means 8 for future digital interactions.

9 And then two, I'm very interested in knowing how 10 would you go about determining a post-COVID baseline for 11 future analysis, especially in really trying to assess like 12 the ER cost avoidance and access advantages of telehealth, 13 what's the potential disadvantage of overuse.

14 MS. TABOR: Do you want me to take a stab at answering that? So I guess I would also be open to the 15 16 Commissioners' discussion on this. I think the next 17 available data to us will be 2022, so we could look at, again, the second half of 2022, which has less effects from 18 19 COVID than 2021. It could also be that a year later, when 20 we have access to 2023, that data is even more of a steady 21 state with COVID. So I think this is something that we 22 just will continue to keep monitoring with the most

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1 available data available to us. And we'll have to kind of 2 consider COVID on a case-by-case, or year-by-year basis, 3 really.

DR. MATHEWS: Ledia, it is also possible that administrative signals might help inform when we can start to make assessments about what a steady state is. So the end of the public health emergency declaration, things like that.

9 MS. KELLEY: Cheryl.

DR. DAMBERG: Thank you for an informativechapter. It was really fun to read it.

You know, you've taken on a really complex task of trying to sort out what's happening with quality of care, particularly in the time frame that you're looking at, and the challenge of disentangling the COVID effect from the telehealth effect. So not an easy task that you were handed.

I think Mike is channeling some of the concerns that I had about the quality-of-care analysis, you know, in part because of that difficulty of disentangling COVID from telehealth effects. And I would encourage the team to potentially think about softening the tone of the

1 conclusions. I don't think from these analyses we can
2 discern whether or not there is a positive or a negative
3 effect of telehealth on quality of care. I think some of
4 the work around access is a little bit clearer to me, but
5 in terms of really understanding what's going on with
6 quality of care I'm not sure that this tells the story that
7 I think we were hoping it might tell.

8 And, you know, as I kind of think about sort of 9 the future work and trying to gather more evidence in this 10 space I think the telehealth story is going to be a more 11 nuanced story. I don't think it's going to be a story 12 about average effects. I think it's going to be a more heterogeneous set of effects on different population 13 14 subgroups and different clinical areas. And I think Lynn 15 nicely pointed out the effects in rural areas could be 16 quite different.

And so I would encourage the team to really try to start unpacking the storyline, because I think that will make it clearer to the range of stakeholders out there where we see the benefit of telehealth and perhaps where it's not adding value.

I would also encourage you, to the extent

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possible, to try to bring MA into the storyline, because I think in the context of population-based payments how those managed care organizations are deploying telehealth may look very different over the long haul, to the extent that that's feasible for you to do that analysis.

And I would also encourage you to broaden the set 6 7 I know MedPAC has an orientation towards of measures. 8 looking at outcome measures, but I think that really 9 understanding sort of what is going on in terms of day-to-10 day management of patients and the best process of care 11 measures can be very important in that regard, and those are measure that are linked to clinical outcomes. 12 So I wouldn't dismiss those type of measures outright. 13

And I would also be looking at other outcome measures such as medication adherence. I think we know that telehealth has been sort of a vital lifeline during COVID to keep people who have chronic conditions on their meds. So that is something I might spotlight.

I think the other thing that I would call out,
particularly for Table 2, two things caught my attention.
One is I kind of wanted to see what the effect of a
particular category of beneficiary characteristic was,

controlling for the others. So I might consider doing kind 1 of a multivariate look there. And also it looked like, in 2 terms of the 25th and the median, there wasn't a whole lot 3 4 of difference there, but in the 75th percentile you've got beneficiaries who are using six telehealth visits, say, and 5 I would want to try to better understand that subgroup and 6 what characterizes them. So are they among the sickest of 7 8 the sick? Do they live in certain areas of the country? 9 So I think, again, it's another opportunity to unpack the 10 data and tell a richer storyline.

11 But again, thank you for the work.

DR. MATHEWS: Cheryl, can I respond to a couple of the points you made?

14 First and foremost, we have tried to be clear in 15 the narrative around the findings that we're aware of the 16 limitations of using data from the second half of 2021 that still very much reflects the effects of the pandemic, and 17 18 we take the position consistent with our 2020 policy option 19 that no one should be making permanent decisions about the 20 telehealth expansions until we are in more of a steady 21 state. So I just wanted to note that.

22 The second thing I wanted to say is just for the

1 record. To the extent that the interpretations of the findings, even given the acknowledgment of the limitations, 2 are too direct, I want to take responsibility for that. 3 4 One of the drawbacks of working as staff on the Commission here is that they have to be able to explain things to me 5 in a way that I understand, and when I sort of pitch things 6 back to them, I say things like, "Well, what this means is 7 there is no correlation." And the initial drafts were much 8 9 more nuanced here, and we can easily walk that back.

But I am trying to convey certain messaging around our findings, you know, preliminary, don't make permanent actions, and if you did, here's the kind of things you would be working with. Is this something you really want to do?

So we can, again, address the tone. I don't think that will be a problem at all in the final draft. DR. DAMBERG: Yeah, I appreciate that, and, you know, to note, I think, Ledia, you were talking about the timeline in terms of when you're going to get the data and also when Congress may be making these decisions, you know, because ideally you would like to have 2023 data. I mean,

2022 looks a bit more normal, and I think it sort of is

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1 kind of a new equilibrium, but it's unclear. And I think
2 people are sitting on the sidelines trying to figure out
3 which way this is going to go and where to invest.

MS. KELLEY: Lynn?

4

5 MS. BARR: Thank you. First of all, I'd like to plus-2 on Cheryl, plus 1 or twice. But, you know, I'm also 6 very interested in seeing more about the MA data and also 7 about the ACO data. I mean, you know, one of the things 8 9 that I think you should be thinking about is: How do we 10 encourage ACOs to really use these waivers? Right? And 11 many -- you know, my experience, most ACOs don't use 12 waivers. You see that as well. And having clear policy, you know, statements -- and the problem with waivers is 13 nobody knows how to use them, and the lawyers get all tied 14 15 up, and then they just stop. And so, you know, if we see 16 that there's benefit, your potential benefit, and we're 17 worried about the cost, maybe we could push ACOs a little 18 bit more. What, almost two-thirds of them now are taking 19 downside risk? So they have that ability to do this, but 20 they're not doing it -- you know, or not really thinking 21 about it. So I think that we might want to think about 22 that a little bit.

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1 I'd also like to plus-1 on Cheryl's comment about 2 process measures. It's really hard to judge cost in the moment, right? I mean, we're looking at chronic disease 3 4 management over time. I sure want to know, you know, how many patients got some of the basic care they needed, you 5 know, how many -- where did the hemoglobin A1C orders go? 6 You know, I mean, we don't have the results, but did they 7 8 even get the test? You know, whatever we can figure out in 9 claims I think would be very important.

10 I'm concerned about including CCM, chronic care 11 management, remote patient monitoring, in this analysis. 12 These are codes that -- remote patient monitoring I think is relatively small yet today, you know, but chronic care 13 management is fairly significant, and it's not the same, 14 15 right? I mean, this is an established relationship with 16 the patient. We've got a nurse that's doing this ongoing 17 management. This is not the same as was this a good 18 alternative to a physician visit. And there's a lot of it, 19 right? And it's really expensive, right? And so I could 20 see where high-intensity HSAs that did a lot of chronic 21 care management would have a cost penalty to them that we think has been over time, but might confound the data. 22

1 Does that make sense?

MS. TABOR: It does, yes, and thank you. So a 2 clarifying point, actually in our definition of telehealth 3 4 intensity, we did not include the chronic care management 5 codes at all. We didn't consider that telehealth. We did include remote patient monitoring and E-visits but not 6 7 CCMs. 8 MS. BARR: I would put remote patient monitoring 9 with chronic care management. As a matter of fact, you 10 know, in rural, we don't -- we can't bill for remote 11 patient monitoring, so we bill it as a CCM code. 12 MS. TABOR: Okay. So we can look into that more, but I just want to for the record --13 14 MS. BARR: Yeah, I think they're the same, but, again, it's so small, it's not going to mess up your 15 16 numbers. Obviously, nobody's really figuring that out. 17 MS. TABOR: Yeah, just to clarify that we didn't 18 use the CCM. MS. BARR: Okay. Well, thanks. I feel better 19 20 about that. 21 A more substantive comment is really about the 22 discussion about using -- I'm going to bring up the words

here, but the discussion that you had about using -- about 1 rural health clinics and FOHCs getting paid under the PFS 2 as opposed to under their billing -- the regular billing. 3 4 And, you know, FQHCs are different. They get a PPS rate. It's, you know, the same rate regardless of their cost 5 report, right? And so it doesn't really mess with them, 6 7 and I don't know how the difference -- how FQHCs have done 8 compared to rural, but I can tell you that the complexity 9 of a rural health clinic billing when you have these 10 external codes that you're using and then you're -- that 11 means that Medicare patient is not coming into the clinic, 12 and because of that, they're not counted on the cost report, has a very deleterious effect on their total 13 14 economics. And during the pandemic, you know, I fought 15 bitterly with our clients -- you know, as you know, we had 16 a couple hundred rural health systems that were working 17 with us. I fought bitterly with them to implement 18 telehealth. And I would say that our success was pretty 19 similar to what you saw in the statistics. About half of 20 them flatly refused because of the complexity. And so 21 those patients didn't get telehealth in those communities, and patients -- I know you could say, well, they could call 22

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1 Teladoc, right? But the research says the patients wanted 2 to deal with their own provider. So these patients either 3 didn't get care, you know, or they went into the clinic. 4 And our clinic visits actually didn't go down as much as 5 the rest of the country.

So I think this is a lot more complicated than 6 this is a fair payment. I think that you really have to 7 8 dig into what does this mean from -- you know, how does 9 this affect their entire rural health clinic payment? And 10 that's what they were afraid of, is that rate would go down 11 so low that they would not be able to continue to employ 12 the physicians. So please, please, consider that in your 13 analysis.

14 Thank you.

15 MS. KELLEY: Stacie.

16 DR. DUSETZINA: Thank you, and thanks for an 17 excellent chapter and body of work.

I want to maybe emphasize a little bit of what Cheryl had said before, and thank you, Jim, for the clarification on the nuance that was in the prior version and then the Jim-friendly version of the piece.

I think one of the things that probably Cheryl

and I are both reacting to around that implied -- like our 1 sense of it implied conclusion around telehealth is the 2 difference-in-differences modeling approach and how that 3 4 tends to get used, including with causal language in some 5 cases. And you all didn't do that, but I think when you see difference in differences, it just implies this level 6 of certainty that we all think isn't really there because 7 8 of the underlying data concerns. So I definitely agree 9 with trying to soften the tone and have more nuance there.

10 I think Betty's initial clarifying question 11 around the clinical significance is also a really important 12 one, because they're relatively small numbers, like the 13 differences. So I think just emphasizing that and how they 14 would flip over, you know, the one that kind of flips to 15 significant -- but it was really a small difference, the 16 dollars in particular, like, well, what does that mean? It 17 means this is way more complicated than what our measures 18 are suggesting.

19 Regarding the chapter, I thought it was
20 excellent. I thought it was very compelling how much of
21 the service use was behavioral health. And it made me
22 wonder quite a bit about the missing FQHC information and,

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1 you know, how accessible is behavioral health care for 2 rural beneficiaries or people going to FQHCs? What is kind 3 of the access to that particular skill set like there?

So I think it is a really important challenge. It may be because I read this and then read the behavioral health chapter, and I was like, oh, my goodness, you know, we've got a lot to deal with here. But I think that to any extent that we can dig further into those areas, it would be really helpful.

10 Like Lynn, I was really concerned with the gap 11 between rural and urban, because I guess conceptually, I 12 just think, well, telehealth would be great for someone who would have to drive a really long way to see their doctor. 13 14 So thinking that rural is underusing the service is kind of 15 opposite of what I would have hoped we would see, but I 16 appreciate that we have this missing data kind of issue 17 there.

Like others, I was concerned about how much of what's happening in the 2021 timeframe is related to Paxlovid and, you know, like the next wave of COVID where there was probably more intensity around just trying to connect with someone quickly because of timing related to

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that. But, again, you have a lot of behavioral health 1 services, so it clearly isn't all related to COVID, but I 2 wondered if there were possibilities of pulling out things 3 4 that looked like COVID or separately looking at those, 5 because, you know, obviously telehealth was great if someone has an infection and you would rather them not come 6 7 physically into the office building. It's great to use it 8 for both.

9 Finally, the one thing I noted would be in the 10 chapter you talk about the changing back after the PHE 11 policy that kind of creates that extra payment. If you 12 could do the math and say how much that would have saved or how much was kind of maybe overpaid because of that add-on 13 payment that was being used, I don't know how easy it would 14 15 be to do that, but it seems like you have all the other 16 pieces there, and it would be maybe compelling when you're 17 saying we should stop paying that fee. Just telling us how 18 much we had spent on that would be good.

19 But really excellent work, you guys.

20 MS. KELLEY: Jaewon?

21 DR. RYU: Yeah, I really appreciated the work as 22 well. A lot of limitations and confounders, and I thought

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1 just dealing with the imperfection, thank you for what you
2 all did.

Just a few points. First, the definition of the 3 4 high-intensity HSAs versus the low-intensity HSAs, really in an ideal setting, to me it seems like you'd want to have 5 not just defining that, but the highest degree of changers, 6 so to speak. And maybe it's a moot point because prior to 7 8 the pandemic, the amount of telemedicine was so minimal and 9 it was constrained to certain use cases only. But this got 10 me starting to think that maybe the comparison point should 11 be at the peak of telemedicine use after the pandemic, and 12 then really when it started dropping again and reverting back to normal levels, and that change of usage could 13 14 become the basis for the comparison and your difference-ofdifferences model. So that was one. 15

The other is I think the reason why this gets complicated, as I start thinking about it, is there's so much overlay, really you have to take into account to what degree or how effectively was telemedicine used to supplemental or replace access? And so I think the -- I wish there was a little more mention or a way to weave in the concept of some of these HSAs may have been underserved

1 from an access point to begin with. So what was the pre-2 universe like even without telemedicine? You know, what 3 did access look like in the primary care space? And so I 4 think that's a question worth exploring a little bit as 5 well.

And then, lastly, I totally agree with Lynn's 6 point that I think it would be interesting also to overlay 7 8 what happened in the ACO world and did these trends look 9 different there? But difference of difference of 10 differences --11 [Laughter.] DR. RYU: -- would be interesting to look at 12 13 there. 14 DR. CHERNEW: That is a thing. Just to be clear, 15 that is a thing. 16 MS. KELLEY: Robert.

DR. CHERRY: Thank you. I certainly do echo everybody's comments about this analysis being well done. Of course, it is very early on, but the value of the work is that it provides some insights, some impressions, so that we can have really a good dialogue about telehealth and where it's going.

I do agree with Mike that, you know, telehealth is sort of a rudimentary part of where, you know, medicine is going. It's really about the digital patient and family experience of which telehealth is one component. And a lot of this is also being driven by the market and consumerism as well.

7 And so one of the missing elements here is 8 patient experience surveys, and I do realize there's an 9 unevenness. You know, some are doing this, some are not in 10 the telehealth space. But I think that, you know, 11 encouraging CMS perhaps to actually have surveys in this 12 space could really be helpful, because I think context is everything. We may or may not be able to demonstrate 13 14 improved quality of care, but we might be able to 15 demonstrate, you know, consumers that are actually 16 benefiting from the access. I think that's a critical 17 element.

Regarding, you know, some of the data, the hospitalization rates, of course, are statistically significant, but the ED visit rates are not. And it will be interesting to see how that holds up or doesn't hold up over time because there still was in the second half of

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2021 a fair amount of ED avoidance by patients, and so that
 could be the reason why you're not seeing those
 statistically significant differences, but you might over
 time.

5 The other thing is that the total cost of care, 6 you're seeing the high-density HSAs cost \$30 more, whether 7 you're low or high density, you're probably still making 8 capital investments into telehealth anyway, so just to keep 9 up with the demand; so it doesn't surprise me that there 10 were incremental costs in both groups.

11 I do have several comments that might inform the 12 design of, you know, future studies. One is the obvious, and it's already been mentioned, that the second half of 13 2021 is still an anomalous year, and I think the second 14 15 half of 2022 that's -- I think it is more the year that is 16 more stabilizing, because I think telehealth was probably 17 now starting to kind of plateau, settle down into a more 18 normal state. So we'll see what happens in the second half 19 of 2022 and beyond.

The second thing is that it will be really interesting to see and apply some of this data to our safety-net model as well, just to see if actually there are

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evolving quality differences for safety-net hospitals or not, and what some of those barriers are. Some of the more obvious barriers with safety-net facilities is the lack of broadband, and although that's not within our scope, it could actually help inform decisions around policy and sort of in other areas outside of Medicare. So it will be interesting to look at that in the future.

8 The other thing, the third comment that could 9 also inform future studies is what you mentioned about, you 10 know, telehealth being 5 to 6 percent of the total 11 encounters currently. And take my comments with -- put 12 them into context, this is just my worldview, but many of the academic medical centers in California are hovering 13 14 around 20 percent right now telehealth. And I think, you 15 know, one of the reasons why is they've ramped up from 16 virtually zero to this particular number, because there's 17 benefit in taking lower-acuity patients and putting them 18 through a telehealth model where they're satisfied with the 19 service and then using the backfill for more complex 20 patients that really need to be seen in person. So there's 21 a balance there that's starting to settle out, and so more 22 -- so health systems that are dealing with more complex

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1 care may, in fact -- and I'm sure we'll see in future 2 studies -- may, in fact, be using telehealth as a leverage 3 point for access to make sure that low-acuity patients are 4 taken care of well and the high-acuity patients are in rate 5 setting as well.

6 Otherwise, great work, and this discussion will 7 continue to evolve over the years, so thank you.

8 MS. KELLEY: Okay. I have a comment from Greq: 9 This is fascinating information. Great work. 10 Very nicely done. I would suggest that telehealth is 11 highly dependent on payment mechanism, which is probably 12 not captured at the HSA level. I'm convinced that telehealth value is dramatically different as provided 13 14 within capitated environments versus fee-for-service 15 programs. This shows up in telehealth use rates much 16 higher in capitated groups, including before COVID, but 17 even more in the degree to which telehealth replaces in-18 person services as opposed to being provided in addition to traditional services. 19

20 So while I agree with the conclusions of the 21 staff for telehealth in the fee-for-service world, I think 22 we would find very different and much more beneficial

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results if we were able to examine prepaid plan performance with telehealth. Lynn mentioned the impact on rural beneficiaries, and my experience supports the concept that within a prepaid world, telehealth has a profoundly beneficial impact on cost, quality, and beneficiary satisfactory.

7 Again, great.

8 And I have Betty next.

9 DR. RAMBUR: Thank you. Really great work, and I 10 really support the comments of my colleagues, and so I will 11 limit my comments to three things that either amplify or 12 address things that haven't been brought up yet.

The first builds very nicely on the last comment from Greg. At one of the very first meetings, I was a supporter of audio-only, and I continue to be a supporter of audio-only because of the areas in rural and some notso-rural areas.

18 That said, I'm also very concerned about audio-19 only because of the patient for dialing for dollars, 20 particularly if there is no cost sharing. And I think 21 often of my time as a nurse practitioner and the amount of 22 time I spent on the telephone every day, and I assume

physicians do, too. It's probably two hours of every day.
 So I think that builds on Greg's comments about the payment
 world matters.

4 My second comment relates to access, and I think we have kind of an implicit bent to thinking access means 5 improved outcomes, but we know from both within traditional 6 7 and telehealth that that's not always true. So if 8 somebody's having equal access to high value and low value, 9 on average there's no difference in outcomes. And so I 10 know this would be really complicated, and I can't imagine 11 how you would do the math on this. But is there a way to 12 sort out access to what? And I'm particularly thinking 13 about a study that came out of Lown Institute that 14 suggested that there were 100,000 unnecessary surgeries in 15 the first year of COVID. So at the same time we're all 16 scrambling to give necessary care, at least in their 17 analysis that was happening. So I think it would be really 18 helpful to think access to what?

And then, finally, I have to pile onto the comments about digital being a really important frontier for us and not necessarily for right now, in the parking lot for now. But I think about chatbots and a recent study

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that found it improved outcomes in mental health and oncology, which seems the last place you would think a chatbot would be effective, right? So somehow or another down the line, you know, perhaps over the next five years, this is going to have to be an area we explore in terms of all our digital health.

So thank you so much. I think it's really
brilliant and important work, and I look forward to next
steps.

10 MS. KELLEY: Larry.

11 DR. CASALINO: First of all, I'd like to thank 12 Lynn for consistently bringing up rural. But seriously, it's a tough position to be in, and I think speaking for 13 myself I think in my career I haven't been aware enough of 14 15 rural issues, and I suspect that's in general true across 16 the Commission. So it's very valuable, and your very 17 detailed knowledge of, like what you just talked about with 18 rural health clinics and FQHCs, why they are reluctant to 19 do telehealth. It's something that I wouldn't have thought 20 of, so it's very valuable.

21 I liked the chapter a lot. I think it's very 22 comprehensive. It's thoughtful. It's really quite

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1 valuable. You know, just my general perceptions,

2 telehealth is extremely valuable, especially in the 3 capitated environments, not so well suited to fee-for-4 service. But it will be important to keep studying it, I 5 think.

And I would say, I would agree with Betty that audio can have a real role, I think, although there are obvious dangers to it, so I hope we will keep looking at and not de-emphasize it.

10 Honestly, my second year in practice, a long time 11 ago, way before there was an internet or the word 12 "telehealth" had been coined, it was very clear to me and the people who worked with me that if someone would pay us 13 just to put our feet up on the desk, me and my medical 14 15 assistant, and just call patients all day long, we could 16 really take a lot better care of people than by having 17 people come in like they were.

I'm glad you had a little section on telehealth companies. I thought it was a good section of telehealthonly companies, direct-to-consumer telehealth. This could be a really important phenomenon. I mean, it really does have the potential -- since I agree that the costs are

probably much lower for those companies, first of all doing telehealth, and secondly, they don't have to support bricks and mortar. This could really hollow out the bricks-andmortar health care delivery system, especially primary care. And when you actually need to see somebody in person they may not be there. So I think this is really worth tracking, and I'm glad that you did bring it up.

8 I do want to mention one other thing. I agree 9 with Mike's point about digital health, telehealth being 10 potentially broader than just visits, and so remote patient 11 monitoring, for example. But I think a really important 12 phenomenon right now is the portal. I think without question this is the issue that most concerns at least 13 14 primary care doctors and some specialists in the country 15 right now, with people reporting literally getting up at 5 16 o'clock in the morning to spend two hours on the portal, 17 unpaid, before they get ready to go to work. It's really 18 the cause my primary care physician gave for retiring.

So I think the portal is very valuable. I'm not anti-portal. But I think some study of utilization payment -- a lot more thought needs to be given to this because right now it really is problematic. Yeah, so patients

being able to message their physicians through some kind of electronic portal, and expecting a response. It's valuable. I'm not saying it's a bad thing, but it is a huge, huge problem right now, and I think it hasn't been systematically looked at, to my knowledge.

And the last thing I had to say is, you know, I 6 think that the report does conclude with the statement that 7 8 nuances, even given all the limitations that were stated 9 ahead of time, is going to be read, like telehealth doesn't 10 work, it doesn't improve quality. That will happen. Even 11 with, like you said, population-based outcomes, more work 12 needs to be done using more data before interpreting results is causal. 13

14 I don't mean to be critical. You guys did the 15 best you could with what you had. But I do think that, as 16 it stands, if the report was published just as it is, I 17 think it would do more harm than good because I think 18 people would draw conclusions really that aren't warranted. 19 You know, it took a lot of time, the 20 presentation, discussing this analysis, and at the moment, 21 at least, it concludes the chapter. And people will read that hypothesis that telehealth improves quality is not 22

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1 supported.

So I think it's pretty substantial to think about how to reframe not just listing limitations at some point, and not just saying, well, it can't be interpreted as causal. I think it's actually more problematic than that. And again, this is not your fault. It's the nature of the data that you have.

8 I would say even the associations are suspect. 9 There's just too much going on, not just COVID, as you 10 mentioned. But there are problems with kind of a 11 geographic area analysis. It's kind of analogous to the 12 debate over the literature on primary care, where people say, okay, in countries that have more primary care 13 physicians they have better quality. And I actually like 14 15 that conclusion, but there's a lot of argument about 16 whether it's warranted or not.

There are a lot of things that could affect both the quality of care and the supply of primary care physicians, and here there are a lot of things that could affect both the intensity of telehealth use in a geographic area and quality in a geographic area. So even as associations I just don't necessarily believe the results.

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1 And you did have a little bit of parallel trend problem too, which is not good, in the D-in-D analysis, 2 although the graphs, I think, look pretty good. 3 4 And I just think you guys had to do the analysis, but I would, rather than emphasize it, I would both in 5 terms of the language and in terms of where it's placed, 6 maybe not with the last sentence in the chapter, you know, 7 summarizing the results, I think it would be a disservice 8 9 to the country not to have these results taken too 10 seriously, honestly. 11 MS. KELLEY: David. 12 DR. GRABOWSKI: Great. Thanks. Super work, and 13 Larry just stole my parallel trends comment, so thanks, 14 Larry. 15 [Laughter.] 16 DR. GRABOWSKI: I'm still going to make it. You 17 were looking at my notes. I saw that. I can't read them, 18 but if you can, that's great. 19 DR. CHERNEW: The last meeting. 20 DR. GRABOWSKI: The last meeting. Things are 21 loose here, Mike. 22 Overall, similar to Larry, I'm very supportive of

telehealth. It's interesting. I don't know, Dana, if you 1 remember this, but in one of our early years there was a 2 congressionally mandated report on telehealth. Maybe it 3 4 was our first year. And the Commission kind of concluded 5 this was generally of low value, there was real concern about the floodgates opening, and I think we were very 6 cautious in that chapter. And it's interesting to think 7 about it here. We did see this big spike but things, as 8 9 Jaewon and others have noted, really came down during the 10 pandemic. And I don't know if that's what I would have 11 predicted, but there's something very interesting about 12 that, and we've seen that across the board.

13 We've been doing research on telehealth in nursing homes, in particular, and the same sorts of trends. 14 15 You have some facilities that are back to almost zero and 16 some that are using it at a reasonable level but not nearly 17 what they were using it at the peak. I find that super 18 interesting, just given, I think, what my prior would have 19 been, that you put forth this waiver we're going to see a 20 real increase in use.

21 Similar to other Commissioners, and folks have 22 said this really well, I would really pump the brakes on

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1 the language in the report, especially in the executive 2 summary. I think Jim has already fallen on that sword. So 3 I think tempering that language. And I appreciate what 4 Larry just said in terms of association.

5 DR. CASALINO: You can keep sticking the sword. 6 DR. GRABOWSKI: Sure. Sure. I'm happy to. I've 7 got to get my shots in this morning here. Last at-bats 8 here.

9 I think for several reasons. One thought I had, 10 I know you controlled for COVID, and lots of Commissioners 11 have already brought up confounders, but I wondered -- and 12 we've done this in some of our COVID-related work where we've separated out sort of the effect of the overall 13 14 pandemic from COVID by looking at markets with and without 15 outbreaks. Lynn mentioned rural versus urban, and there's just been different timing, and could you actually look at 16 17 an overall effect of the pandemic versus COVID. You may 18 not have the power to do that, but at least one way is to 19 control but do some conditional analyses could help tease 20 some of that out.

21 Final comment. I was going to make the parallel 22 trends comment. You wrote in Footnote 30, "The DID with

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the set of controls did pass some but not all of these parallel trends tests." I think if I went and presented this at Amol's group at Penn, I don't think they'd get past that point. Like he just doesn't have a good experiment. This is not valid. And I think that would be a bit of a showstopper.

Mike and I have a colleague. Her whole career is basically, David's been around this issue, and how do we design good DID studies.

10 So I once again want to double down on this idea 11 of being really cautious with how we present and interpret 12 these results. To Larry's point again, I just don't want 13 folks to take this and run with it. Thanks.

14 MS. KELLEY: Amol.

15 DR. NAVATHE: Thanks. I'm super appreciative of 16 this body of work, and overall I think, obviously, this 17 morning is sort of dedicated to emerging trends that are 18 even more and more important over time to behavioral 19 health, as Stacie pointed out, the intersection between 20 telehealth and behavioral health. So I think there are a 21 number of dimensions here, and there is a lot of work that 22 we've done prior to the work specifically for this session

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1 also that is captured in the report, which I think is very 2 valuable.

And I would say that the descriptions that have 3 4 been done around the trends in use but also how those 5 trends tend to vary by different populations, by disability, by dual eligibility, by essentially safety net 6 populations and the like, I think this is really 7 8 fundamentally important work as we try to understand what's 9 happening for Medicare beneficiaries in terms of access and 10 how they utilize care, and as Robert and others have 11 pointed out, how they will prefer to utilize care in terms 12 of patient experience and consumer experience.

13 So I'm very supportive of this broad body of 14 work, and I think you should be commended for just the 15 volume of stuff that's been done here. And I hope we 16 continue to do more, given its growing importance.

I certainly appreciate the challenges, and I won't rehash many of the different suggestions that our colleagues have made today. I think looking forward a little bit, I don't know how David did it but he somehow looked at my notes and stole my comments. I don't know you did that, David. It's impressive.

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1 No, I think there is, as you pointed out, Ledia, there were some differences by geography. I think it would 2 be really interesting to dig into that, you know, 3 4 extrapolate by hour or sort of crosstab that with the 5 timing of the pandemic. I support the ideas that have been presented around different outcomes, not actually just in 6 7 the context of DID analysis but just more broadly speaking, 8 thinking about what are the different elements. You know, 9 Cheryl mentioned medication adherence, which may have been 10 potentially important. I think Robert mentioned patient 11 experience.

I think there is so much going on here, and I think the more that we can round out the kind of different contours of what's happening with telehealth, I think we'll make a better, more comprehensive contribution in that sense.

But taking a step back, I think this is super important work and I'm very supportive. And thank you for all the just amazing volume of work that you have done in the short period of time for this.

21 MS. KELLEY: Marge.

22 MS. GINSBURG: Fabulous report, and making great

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1 progress towards trying to unravel all this.

I have some frustration that I feel like we're closing the barn door after the horses have escaped, and that there is virtually, well, very little that MedPAC can do to stop the stampede.

I've been, I will admit, cynical I think is the
word, from day one, about telehealth, except for rural
areas, which I greatly support with some personal
experience. A close friend of mine benefitted fabulously,
who lives in a frontier area, who simply couldn't have
survived without it.

Having said that, at the end of the day I'm not sure what MedPAC is ever going to be able to do -- I'm speaking honestly -- to in any way restrain the things that really aren't working well. And I'm really talking financially, the impact this has on the cost of health care, to Medicare, to consumers. So it feels very frustrating in that way.

19 I think my only suggestion -- and I'm hearing a 20 lot of enthusiasm here, more enthusiasm for telehealth than 21 I sensed this group was when we started, so maybe I'm the 22 outlier, that I just haven't gotten with the program.

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1 Going to a doctor used to be kind of a big deal. I mean, it's not something you just did on a routine basis. 2 You had a particular need, you scheduled, you worked it 3 4 out, and you went. There are many people, on Medicare, obviously, for whom getting to the doctor is a problem, and 5 I can really see how the benefits of telehealth are 6 tremendous. And there are many that, in fact, don't really 7 8 need it but are using it because it's available. And I 9 don't know where we look at drawing the line, but my 10 primary concern isn't for the benefit of individual 11 patients. It's the cost impact.

12 My last really, maybe my only, suggestion is not a focus group but a deliberative discussion with the public 13 14 where they can actually start weighing the pros and cons of 15 telehealth and how it applies to the Medicare program. 16 Again, not a focus group but asking people to comment, to talk about are we, as a society, getting our money's worth? 17 18 Is this really going to be important going forward, and to 19 what extent? What limitations should we be putting on the 20 use of telehealth so it doesn't become just one more item 21 that causes the Medicare budget to change.

22 So that's all. Thank you. Great work, and I

1 know all of you will be doing great work in the future on
2 this as well. Thanks.

3 MS. KELLEY: Scott.

4 DR. SARRAN: In the interest of time just two brief comments. First, just taking off from Marge's 5 comment, I think, yeah, the horse is out of the barn, as 6 well as it should be, right, because there is no question 7 8 that for some beneficiaries telehealth services are very 9 clinically meaningful and valuable, and that almost doesn't 10 need to be proven. I mean, we all know that. I think we 11 can ask beneficiaries across a wide enough subset, a wide 12 group of beneficiaries, and there definitely will be some for whom it's clinically valuable. And for many 13 14 beneficiaries it is more convenient and we should respect 15 that as adding value as well to the Medicare program.

So I agree with Marge. I think our biggest task, or CMS's biggest task, and I think we can be most helpful to CMS in terms of refining how to most appropriately pay for telehealth services, inclusive of issues around program integrity. So I think when we think about new analyses, I think to the extent that we can really add new knowledge in those areas we will be most helpful to CMS as they

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1 deliberate.

And then I can't help but, and by reinforcing 2 Larry's point about impact of many new things going on now 3 4 in primary care telehealth, only companies, patient portal, and the change in workload and workday for primary care 5 physicians. And it's just, I think, so overwhelmingly 6 clear that successful primary care is going to be a team 7 8 sport. It has to be the team sport within which primary 9 care physicians are not compensated primarily on fee-for-10 service productivity measures. However, the practice 11 itself, or the parent organization, receives most of its 12 revenue.

13 And so again, to the extent that we can keep 14 highlighting the need to transition nationally to a set of 15 primary care practices that really add value, but again are 16 not dependent on a solo or a very small group of physicians 17 acting in isolation from other providers, and move away, in 18 primary care, from compensation dependent on fee-forservice productivity, we will be aligning with the future. 19 20 MS. KELLEY: Dana.

21 DR. GELB SAFRAN: Thank you. I know we're 22 getting close on time so I'll be as brief as I can.

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First, I would just say that this work is so important for so many reasons, but including, for David and me, in the six years we've been here there has been no bigger transformation of health care, particularly in terms of the beneficiary experience, than this one.

And I can recall when I was doing the work on 6 payment model design, one of my colleagues who was in 7 8 practice saying it was a way to "get rid of the tyranny of 9 the office visit." And I always loved that phrase and what 10 it connoted about kind of what Larry said, the value that 11 he thought he could provide if he didn't have to be 12 bringing patients into the office, and what I've referred to as "building-centered care." 13

14 So I think it's such an exciting development, and 15 we've grappled in the past several years of how do we not 16 have it break the bank once we go back to in-person visits. 17 And I think our answer has been, and continues to be, that 18 it makes the most sense in MA, in ACO or other global budget models, and I continue to wonder if there are ways 19 20 that we could create some policy recommendations that limit 21 it in that way.

22

And I do wonder whether that would give us a

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strong market signal about how much beneficiaries do value it, because might they really prioritize finding their way into systems that can enable those visits if that was the only way.

5 I'll just say two other things about the modeling of quality, as you might expect I would. I agree with all 6 the comments that have been made. I just want to point 7 8 back to Amol's question in Round 1. I think you want to 9 give some close attention to what were those controls and 10 what were the ones that made a difference, and why did they 11 make such a difference. And I think that kind of can help 12 with some of the skepticism about what we're seeing in the results, just to better understand what the data are doing 13 14 and why they're doing it.

15 But I also want to say, and I know this point has 16 been made, but first of all just to commend you for 17 attempting this analysis on quality, because we do need 18 that information and we don't currently have it. And I 19 know you know the limitations of the two measures that 20 you've used. What we can love about them is their outcome 21 measures, to a point, intermediate outcomes anyway. 22 But what they miss is the fact that sometimes

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those outcomes could take longer to show up, and so we need 1 to know, in the more proximal way, what was the impact on 2 quality. And I think Lynn was pointing to some 3 4 opportunities there. And understanding the confounding of 5 the COVID period, but looking at preventive service delivery, including chronic care management services, you 6 know, the hemoglobin, A1Cs that Lynn mentioned, and so 7 8 forth. I think we need that to balance this other view, 9 and we will need patient care experiences.

10 So I guess the final thing I would say is within 11 whatever recommendations we're going to make about post-PHE 12 allowances for this to continue, it has to be done in a way that we really rigorously plan for, the ways that we will 13 14 measure its impact on quality and access and cost, 15 including patient experience, but not limited to that. And 16 that does have implications, for example, in MA, around 17 data and, you know, claims capture, and all the things 18 we've talked about in other meetings.

19 So those are my thoughts. This is very exciting, 20 and as Marge said, the horse is out of the barn. This is 21 here to stay, but I don't regret that. I think it is a 22 really important development for care, but has to be used

1 properly. Yeah, thanks.

DR. CHERNEW: So we're three minutes into our 2 We have a very important topic next, behavioral 3 break. 4 health. We have two more people that want to say 5 something, Cheryl and Robert. What I think we should do is if you need to get up and take a break, now is your time to 6 get up and take a break. Cheryl, if you can be quick, and 7 8 Robert, if you can be quick, you can get your comments out 9 and you're going to then, just to make sure everyone 10 understood, this is actually your time to get up if you 11 want to take a break, because we are going to start as close as we can to time for the behavioral health session. 12 13 DR. DAMBERG: Okay. This is super quick. To the 14 direct-to-consumer vendors and the ability to track them, I 15 think there's potentially an opportunity in the CMS PECOS 16 datasets in terms of designating type of provider. So you 17 may think about building in some type of recommendation about an action CMS could take around sort of refinement of 18 data collection in terms of the type of provider needed. 19 20 MS. TABOR: I'll just respond to that quickly. 21 The OIG did also put out some recommendations, some actual 22 recommendations to CMS about how they can collect this

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1 information, so we can reference that in the paper.

2 DR. CHERRY: And briefly, I just wanted to 3 underscore Larry's comments from earlier. The ability of 4 patients now to go into the electronic medical record and 5 direct message their physicians is pretty significant. 6 What's happening is that sometimes it's not one or two 7 simple questions. It has the feel of a telehealth visit.

8 I don't know if there's any way of objectively 9 studying that, but there may need to be some sort of 10 qualitative assessment and what are the appropriate 11 parameters to put around patients that engage in sort of 12 that channel of interacting with their physicians, and 13 what's appropriate and what's not. And it's across 14 multiple specialties, primary as well as other areas.

DR. CHERNEW: Okay, great. So again, wonderful job. Thank you all very much for doing this work. I think we had a very, very rich and somewhat longer than scheduled discussion.

We're going to just take a few minutes, two or three minutes to do our transition, so for those of you that stayed we'll just take a minute or two, and then we're going to come back, and my guess is we're going to start

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1 around 10:33, 10:34, something like that, when people start
2 to get back.

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3 [Recess.]
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DR. CHERNEW: Okay. Welcome back, everybody. We have another really, really important topic and a really challenging one, I think, both for the Medicare program and for the country overall, which is behavioral health. So we really are now going to hear a report on what for those at home need to understand is a spectacular chapter, pushing 10 pages -- spectacular in quality and quantity.

In any case, Betty, I think you're going to start.

DR. FOUT: Yes, thank you very much. Good morning.

This presentation will discuss behavioral health services in Medicare in response to a congressional request. A PDF of the slides is available in the Webinar's control panel on the right side of your screen.

19 In January 2022, the Chair of the Committee on 20 Ways and Means requested that the Commission conduct an 21 analysis of Medicare behavioral health services. We 22 presented last September and January on various components

1 of this request.

2	This combined chapter, which incorporates
3	feedback from prior meetings and includes analyses with
4	newly available data, was provided in your meeting
5	materials and will result in an informational chapter in
6	the June 2023 report to Congress.
7	The chapter is composed of the following
8	sections: Medicare's coverage of behavioral health
9	services, clinician and outpatient provision of Part B
10	behavioral health services, and trends and issues in the

11 provision of inpatient psychiatric care by inpatient 12 psychiatric facilities, or IPFs. As part of this last 13 topic, we apply and assess MedPAC's various payment

14 adequacy indicators, which are listed on the slide.

Per the congressional request, the use of behavioral health services by beneficiaries enrolled in Medicare Advantage are discussed throughout the paper, to the extent analyses were possible.

19 In today's presentation, I'll overview some of 20 the high-level findings on clinician and outpatient 21 provision of behavioral health services. These findings 22 were already covered in our January 2023 presentation, so

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today we will mainly focus on newly available data since 1 the last presentation on IPFs. This will include 2 information on IPF use, spending, and supply using 2021 3 4 data, characteristics of beneficiaries meeting the 190-day coverage limit in freestanding IPFs, and inconsistencies in 5 the reporting of IPF costs. Throughout the presentation, 6 we will highlight findings from interviews recently 7 conducted with IPFs. 8

9 Additional analyses are described in your reading10 materials.

11 To better understand the services IPFs provide, 12 how they vary by patient and facility characteristics, and 13 the challenges faced by IPFs, we needed more information 14 than available in administrative data.

15 In the fall, we contracted with L&M Policy 16 Research to conduct interviews with 10 IPFs. IPF 17 interviewees were selected for diversity in IPF type, 18 ownership, affiliation, teaching status, size, geography, 19 and all-inclusive rate designation. Interviews were conducted with the chief medical and the chief financial 20 21 officers or individuals in similar roles at the IPFs. Topics included patient mix, services provided, resource 22

1 intensity and its drivers, and reimbursement.

2 Findings from these interviews are discussed
3 throughout the presentation.

Now I'll highlight some the main findings of our
analyses on clinician and outpatient provision of
behavioral health services under Medicare. For more
detail, please refer to your meeting materials.

8 In 2021, 16 percent of Medicare beneficiaries 9 used behavioral health services covered under Part B. This 10 percentage has been steady over the last five years. These 11 beneficiaries are more vulnerable (such as more likely to 12 be low-income and disabled) and more costly than other 13 Medicare fee-for-service beneficiaries.

We found growth in the treatment of substance use disorders among fee-for-service beneficiaries, driven in recent years by growth in opioid use disorders.

The types of clinicians providing behavioral health services has shifted, most notably from psychiatrists to nurse practitioners in the last five years.

21 We found substantial use of tele-behavioral 22 health beginning with COVID-19 and growing even more in

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2021, even as overall telehealth decreased in 2021 compared
 to the prior year.

A limitation of our work that applies throughout the paper is that we rely upon claims (or encounter) data for our analyses. We used diagnosis, procedure, and other codes to identify services and beneficiaries. To the extent behavioral health services are under-coded or coded differently, our results would undercount utilization and spending.

Medicare beneficiaries experiencing an urgent, acute mental health, or substance use crisis may be treated in IPFs. These facilities can be stand-alone psychiatric hospitals (or what we call freestanding IPFs) or distinct part units of acute-care hospitals (or what we call hospital-based IPFs).

Medicare reimburses IPFs for the inpatient care they provide to fee for service beneficiaries through the IPF prospective payment system.

To determine the payment for an IPF stay, a baseper diem rate is set and updated annually.

21 The per diem base rate is then adjusted for 22 geographic, patient, and facility factors. Geographic

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factors include the wage index, cost-of-living adjustments 1 for Alaska and Hawaii, and rural location of the IPF. 2 Patient factors include age, principal diagnosis, presence 3 4 of certain comorbidities, use of electroconvulsive therapy, and length of stay (with the per diem for each additional 5 day decreasing for longer stays). Facility adjustors 6 7 include teaching status and the presence of an emergency 8 department.

9 The IPF PPS also has an outlier policy for stays 10 that have extraordinarily high costs.

In 2021, there were 1,480 IPFs in which a Medicare fee-for-service beneficiary had at least one stay. Nearly 160,000 beneficiaries had over 230,000 stays, and the Medicare program spent \$3 billion on these stays.

15 The volume of IPF services (and corresponding 16 Medicare program spending) decreased substantially in 2020 17 and 2021 compared to 2019. Part of this decrease is likely 18 related to COVID-19 and its subsequent changes to the 19 health care landscape, but to a lesser extent, there has 20 also been longstanding declines in IPF utilization. We 21 will discuss these changes in more detail later in this 22 presentation.

1 This chart depicts changes in the number of IPFs 2 serving Medicare fee-for-service beneficiaries by IPF type 3 and ownership.

As shown in the left-most bars, the most common type of IPFs are hospital-based nonprofit IPFs, though the number has been declining. They remain about 40 percent of the total.

8 In contrast, the number of freestanding for-9 profit IPFs are increasing and now represent about 20 10 percent of the total.

11 Freestanding government IPFs, shown in the right-12 most bars, were the predominant form of psychiatric 13 hospitals in the 1960s and '70s, but now are a small share 14 of the total (about 10 percent).

15 There was an overall decline in the number of 16 IPFs from 2017 to 2022 of about 2 percent. However, 17 because freestanding IPFs tend to be large, the overall 18 number of inpatient psychiatric beds actually slightly 19 increased over the same time period.

Although the number of IPF beds has been stable in recent years and the overall utilization has declined, there have been reports of shortages in wait lists for IPF

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bed across the country, which have been exacerbated by 1 COVID-19. The shaded region of this chart shows that the 2 range of occupancy rates across IPFs was wide, from 40 to 3 4 90 percent for the 10th and 90th percentiles in 2021. The aggregate occupancy rate shown on the black dotted line has 5 decreased over time, indicating some capacity available. 6 7 This rate was 70 percent in 2021. In contrast, it was 65 8 percent at short-term acute-care hospitals.

9 The red line shows that the occupancy rate was 10 higher among freestanding government IPFs. These IPFs 11 frequently function as provides of the last resort, serving 12 patients with severe mental illness who are difficult to place in other facilities. The higher occupancy rate for 13 14 these hospitals suggests that access to inpatient 15 psychiatric services for some of the sickest beneficiaries 16 may be inadequate in some areas.

Occupancy rates based on Medicare cost reports may not account for beds that are temporarily unavailable due to staffing shortages or the need to convert semiprivate rooms to private rooms to isolate a psychiatric patient for COVID-19 or other reasons. Almost all of the IPF interviewees noted difficulty in staffing all licensed

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1 beds. Those occupancy rates, as noted in cost reports, are 2 likely underestimated. As one IPF administrator put it, 3 "We have the space. We don't have the staff."

Medicare patients admitted to an IPF are among the most vulnerable and costly. In these charts, the top blue bars represent Medicare fee-for-service beneficiaries with at least one IPF stay in the year. The bottom pink bars represent all other Medicare fee-for-service beneficiaries.

10 The top bars on the chart on the left show that 11 beneficiaries with IPF stays are much more likely to be 12 low-income compared to other beneficiaries. They are also 13 more likely to be disabled, as shown in the bottom bars.

On the right, we show that per capita Medicare Part A and B spending for beneficiaries with IPF stays were over four times higher than all other beneficiaries. Per capita Medicare Part D prescription drug spending for these beneficiaries was also higher than for other fee-forservice beneficiaries.

In addition, beneficiaries with an IPF stay were more likely to be younger, Black, and have higher risk scores compared to other fee-for-service beneficiaries.

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1 The characteristics of Medicare fee-for-service beneficiaries using IPFs differed by the type of IPF. 2 3 Hospital-based IPF patients tend to be older, have higher 4 risk scores, and be more likely to have dementia and other 5 chronic conditions compared to those at freestanding IPFs. This chart shows that the prevalence of certain chronic 6 conditions were higher among beneficiaries having an IPF 7 8 stay at a hospital-based nonprofit IPF, the left gray bars, 9 compared to those having stays at freestanding for-profit 10 IPFs, the right pink bars. Together these IPF types 11 account for 70 percent of fee-for-service beneficiaries 12 using an IPF.

13 The differences in patient characteristics can 14 have implications for Medicare beneficiaries needing IPF 15 services, especially as hospital-based IPFs decline and 16 freestanding for-profit IPFs grow. IPF interviewees 17 indicated that free standing IPFs tended to have more restrictive admission criteria related to patients' medical 18 19 stability or complexity compared to hospital-based IPFs. 20 But patients admitted to freestanding IPFs with medical 21 comorbidities generally had conditions that were well 22 controlled or stable and were less likely to need

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1 specialized medical equipment.

Medicare beneficiaries appear to be a declining share of total IPF patients. The percentages on this chart represent Medicare's share of IPFs' total days for each type of IPF. The gray bars represent Medicare shares in 2017, and the blue bars represent Medicare shares in 2021. Medicare here includes both fee-for-service and Medicare Advantage enrollees.

9 In 2017, as shown in the left-most bars, 35 10 percent of all IPF days at hospital-based nonprofit IPFs 11 were for Medicare beneficiaries. This fell to 31 percent 12 in 2021. The remainder of IPF days were for individuals covered by Medicaid, commercial, or other payers, including 13 14 self-pay. Medicare's share of days varied by IPF type but 15 declined across all types between 2017 and 2021. The share 16 of Medicare-covered days dropped particularly steeply among 17 freestanding for-profit IPFs, from 23 percent to 15 18 percent.

19 IPF interviewees also frequently noted that 20 Medicare patients were a small share of their patient 21 census. Moreover, most IPFs we interviewed had dedicated 22 geriatric units that composed only a subset of beds within

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1 the IPF. Although Medicare beneficiaries may use beds in other units, depending on patients' medical needs and 2 functional health status, older age was frequently a 3 4 limiting factor in admitting patients. Thus, not all beds 5 in IPFs may be available to over-65 Medicare beneficiaries. Interviewees noted that geriatric patients generally 6 require additional staffing to treat medical comorbidities, 7 8 cognitive decline, mitigate fall risk, and assist in 9 activities of daily living.

10 Lastly, a few interviewees noted that some
11 Medicare Advantage plans would deny longer lengths of stay
12 and reviews were difficult to overturn.

13 IPF use by fee-for-service beneficiaries has 14 declined over time, but the decline was particularly steep between 2019 and 2021. Avoidance or deferral of inpatient 15 16 stays in response to the spread of COVID-19 likely played 17 an outsized role in this decline, but while acute-care 18 hospitalizations rebounded somewhat in 2021, IPF stays continued to steeply decline. This may reflect shortages 19 20 of staff limiting capacity as well as the common use of 21 semi-private rooms in IPFs, requiring one bed to be taken 22 offline to accommodate patients needing a single room.

1 We found that average lengths of stay have increased over time, by 4.6 percent between 2019 and 2021 2 (and Medicare payment per stay also increased). Decreasing 3 4 overall utilization and increasing length of stay indicate potential changes to the mix of Medicare beneficiaries who 5 are using psychiatric hospitals. Several interviewees 6 noted general increases in patients' aggression and 7 8 severity over time. Almost all interviewees emphasized 9 increased challenges with identifying safe and supportive 10 discharge options for patients, resulting in prolonged 11 lengths of stay.

12 Under Medicare, coverage of treatment in 13 freestanding psychiatric hospitals is subject to a lifetime 14 limit of 190 days, after which beneficiaries are 15 responsible for all costs.

16 This provision was established in 1965 (with the 17 implementation of Medicare) when the majority of inpatient 18 psychiatric care was provided by government freestanding 19 facilities.

The 190-day limit does not apply to hospitalbased units, which now compose 60 percent of IPF stays, and may therefore affect the type of facilities from which some

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1 beneficiaries seek care and possibly disrupt patient care 2 when beneficiaries reach the limit during a stay.

For the cohort of beneficiaries with Medicare in 3 4 2021, we examined admissions to IPFs from the time of their initial date of Medicare enrollment through January 2023 5 and found that nearly 850,000 of these beneficiaries had 6 used at least one day in a freestanding IPF, nearly 40,000 7 8 had exhausted all 190 days, and over 10,000 beneficiaries 9 were within 15 days of reaching the limit. These numbers 10 include both fee-for-service and Medicare Advantage 11 enrollees. However, we were unable to determine the type 12 of coverage the beneficiary had when the 190 days were 13 exhausted.

14 Beneficiaries at or near the 190-day coverage 15 limit in freestanding IPFs were a high-risk group. Their 16 characteristics are shown in bold on this table. We 17 compared them to other fee-for-service beneficiaries who 18 had an IPF stay in 2021 in the last column of this table. 19 The majority of beneficiaries near or reaching the limit 20 were disabled and low-income. They were younger, more 21 likely to be male, and Black and had higher risk scores 22 than other fee-for-service Medicare beneficiaries using

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1 IPFs.

2 While beneficiaries near or reaching the limit 3 spent more on Part D prescription drugs, Medicare Part A 4 and B spending appeared to be lower.

5 The lower Part A and B spending may be due to 6 reaching coverage limits such as the 190 days in 7 freestanding IPFs and the lifetime reserve days for 8 inpatient and skilled nursing home care. Medicaid may also 9 cover additional care for these beneficiaries that are not 10 captured in Medicare claims data.

11 Some IPF interviewees discussed the implications 12 of the 190-day limit. They noted that the limit can present significant issues for patients who have chronic 13 serious mental illness. Some of the interviewees reported 14 15 that after surpassing the 190-day limit, the IPFs provide 16 uncompensated care and help the patients obtain Medicaid 17 coverage. One noted that they try to get patients who meet 18 the 190-day limit into acute-care hospitals (or hospitalbased IPFs) so that they can have Medicare coverage. Most 19 20 IPFs considered the 190-day limit insufficient for patients 21 living with chronic mental illnesses.

22 We calculated Medicare margins for IPF services

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by comparing payments made under the IPF PPS to providers'
 costs for their Medicare fee-for-service patients.

Overall, IPFs' margins have decreased over time. In 2021, the aggregate Medicare margin among all nongovernment IPFs was negative 9.4 percent, down from negative 2.1 percent in 2017.

However, as shown in the chart on the right,
IPFs' Medicare margin varied widely across the type of
IPFs. In 2021, the aggregate Medicare margin among
freestanding for-profit IPFs was a positive 21.7 percent
(or the solid white line) compared with negative 34.8
percent among hospital-based nonprofit IPFs (or the bottom
red dotted line).

14 The high positive margin among freestanding for-15 profit IPFs was driven by low costs among these facilities. 16 However, understanding IPF costs (so that 17 payments can be made more accurate) is challenging due, in 18 part, to inconsistent reporting of ancillary services. IPFs' costs of caring for Medicare beneficiaries 19 20 generally consist of routine and ancillary costs. Daily 21 routine costs include costs for staffing and room and

22 board, which are typically provided to all patients and

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generally do not vary across patients within a facility.
 In contrast, cost for ancillary services (such as
 prescription drugs and laboratory services) can vary for
 each stay.

5 While almost all IPF patients should receive some 6 of the most common ancillary services, reporting of them 7 varies significantly. This chart shows the percent of IPF 8 stays for which prescription drug charges (shown in the 9 gray bars) or laboratory charges (shown in the blue bars) 10 were present on the claim.

Hospital-based IPFs reported providing
prescription drugs and laboratory services to nearly all
their patients.

This was not the case among freestanding IPFs,especially among freestanding for-profit IPFs.

16 IPF interviewees confirmed that almost all 17 patients receive some ancillary services, especially drug 18 and laboratory services, though they noted that ancillary 19 services were generally a small portion of overall costs. 20 While interviewees did internally track some ancillary 21 services, many did not perceive benefits in comprehensively 22 reporting ancillary services, nor any repercussions for not

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1 reporting them.

Overall, additional information is needed to
 improve payment accuracy.

4 First, the administrative data available does not appear to be sufficient to capture the variation in per 5 diem costs related to differences in patient severity. The 6 majority of IPF patients fall within the same diagnostic 7 8 group under the IPF payment system, demonstrating the 9 difficulty in using diagnosis codes to differentiate the 10 costs of IPF patients. Prior studies have found that 11 activities of daily living deficits, "serious danger to 12 self or others," and involuntary admission to be important cost drivers. IPF interviewees also noted that functional 13 impairment and history of aggressive behavior, among other 14 15 factors, affect nursing and staff time.

Second, we lack information on how staff spend their time providing IPF services, and as discussed earlier, information on ancillary services, which are supposed to be collected by most IPFs, but are not always well reported.

21 Quality of care is also difficult to assess with 22 the existing quality measures.

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1 The Medicare program currently has an IPF pay-2 for-reporting quality program that includes 14 measures, of 3 which the vast majority are process measures.

Providers report results in aggregate for each
IPF, meaning they report numerator and denominator values
based on their own administrative and clinical data.

As IPFs begin to report patient-level quality results beginning this year, CMS and others will be able to better assess the quality of care provided by IPFs.

10 The program does include one claims-based outcome 11 measure, 30-day all-cause unplanned readmission following 12 psychiatric hospitalization, which measures the impact an 13 IPF has on care during the stay and at discharge to prevent 14 patients from returning to the hospital. The national mean 15 for the measure was about 20 percent.

Fortunately, additional data collections are planned. The Consolidated Appropriations Act of 2023 requires CMS to begin collection of IPFs' resource use, behavioral monitoring, and other use of interventions through cost reports, claims data, or other sources later this year. The legislation also mandates the development of a patient assessment tool that would collect information

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on patients' functional status, cognitive status,
 comorbidities, and other patient characteristics. Data
 collection using this tool will begin in 2028.

In addition, required reporting of patient-level quality measure results started this year, and CMS is planning additional development of quality measures tied to clinical outcomes and patient experience surveys.

8 For discussion today, we would like the 9 Commissioners to comment on whether there is any additional 10 guidance for us to consider in putting together this 11 chapter for our June 2023 report to the Congress.

12 After the report, we plan to continue to assess and monitor important issues uncovered by these analyses. 13 14 This includes tracking who reached the 190-day lifetime 15 limit on freestanding IPF care and future analyses on the 16 types of care patients receive after reaching this limit. 17 We will continue to monitor refinements to the IPF payment 18 system based on the additional data collections. It will 19 also be important to continue to monitor patterns in tele-20 behavioral health provision.

21 And now I hand it back to Mike.

22 DR. CHERNEW: Great. So much information there.

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1 Thank you so much.

2 Dana, I think we should start with Round 1. MS. KELLEY: Yes. Larry, I believe, is first. 3 4 DR. CASALINO: Just one quick question. Could you show Slide 14 please? By the way, terrific report. 5 We're going to have to start calling you guys Tolstoy. 6 7 It's like War and Peace, a book nobody should die without 8 reading, actually. 9 [Laughter.] 10 DR. CASALINO: I'm talking about War and Peace, 11 not the report, but the report is very good. 12 So just a quick question. The beneficiaries who are nearing the 190 days, is that within the 2-year period 13 we looked at or is that beneficiaries that you looked at in 14 15 that year who had maybe been accumulating days toward the 16 190 before the 2-year period? 17 DR. FOUT: Yeah. It is historical. So it is as 18 of January 2023, the number of beneficiaries who were alive in 2021 and enrolled in Medicare, who reached the limit. 19 20 DR. CASALINO: But it could have gone back to --21 DR. FOUT: It could have gone back. 22 DR. CASALINO: -- to prior years.

1 DR. FOUT: Yeah.

DR. CASALINO: It wasn't just in those two years.
DR. FOUT: Right. Exactly.

4 DR. CASALINO: Okay. Thanks.

5 MS. KELLEY: Dana?

6 DR. GELB SAFRAN: Thanks. On Slide 15, please, I 7 just wondered, I thought it was interesting that total 8 Medicare Part A, Part B spending was lower among this 9 cohort that reached the limit, relative to others that had 10 an IPF stay. And I just wondered what insights you could 11 offer about that.

12 DR. FOUT: Yeah, we thought the same thing, and it could be related to reaching coverage limits. So one of 13 14 them is the 190 days in a psychiatric facility. And there 15 is also a lifetime limit on reserve days in the hospital 16 during a spell, that the beneficiaries disproportionally 17 reached that limit as well. And a lot of them are on 18 Medicaid, and we don't see any coverage or any services 19 that Medicaid provided that was not covered under Medicare. 20 So they could have had more days in the IPF covered by 21 Medicaid.

22 DR. GELB SAFRAN: I see. Yeah. So their

utilization data is kind of censored to us. But in terms of the non-psychiatric care they're receiving, I'm showing my ignorance here about how things go between Medicare and Medicaid in those instances, we do know that, and you showed it in an earlier slide, patients who have psychiatric illnesses tend to spend more overall, right, on care.

8 DR. FOUT: Yes.

9 DR. GELB SAFRAN: And so that was part of my 10 question. So are you saying for their other medical care, 11 forgetting for a minute the censoring of the after 190 days 12 for psychiatric care, but for other medical care would that 13 be happening in Medicaid and that could explain it?

DR. FOUT: You mean, is Medicaid covering their -I mean, most of these patients are dual eligible, so covered under Medicaid. We have not looked deeply into the specific types of services that are composing this \$22,000. But we hypothesized that could be related to reaching coverage limits and Medicaid possibly covering things that Medicare was not covering.

21 DR. GELB SAFRAN: Thank you, Betty. And just a 22 small suggestion then. This is probably Round 2, but I'm

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going to slide it in there. I would add to this table dual 1 eligibility, because that will help explain what we're 2 looking at here, you know, a very high percentage in your 3 4 column there are going to be dual eligible, and presumably 5 almost none in --6 DR. FOUT: I mean, there are subsumed in that 7 low-income row, but they're a share of that. 8 DR. GELB SAFRAN: Yeah. And I think calling it 9 out --10 DR. FOUT: Sure. 11 DR. GELB SAFRAN: -- is going to help explain 12 these. 13 DR. FOUT: Yeah. 14 MS. KELLEY: Jonathan. 15 DR. JAFFERY: Yeah, so great work. My 16 undergraduate degree is in Russian literature, and I'm a 17 little thrown off by Larry's comment. 18 [Laughter.] 19 DR. JAFFERY: But my question actually, is there 20 some legislation or something put out around getting rid of 21 the 190-day limit that's pending? DR. FOUT: Yes. It's been in various bills. 22 Ι

1 think it was in the President's budget.

2 DR. JAFFERY: So it's a budget thing. Thanks. 3 DR. FOUT: Yeah, and it's been scored but it's 4 not --

5 DR. JAFFERY: Okay. So it's in the President's 6 budget, obviously very different from the legislation. 7 Okay, great. Thank you.

8 MS. KELLEY: Kenny.

9 MR. KAN: On pages 10 to 15 and probably for 10 future updates of this analysis -- by the way, before I 11 forget, great report, and it's really outstanding. It's 12 very insightful 103-page report.

So two points. Number one, on pages 10 to 15 --14 10, 11, 12, 13, and 15 -- would it be possible, if 15 bandwidth is possible on future updates to have a split 16 between to see how people's service compares to MA? That's 17 question one.

18 And then question two, I'll save question two for19 Round 2.

DR. FOUT: I'll just say, I'll should look more closely at that. There is a textbox with the Medicare Advantage enrollees compared to Medicare fee-for-service

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beneficiaries on their outpatient and ambulatory behavioral 1 2 health services. Let me just quickly tell you what page that is. On page 25, and that might be some of what you're 3 4 referring to. 5 MR. KAN: Okay. Thank you. MS. KELLEY: Wayne. 6 7 DR. RILEY: Yeah, Betty, Jamila, great work. 8 Incredibly important topic for Medicare beneficiaries and 9 also for the country, obviously, as we have so many 10 manifest mental health challenges that we almost hear about 11 daily, unfortunately. 12 Per the 1965 statute, what are the restrictions, 13 if any, to the 190-day inpatient limit? For example, there 14 are no limitations by disease category, I would assume, or, for example, substance abuse versus schizophrenia 15 16 admission, et cetera. Are you aware of any to her 17 restrictions within that 190? 18 DR. FOUT: No. Just freestanding, no matter the 19 diagnosis. That's right. 20 DR. RILEY: So there's no specific diagnosis-21 related restrictions. 22 MS. KELLEY: Lynn.

MS. BARR: Thank you. Great report. I really
 learned a lot from this and look forward to learning more.

I have a couple of question. One of them is 3 4 around drug therapy. So when I look at high-cost drugs in 5 our data there are a lot of drugs for schizophrenia that come up in our top spend in drugs. And I'm wondering, is 6 there a difference in the drugs that are given in IPFs 7 8 versus other sites of care? I mean, there are less-9 expensive drug alternatives that are arguably not as 10 effective but they are still a standard of care. And I was 11 just wondering, is there any stinting on the 12 pharmaceuticals that's happening in these freestanding? Is there any way to kind of tease that out of the Part D data? 13 14 DR. FOUT: These are great questions. Under the 15 IPF PPS any drugs given during your psychiatric stay should 16 be covered under that bundle, and so you technically should 17 have no Part D drugs during that time you're at the 18 hospital.

19 That said, some of our interviewees noted that 20 some drugs are quite expensive, the newer injectable drugs 21 for schizophrenia, and a lot of the IPFs do consider the 22 fact that the patients will have to get it themselves after

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1 they are out of the IPF, and so in that case they really do 2 think that long-acting injectables are good. But at the 3 same time they also have to be able to afford it afterwards 4 too.

5 MS. BARR: But they tend to have a higher 6 socioeconomic group, right, in the freestanding IPF? I'm 7 just really worried that there is a for-profit motive here, 8 and if we're not tracking drugs specifically, that could, 9 in a large part, explain the difference in profitability 10 between these two settings.

11 So is there any way in all of this reporting and 12 changing, are they going to be reporting what actual drugs 13 they're going to be giving?

DR. FOUT: They're supposed to report the amount of money spent on drugs. I mean, they wouldn't say exactly which drugs are provided. But that's already in a

17 requirement to report that.

18 MS. BARR: Got it.

DR. FOUT: But what we found is it's not well reported, just by the fact that it isn't a requirement. Maybe it is. We'll have to wait for it.

22 MS. BARR: At any rate, I would be very

interested in some policy that would allow us to maybe
 track that they're not making money based on stinting on
 best practices. Thank you.

4 MS. KELLEY: Amol.

DR. NAVATHE: Thanks for this great, very6 important body of work.

7 If you can go to Slide 12, I just had what may be 8 a quick question, or may just reflect my ignorance of 9 what's going on here. So the third bullet under IPF 10 Interviewees you note that some did not admit patients over 11 a certain age, as low as 55. And I was curious if you 12 could tell us a little bit more about that and what's 13 happening there.

14 DR. FOUT: Some of the IPFs we interviewed noted 15 that they had limits on the number of kind of geriatric 16 patients they would take, or almost all of them noted they 17 could only take patients with certain medical comorbidities 18 and certain stability comorbidities or who need certain 19 special equipment. And some of the IPFs also noted the 20 older beneficiaries tended to be the ones who had those 21 comorbidities and needed specialized equipment, and 22 sometimes they would just use age as the criteria. So over

a certain age they did not feel like they could adequately
 serve in their facility.

DR. TORAIN: In addition to that, we found in the 3 4 interviews that the term "geriatric" was sometimes used in 5 IPFs as to describe a very high resource-intense patient. Age was definitely a factor, but sometimes what they were 6 7 describing would be someone who is under 55, who was just 8 more resource intensive, versus if you were talk about any 9 other setting, geriatric is definitely relatedly mostly to 10 age and comorbidities.

DR. NAVATHE: I see. Okay. So the descriptions of the relationship between morbidity and complexity and age totally makes sense. I guess I was just thrown off that it seemed like there was literally an age cutoff here, and that seemed peculiar. It's not actually describing the setting of some complexity.

I don't know that there's more to say about that.
It was just somewhat kind of a surprising cutoff. Thanks.
MS. KELLEY: Scott.

20 DR. SARRAN: Just a quick question. Long-acting 21 injectable antipsychotics administered in an ambulatory 22 setting, Part B or D?

1	DR. FOUT: Part B.
2	DR. SARRAN: Okay.
3	DR. CHERNEW: That's the kind of Round 1
4	question.
5	[Laughter.]
6	DR. CHERNEW: Just so you know, the poster child.
7	We need that in training materials. Yours was fine, but,
8	you know, that was here's the question, here's the answer,
9	very clarifying.
10	I think that was the end of Round 1.
11	MS. KELLEY: I believe so.
12	DR. CHERNEW: So can we start with Kenny for
13	Round 2, and then we'll go through the Round 2 queue?
14	MR. KAN: Yes. On Slide 16, you noted that the
15	for-profit freestandings have a 21.7 percent margin, and
16	you also noted that especially for this for-profit
17	freestanding they also have lower costs. Do you think
18	that's the primary driver of that margin? I was curious if
19	you have any insights or color on to what extent maybe risk
20	selection or practices at those for-profit freestanding
21	could be driving some of the high level of margins?
22	DR. FOUT: Certainly, on a mathematical

1 calculation basis the higher margins for the freestanding, 2 for-profit IPFs are because of lower costs. What causes 3 the lower costs is a great question. I mean, part of it is they're larger, so they have more efficiencies or spread 4 out across a greater number of beds and patients. We did 5 find from the interviews they tended to have more 6 7 restrictive admission criteria. That could also play a 8 role.

9 MS. KELLEY: Stacie.

DR. DUSETZINA: Thank you. Thank you for the excellent work here. It was really a pleasure to read this chapter, but also somewhat horrifying in some of the context because you did such a nice job of laying out the history and how things have changed about coverage for people with severe mental illness. So I appreciate the incredible amount of work here.

I did want to, like others have brought up, mention the 190-day lifetime limits and how the work in the chapter was just excellent for pointing out the problems with those limits. So it's good to hear that at least it's being mentioned in the budget. It would be nice to hear it being mentioned more in other bills, because I think you're

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finding that the people who are most likely to hit the limit were those who were younger, disabled, had schizophrenia, and were largely Black and male suggests that this is really an area where we could do much, much better. These are people who will need a lot of support, and the fact that this hasn't been updated since 1965, is really problematic.

8 So I think, to me, it's like just a slam dunk. 9 Someone needs to really focus on this and pay attention to 10 this because it's such a travesty for those patients.

11 One of the things I also was glad to hear you 12 point out is the new quality and cost measures that will be 13 going into place. These are absolutely needed and it will 14 be helpful to see those as they start to get implemented 15 and move forward.

Only just one minor suggestion for the chapter, and this is just a language-related issue. And mostly I didn't see this but occasionally there were places where there was language around difficult-to-treat or difficultto-place. And most of the language throughout the chapter was very sensitive to it, but I'd say just re-searching for that and making sure it doesn't sort of imply that the

1 patient is difficult to treat or the patient is difficult 2 to place, that it is the patient with an illness that is 3 difficult to treat, just around that tone.

4 But again, really excellent work.

MS. KELLEY: Jonathan.

5

DR. JAFFERY: Thanks, Dana. Yeah, so once again 6 7 Thanks so much. I'm just thrilled that this is fabulous. the Commission is putting more focus on behavioral health. 8 9 And I echo some of Stacie's comments, but really I wanted 10 to just put in a plug for as we continue to think about 11 this that we also think about substance use disorder sort 12 of in a parallel way. You talked about the opioid use, and 13 Robert spoke eloquently about this a couple of meetings 14 There are a lot of dual diagnoses, beneficiaries and aqo. 15 just individuals in the country, and that plays such an 16 important factor in how people can get care and what the outcomes are that goes beyond just whether they have a 17 substance use disorder or a behavioral health disease. So 18 19 I just wanted to make sure we capture that as we go forward 20 with this work.

21 But I'm thrilled about this chapter and the work 22 you've done so far.

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1 DR. FOUT: As was mentioned, we did add a table 2 on dual diagnosis and how they are more costly. DR. JAFFERY: Oh, great. Great. 3 4 DR. FOUT: In the 100 pages. 5 DR. JAFFERY: Right. And there's probably a whole bunch of work that can build on that beyond the costs 6 7 and whatnot. 8 MS. KELLEY: Cheryl. 9 DR. DAMBERG: Thank you. This was an amazing 10 chapter. I learned a lot, and there's a lot in here to try 11 to unpack. 12 One of the things that I noted was I think as I headed towards the tail end of the report it seemed like 13 there were some observations and recommendations that I 14 15 think were buried in the back of the chapter that would be 16 helpful to bring forward, you know, in terms of telling the 17 story. One of those areas is around the challenges of 18 obtaining appropriate follow-up care, which I think is 19 really sort of a critical issue in this space. So if we 20 could try to go back and take a look at the chapter and see 21 what you could bring forward to spotlight some of those 22 challenges.

1 The other thing that I noted, you know, it's interesting to see the fraction of providers who were only 2 providing telehealth care now and have gotten rid of their 3 4 office practices. And I think now that there's a provision 5 for patients to be seen, you know, within six months, it would be interesting over time to track whether some of 6 those providers decide to just drop out of Medicare. I'm 7 8 not sure if, on the commercial side, there are similar 9 provisions, but it would be interesting to see whether that 10 creates another barrier for them to practice.

11 The other thing that I wasn't totally clear on, 12 and I don't know if this is a Round 1 question but it's maybe a Round 2 comment, is at what I hear in talking to 13 14 colleagues of mine who are physicians is that a lot of 15 behavioral health is provided by primary care physicians. 16 And so I wasn't exactly sure what's the storyline in this 17 chapter related to sort of primary care providers 18 delivering behavioral health versus specialists in this 19 space. And maybe that's kind of a future looking area of 20 exploration or describing.

21 DR. FOUT: We have a section. I think it's in 22 the outpatient and clinician-provided care, where we show

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those trends that you're talking about, that there is a 1 decrease in traditional behavioral health providers 2 providing behavioral health and an increase in nurse 3 4 practitioners, but also other types of primary care. And, 5 I mean, there is literature on that, and we reviewed a little bit of the literature there, and it's definitely an 6 area to keep monitoring because the trends are moving. 7 8 DR. DAMBERG: Great. Maybe it was this Tolstoy 9 effect.

10 [Laughter.]

DR. DAMBERG: Yeah. And then the other thing that I was scratching my head on, and I found kind of curious that 30 percent of beneficiaries who use behavioral health services received only one behavioral health visit. And I wasn't exactly sure what was going on in that space. MS. KELLEY: Betty.

DR. RAMBUR: Thank you. Fabulous work and great comments from the Commissioners. I have just a couple of things that I'd like to point out.

I'm curious about the statement of "have space but not staff," and I assume that means registered nursing staff as well as others. And I'm really curious, and I

don't know and I haven't seen, and I don't know if you can 1 easily find, is that staffing situation more dire than 2 other settings of inpatient hospitals or whatever? And 3 4 just to understand where I'm coming from, when a person graduates with a bachelor's degree in nursing they are a 5 generalist, and they can legally work in mental health, 6 med-surg, primary care, or whatever, and there is a lot of 7 8 interest in that space. So I'm really curious how all that 9 looks.

10 And then the nurse practitioner piece, just to 11 have on the record, that's an advanced practice degree 12 either at the master's or at the doctoral level, and certification in adult or child, and there is enormous 13 interest in that, including in people hiring nurse 14 15 practitioners in other areas. And the rate-limiting factor 16 is faculty and clinical placement sites, because the 17 clinical placement sites are under so much duress that they 18 can't take more students. So that goes back to the 19 workforce piece, how we kind of cannibalize ourselves. 20 And then I know I'm a broken record on this, but 21 the piece about NP and physician psychiatrists here, again

22 it's masked by the "incident to" billing, I assume. We

1 don't know how much "incident to" billing happens there. I
2 assume some. I know MedPAC has made a recommendation in
3 the past, and I just wanted to point that out as well. It
4 may be even higher than we can see.

But thank you so much for this great work.
MS. KELLEY: Robert.

DR. CHERRY: Thank you. This is really terrific
work. I really appreciate the detail and the analytical
work.

I'll start off with talking about some of the quality challenges and opportunities. I am encouraged, though, that CMS is actually looking at this and they're talking about rolling out additional measures in improving depression as well as all-cause 30-day mortality, so that's encouraging, although I do think they could be moving faster than just two measures.

17 A lot of the current measures are really process 18 measures. I think other opportunities include ED visits, 19 discharge to home as opposed to, let's say, a residential 20 treatment facility or a partial hospitalization program. 21 Because there are a number of patients that do 22 have significant medical comorbidities, I think looking at

1 timeliness of primary care visits and follow-up after 2 discharge could be an opportunity for a quality 3 measurement.

4 Functional status is also important. So take, for example, in child psychiatry, school attendance after 5 discharge. Now some of that may require longitudinal 6 follow-up, but there is precedent for it in vascular 7 8 surgery, transplant surgery, bariatrics, where they follow 9 those patients one, two, three years out and are expected 10 to keep data. Now it is more challenging in this patient 11 population but it doesn't mean that we shouldn't attempt to 12 look at functional parameters as well.

13 Readmissions, although it's included in the 14 quality measures it probably should be broken out by a few 15 categories of concern. You know, that could be around 16 addiction medicine, for example, eating disorders, and 17 autism. The same way we break out readmissions along COPD 18 and heart failure, and MI on the acute care side, in terms of behavioral health they should probably also be broken 19 20 out around high-impact diseases as well.

21 In addition, there is no real CMI -- I mentioned 22 this before -- in psychiatry, so it does represent an

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opportunity above and beyond the DRG model, to look at a risk-adjusted model that can be embraced by psychiatric facilities in terms of being able to compare risk adjustments between them.

5 Getting away from sort of quality for a moment, 6 many of the Commissioners have already mentioned the 190-7 day rule being problematic. So we'll have to see how this 8 legislation rolls out over the course of the calendar year. 9 But depending on whether that is successful or not, there 10 are certain things to consider in terms of exceptions to 11 that rule as sort of a middle ground.

12 A lot of patients, I think, are having long stays 13 like that is because of difficulties with the discharge 14 process, conservatorship being one of them, going through 15 the court system, trying to obtain those issues. 16 Homelessness is another challenge as well. And also those 17 that need other resources like residential treatment

18 centers or partial hospitalization programs. Basically the 19 psychiatry post-acute care space can also be bottlenecks to 20 the discharge process. So hopefully maybe if that doesn't 21 pass, we can propose some reasonable exceptions to the 190-22 days rule.

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1 The other thing, and I've mentioned this before, it would be great to look at sort of the ecosystem within 2 behavioral health as a whole. And this may require 3 4 breaking out the report into its different components. I'm 5 not sure because there is a lot of inpatient focus here, but we also need to look at the outpatient environment as 6 well in terms of the clinic and physician offices, but also 7 8 residential treatment centers, partial hospitalization 9 programs, as well as crisis mobile units as well that can 10 respond to the scene of an acute mental health crisis. So 11 maybe that's a separate report.

12 The same with regard to staffing, both the 13 inpatient and outpatient side, because there is going to be 14 probably a need for additional clinical social workers, 15 clinical psychologists, nurse practitioners trained in 16 mental health as well. So it would be helpful to 17 understand the workforce in this area.

18 The other thing that you mentioned was the fact 19 that are utilization review challenges within the MA 20 population. I think another challenge also, particularly 21 since a lot of behavioral health patients do have 22 significant medical comorbidities is transfer out to

1 another facilities when those comorbidities become

2 exacerbated during the course of their inpatient

3 psychiatric hospitalization. And so the timely transfer of 4 patients in acute care facilities is also something to look 5 at as well.

6 But overall this is a great report. I think 7 there's still a lot to unpack because it's just a space 8 that many of us are concerned with because the behavioral 9 health crisis in this country, we are going to have to 10 figure out how to resource it in a fiscally responsible 11 way, and to make sure that people are kept whole. So thank 12 you.

13 MS. KELLEY: Larry.

14 DR. CASALINO: I've got a couple of questions and 15 a fairly brief comment.

Do people who get to the 190-day limit, do you have a sense of how difficult it is then if they need further care for them to be admitted to a hospital-based facility, where there is no limit?

20 DR. FOUT: Those are future analyses we need to 21 look at, is where they are going in the data. From the 22 interviews, which are only 10 IPFs, I think one of them did

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1 note trying to get them into a hospital-based facility.

DR. CASALINO: All right. And then a couple of 2 other comments. You mentioned in the chapter, I think 3 4 appropriately, and you said it actually briefly in your presentation, that probably a fair amount of mental health 5 care, not necessarily for the most seriously ill patients, 6 or behavioral health care is given in physician offices and 7 maybe not coded as behavioral health at all. I don't know 8 9 it well but I think there is literature on this, primarily 10 in primary care, where there are a lot of patients who get 11 seen for anxiety, depression, treated by their primary care 12 doc, but coded as just a regular office visit, and also coded with a diagnosis like fatigue or something like that, 13 14 because I think docs are still concerned about, rightly or 15 wrongly, possible insurance effects and things like that.

So my only suggestion there is just to say it more directly, and maybe cite a little bit of the literature to show the magnitude of this, which is probably very great. And I think this literature also has a component of these patients that probably have not that well treated, necessarily, depression or anxiety, generate a lot of medical costs through coming in with various

symptoms that result in imaging tests, and so on and so
 forth. And this can go on. There's a lot of this. I
 think every primary care physicians sees this.

4 So maybe just a little more direct allusion to 5 that.

The last thing I have to say -- oh, two other 6 7 things, briefly. One is it would be great to see some more 8 work, and maybe there's inadequate literature on this, I 9 don't know, but on the impact of the behavioral health 10 networks available through Medicare Advantage plans. One 11 of the most frustrating things to me when I was in 12 practice, dealing with Medicare Advantage, was that, you know, I had a network of behavioral health practitioners 13 14 that I liked and trusted and could have a pretty good bet 15 that when I saw the patient again, they wouldn't come back 16 to me and say, "Why did you refer me to that horrible 17 psychiatrist?" And often it took a lot of persuading to 18 get people to go, and I'd say I know Dr. So-and-So, she's really good, blah-blah-blah. And that could tip them over 19 20 into being willing to follow my advice to go.

21 But with MA, I basically had to say, I think you 22 really should see a whatever, and he'd call this 800

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number, and then it was just completely out of my hands. I couldn't select. I didn't know the people. And believe me, that did not work well, I don't think, for the patients. So more work on that would be interesting, if there's not already an adequate literature.

And the last thing is a very broad question, and 6 if you have something to say about it now that's great, but 7 8 if not, it might be worth thinking about some more in the 9 future. Is there anything Medicare can do, as opposed to 10 possibly other government agencies, but is there anything 11 that Medicare can do for patients post-discharge? Because 12 obviously that's a lot of the problem, right, that for seriously mentally ill patients that there's just not much 13 for them post-discharge. And I don't know if there is 14 anything Medicare can do about that or not. 15

But living in New York City, as I do, you can't really walk down the street without seeing several people who are probably schizophrenics, and it's awful. And every time you do it, it's bad for them but it also diminishes each one of us every time we walk past somebody like that. I think it's horrible to see. If there's anything Medicare can do in the post-discharge phase I think that would be

very helpful, not necessarily from a straight medical care
 point of view, but is there anything else Medicare can do.
 Off the top of my head I don't know anything, but it would
 be worth some thinking, I think.

5 MS. KELLEY: Lynn.

MS. BARR: Thank you. I'm still obsessing about 6 the drug issue. It's funny that you only heard this from 7 8 the IPFs. I mean, don't the other facilities also care 9 about post-discharge costs of drugs? I don't know why but 10 my private equity antenna is like quivering. And I was 11 wondering if in your analysis you could look at post-12 discharge, what drugs people are on versus the different 13 types of settings, because that will tell you what types of 14 drugs they were prescribed. And we might be able to tease 15 it out that way and see if there is a disparity there that 16 might need to be addressed. Thank you.

17 MS. KELLEY: Kenny.

MR. KAN: On page 26 of the 103-page report you noted that the gross Medicare Part D spend for MA beneficiaries is \$5,500, which is about 15 percent lower than the fee-for-service beneficiaries that use behavioral health of \$6,500. I was trying to think through that 15

1 percent lower cost. In context, and it was noted also in 2 the chapter, that behavioral health providers were found to 3 be among the least likely to be included in any MA network, 4 so there are a lot of out-of-network behavioral health 5 providers.

6 So I was just curious if you have any color on 7 what could be driving that cost differential. I mean, it's 8 also about both cohorts are approximately the same age. 9 Actually, MA is actually two years older, at age 70, versus 10 68 for fee-for-service. I was just curious if you have any 11 color on that.

12 DR. FOUT: I mean, I will say that when we looked 13 at the same analyses within the IPF patients, in which you 14 can compare a diagnosis -- and this is what you're talking 15 about. This is the outpatient and clinician analyses --16 but in IPF you can look at their IPF's reason for being 17 admitted into the IPF, there are differences in the 18 diagnoses within MA and fee-for-service, but not huge 19 differences. So I think that there are probably 20 differences in those populations that are not shown in just 21 looking at their demographics that could be driving that. 22 But then we did not look closely into what was driving

1 those two differences, and we could do more there.

2 MS. KELLEY: Scott.

3 DR. SARRAN: Just quickly building off of 4 Robert's, and your comments I thought were really eloquent 5 around the particular needs and challenges of the 6 population of beneficiaries who experienced repeated IPF 7 stays, and how anything other than a dedicated, specialized 8 model is going to continue to fail those beneficiaries. I 9 mean, they've been failed for the last 100 years.

10 So I think it really does cry out, and maybe 11 there is a way to tease this out in the report, for CMMI to 12 look at some work in this space, in a specialized ACO or 13 the really creative one would be an MMP, a dual program 14 focusing on this population with auto-enrollment. I mean, 15 that is probably what it would take to really move the 16 quality and outcome needle ahead dramatically, because 17 there's just nobody out there pulling these threads 18 together -- you know, housing, dual diagnosis, homelessness, I mean, everything. 19

20 MS. KELLEY: Dana.

21 DR. GELB SAFRAN: Thank you. Just a couple of 22 comments, and the first one prompted by something Larry

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pointed to around exploring symptoms. And it occurred to 1 me, and I know this is outside the scope of this chapter 2 and this timeline, but this issue that we referenced 3 4 earlier and that you showed in the slides and in the chapter of higher medical spending for beneficiaries who 5 have comorbid medical and behavioral health conditions is 6 very well documented, a kind of multiplier effect, in 7 8 commercial populations as well, but not very well 9 understood.

10 And what I heard Larry point to is a hypothesis 11 that I've had and never been able to really dig deep in the 12 data to see if it's supported, but I think if we could it would be really important to either demonstrates that's the 13 14 reason or that it's not, which is do patients who have a comorbid medical condition and behavioral health condition 15 16 present with a whole manner of symptoms that then are 17 really somaticizing around anxiety, depression, et cetera, 18 and getting referred out to this specialist and that 19 specialist, and this test and another test, and there 20 aren't good answers.

21 So I think you have the data that would enable 22 that kind of analysis, and I've seen this multiplier effect

documented again and again in every population, but never
clarity about what's underneath it. And if we could
understand what's underneath it, we might better understand
what we can do about it. So I just wanted to make that
point.

And then one other point, also probably beyond 6 the scope of what can be done here, but just last dibs, I 7 8 quess. You know, in some work that we're involved in right 9 now, in my organization, in talking with behavioral health 10 clinicians and primary care clinicians, what they say is 11 that a very large share of behavioral health conditions 12 could be cared for in primary care settings, with the right 13 kind of integrated behavioral health model into primary 14 care. And that's not a new observation, but the magnitude 15 of what they've said could be handled in primary care, and 16 therefore take pressure off an already strained situation 17 around access to specialist behavioral care is I think a 18 pretty interesting prospect.

So I just wanted to kind of leave that with you all as you're continuing to pursue this work and to really explore not only how that could improve access but how it could improve quality and reduce costs, because, you know,

reducing logistics and complexity for patients who are already seeing a primary care clinician, and right there in the office can also be seen by somebody who can handle the other things, and therefore free up capacity outside with a behavioral health expert is just something I haven't seen us talk about and think about, but I think it's a really important aspect of this.

- 8 So thanks.
- 9 MS. KELLEY: David.

10 DR. GRABOWSKI: Yeah, thanks. Let me just echo 11 everyone else. This is really great work. I just wanted 12 to make one quick point that's really triggered by something you wrote in the report, I guess it's page 66. 13 You discussed some of the interviewees who indicated that 14 15 referring organizations such as skilled nursing and 16 assisted living facilities do not want to readmit patients 17 who require a high level of care and supervision, and this 18 kind of interrelationship between these long-term care 19 settings and the psychiatric hospitals to me is really 20 important. We've seen increasing numbers of individuals 21 with serious mental illness in these settings, like 22 assisted living and nursing homes. I think often they

1 become the de facto settings, and it's really not

2 appropriate. I don't think they have the staff. To
3 Scott's point earlier, it's really a second-best solution.
4 And so yes, they are referring, yes, they don't want to
5 accept them back, but oftentimes they shouldn't have been
6 there in the first place.

And so how they fit in this kind of puzzle going
forward is really important for a lot of our beneficiaries.
Thanks.

10 MS. KELLEY: That's all I have. Did I miss 11 someone? I feel like you're telling me that I missed 12 someone.

13DR. CHERNEW: Greg sent a message, and I wasn't14sure if we were going to read it. I can't see Greg's face.15Okay. This is welcome to our virtual world.

So I'll make a general comment and then thank
everybody for all their work and stuff.

One of the things I think is a challenge across a lot of health care these days is that there is widespread patient heterogeneity, and certainly that is true in the behavioral health space. And that creates a complicated dilemma because some organizations can specialize in

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treating certain people in that space, which is a completely reasonable thing you might want them to do, but of course, that also may involve them picking patients that are profitable or siphoning patients away from the rest of the system, leaving a bunch of patients in the other parts of the system that aren't able to access the care that they need.

8 And in this particular space, getting access to 9 care for behavioral health problems is just a real problem, 10 in part because the behavioral health issues, I think, in 11 many ways, and has been mentioned, interact with a bunch of 12 other comorbidities and issues that make caring for these 13 beneficiaries just particularly challenging. You know, 14 we've tried to make the system work for everybody across 15 physical health, behavioral health, and we just really have 16 struggled for a long time in this space and we continue to 17 do so.

18 So I guess on that cheery note, for the 19 Commissioners and for the folks at home, we will continue 20 to look at this. I think that's sort of the theme here. I 21 am really glad that we did. There was a lot of information 22 here. I think there were a lot of engagements in this

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1 topic and a lot of concern about the populations and the 2 conditions discussed.

But for now I'm going to leave us with both a thank-you for all the Commissioners and the staff for their work this meeting and for their work this cycle. I personally think it's been really a productive cycle, and I'm quite happy with where we got on the things that we got to places on. We obviously have a lot more work to do in coming cycles.

And for the public we obviously would like your comments on all these topics, and so you can reach us at meetingcomments@medpac.gov, or go to the website and you can leave comments there.

But again, to the staff, really a genuine thankyou to everybody around the table for their comments. Thank you. And we will, I guess, see you all again at the strategic planning meeting in the summer, and we will be back in September with a new set of topics, some continued topics.

20 But anyway, thank you all.

21 [Whereupon, at 11:45 a.m., the meeting was 22 adjourned.]

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