

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

Via Go-To-Webinar

Monday, November 9, 2020  
10:47 a.m.

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P R O C E E D I N G S

[10:47 a.m.]

1  
2  
3 DR. CHERNEW: Hello, everybody, and welcome to  
4 our November MedPAC meeting. I think it's going to be a  
5 terrific set of sessions. There's been a lot of staff work  
6 done and a lot of back-and-forth reading the materials.  
7 We're looking forward now to having our general discussion.  
8 So with that, I'm going to turn this over, I believe, to  
9 Ariel, maybe Ledia.

10 MS. TABOR: Hi, this is Ledia.

11 DR. CHERNEW: Ledia.

12 MS. TABOR: Good morning. The audience can  
13 download a PDF version of these slides in the handout  
14 section of the control panel on the right hand of the  
15 screen.

16 We would like to thank Bhavya Sukhavasi, Rachel  
17 Burton, and David Glass for their input into this work.

18 During the COVID-19 public health emergency, CMS  
19 has temporarily expanded coverage of telehealth services,  
20 giving providers broad flexibility to furnish telehealth  
21 services to ensure that beneficiaries continue to have  
22 access to care and reduce the risk of exposure to COVID-19.

1           The PHE is currently expected to end mid-January  
2 2021, but it has already been extended several times.  
3 Without legislative action, the majority of these changes  
4 will expire at the end of the PHE. CMS made these changes  
5 quickly out of necessity. However, there is now time to  
6 more carefully consider whether these expansions should be  
7 made permanent after the PHE and, if so, which ones.

8           This presentation continues the Commission's  
9 September discussion and will be included in an upcoming  
10 report to the Congress.

11           We know from several sources that physicians and  
12 other providers have responded to the PHE and the  
13 telehealth expansions by rapidly adopting telehealth to  
14 provide continued access to medical care for their  
15 patients.

16           Even before the COVID-19 pandemic, there was  
17 growing interest in expanding Medicare telehealth coverage.  
18 Advocates assert that telehealth can expand access to care  
19 and reduce costs relative to in-person care.

20           However, others contend that telehealth services  
21 have the potential to increase use and spending under a  
22 fee-for-service payment system. Telehealth has recently

1 been implicated in several large fraud cases related to the  
2 ordering of durable medical equipment and cancer genetic  
3 tests.

4 Current evidence on how telehealth services  
5 impact quality of care is limited and mixed.

6 A key issue is how to achieve the benefits of  
7 telehealth while limiting the risks.

8 At the Commission's September 2020 meeting, we  
9 discussed granting clinicians who participate in advanced-  
10 alternative payment models, such as accountable care  
11 organizations that bear two-sided risk, more flexibility to  
12 bill for telehealth services than other clinicians in fee-  
13 for-service Medicare. As part of this discussion, many  
14 thought it would be beneficial to have a foundational  
15 discussion on telehealth expansion in the fee-for-service  
16 environment and associated guardrails. In future meetings,  
17 we may discuss how to structure additional telehealth  
18 flexibilities for clinicians in A-APMs.

19 Based on the Commission's previous discussions,  
20 we describe a policy option for expanding Medicare's  
21 coverage of telehealth services that would apply to all  
22 fee-for-service clinicians after the PHE. As context for

1 each part of the policy option, we present Medicare's  
2 telehealth policies for the physician fee schedule before  
3 the PHE and the telehealth expansions under the PHE.

4 I'm now going to begin describing the potential  
5 permanent policy options for telehealth expansion.

6 Starting on the left side of the screen, prior to  
7 the PHE, Medicare paid for telehealth services provided to  
8 beneficiaries who lived in rural areas and who received the  
9 service at certain facilities (known as "originating  
10 sites"). During the PHE, Medicare temporarily expanded  
11 payment for telehealth services provided to all Medicare  
12 beneficiaries, including telehealth visits to patients at  
13 home. Under the potential policy option for your  
14 discussion today, the PHE expansion would become permanent.

15 Moving to the right-hand side of the screen, in  
16 our focus groups in the summer of 2020, clinicians and  
17 beneficiaries were generally supportive of maintaining  
18 expanded access to telehealth services and agreed that a  
19 balance of in-person and telehealth visits would be ideal,  
20 depending on the patient's needs and health conditions.

21 In September, the Commission discussed potential  
22 benefits of using telehealth for follow-up visits with

1 patients with chronic conditions. Since about 70 percent  
2 of beneficiaries have at least one chronic condition, this  
3 would mean covering telehealth services for the majority of  
4 beneficiaries. It may be impractical to limit telehealth  
5 services to just these patients.

6           Because this option would allow all fee-for-  
7 service beneficiaries to receive certain telehealth  
8 services from their homes, companies that offer direct-to-  
9 consumer telehealth services for urgent care and behavioral  
10 health primarily to patients in their homes might be able  
11 to bill Medicare. Although these DTC services would  
12 potentially improve access to care, they have the potential  
13 to increase program spending. In addition, if  
14 beneficiaries receive DTC services from clinicians who are  
15 not their usual source of care, their care may become  
16 fragmented.

17           Prior to the PHE, CMS allowed clinicians to bill  
18 for about 100 services provided by telehealth to  
19 beneficiaries in rural areas. CMS has added over 140  
20 services to the list of telehealth services during the PHE.  
21 In the policy option for your discussion today, Medicare  
22 would continue to pay for many but not all of the expanded

1 services.

2 Consistent with our position in the 2018 report  
3 to the Congress, CMS could cover services provided by  
4 telehealth for which access is limited and that either  
5 improve or do not reduce quality of care. Examples of  
6 these include mental health services. Allowing telehealth  
7 mental health visits for all fee-for-service beneficiaries  
8 could ameliorate shortages of mental health providers.  
9 There is also evidence that telehealth may improve  
10 adherence to psychotherapy visits for some populations with  
11 diagnoses of mental disorders.

12 Medicare would not cover high-touch services  
13 where there are no major access concerns and/or there are  
14 quality concerns. For example, beneficiaries do not appear  
15 to have difficulty accessing physical and occupational  
16 therapy, and these are high-touch services that require a  
17 clinician to guide a patient through exercises. PT done  
18 virtually may also put beneficiaries at risk because if  
19 they fall during an exercise, the therapist is not  
20 physically there to assist them.

21 Prior to the PHE, Medicare paid for telephone  
22 communication between clinicians and beneficiaries in



1 certain circumstances, for example, through virtual check-  
2 ins and chronic care management codes. During the PHE,  
3 because of concerns that some beneficiaries do not have  
4 access to the technology to do a telehealth visit, CMS  
5 allows clinicians to provide certain services -- for  
6 example, E&M and behavioral health -- by telephone. Under  
7 this policy option, Medicare would not continue to allow  
8 billing of E&M, behavioral health, and other services  
9 delivered by telephone after the PHE.

10           It is difficult to conduct a full medical  
11 evaluation without the clinician being able to physically  
12 see the patient, whether in-person or over video. Some  
13 research has shown that video consultations are considered  
14 superior to telephone consultations in providing visual  
15 cues and reassurance.

16           Also, Medicare already has existing payment  
17 policies to cover some telephone communication between  
18 clinicians and beneficiaries.

19           Allowing clinicians to bill for audio-only visits  
20 will likely lead to additional services. Because  
21 clinicians are unable to visually examine patients during  
22 audio-only visits, patients may require an in-person or

1 telehealth follow-up visit, which would increase program  
2 spending and beneficiary cost sharing. Also, during our  
3 summer focus groups, several clinicians indicated that they  
4 were already calling patients to provide their test results  
5 or follow up on appointments, but now they could get  
6 reimbursed for it.

7 I'll now turn it over to Ariel.

8 MR. WINTER: Prior to the PHE, CMS paid for  
9 telehealth services at the lower, facility-based payment  
10 rates in all cases. But during the PHE, Medicare pays the  
11 same rate that would be paid if the service were furnished  
12 in person. In other words, it pays the higher, nonfacility  
13 rate to clinicians who practice in an office.

14 Under this policy option, Medicare would pay  
15 lower rates for telehealth services than for in-person  
16 services. The rationale is that services delivered via  
17 telehealth probably have lower practice costs than services  
18 provided in a physical office because they require less  
19 space, equipment, supplies, and staff time.

20 Therefore, continuing to set rates for telehealth  
21 services equal to rates for in-office services could  
22 distort prices and could lead clinicians to favor

1 telehealth over comparable in-person services.

2           Before the PHE, telehealth technology and  
3 services were required to be provided with HIPAA-compliant  
4 products. But during the PHE, HHS has waived enforcement  
5 of HIPAA in connection with the good-faith provision of  
6 telehealth.

7           Under this policy option, HHS would reinstate  
8 enforcement of HIPAA for telehealth technology and services  
9 after the PHE. Enforcing HIPAA would help protect patient  
10 privacy and reduce the risk of identity theft.

11           Also, most clinicians in our summer focus groups  
12 were already using low-cost, HIPAA-compliant applications,  
13 implying that it's not very difficult to obtain such  
14 applications.

15           During the PHE, the Office of Inspector General  
16 allows clinicians to waive beneficiary cost sharing for  
17 telehealth services. Under this policy option, clinicians  
18 would no longer be allowed to do that after the PHE.

19           Requiring beneficiaries to pay a portion of the  
20 cost of telehealth services could reduce the possibility of  
21 overuse. Because telehealth services are more convenient  
22 for patients to access, they have a higher risk of overuse

1 than in-person services. This is particularly relevant for  
2 fee-for-service payment systems because providers have a  
3 financial incentive to bill for more services.

4 We assume that after the PHE, CMS will monitor  
5 telehealth services to prevent fraud, waste, and abuse  
6 using its regular program integrity tools. However, CMS  
7 should establish additional safeguards to protect the  
8 program and beneficiaries from unnecessary spending and  
9 potential fraud related to telehealth.

10 On the next three slides, we describe four types  
11 of safeguards that would apply after the PHE.

12 The first is for CMS to study whether to set  
13 frequency limits for certain telehealth services, such as  
14 the number of times a service could be billed for a  
15 beneficiary per week or per month. CMS could set limits on  
16 services that experience rapid growth or have evidence of  
17 inappropriate use. To do this, CMS would need to analyze  
18 claims data for telehealth services provided after the PHE  
19 because there was low use of telehealth before the PHE.

20 The second safeguard would require clinicians to  
21 provide a face-to-face visit with a beneficiary before they  
22 order high-cost DME items or lab tests.

1           As Ledia mentioned earlier, telehealth companies  
2 have recently been implicated in very large fraud cases.  
3 For example, the Department of Justice recently brought  
4 charges against several telemedicine companies for  
5 allegedly paying physicians and nurse practitioners to  
6 order unnecessary DME, genetic lab tests, and pain  
7 medication.

8           These schemes resulted in more than \$4.5 billion  
9 in false and fraudulent claims being submitted to federal  
10 health programs and private insurers.

11           Telehealth makes it easier to carry out large-  
12 scale fraud because companies can talk to so many  
13 beneficiaries in a short amount of time. This policy would  
14 prevent clinicians from ordering expensive DME items or lab  
15 tests during telehealth visits.

16           The third safeguard would prohibit "incident to"  
17 billing for telehealth services that are performed by any  
18 clinician who can bill Medicare directly. This would  
19 improve transparency and make it easier for CMS to prevent  
20 overuse. Under "incident to" billing, Medicare pays the  
21 full fee schedule rate for services that are billed by  
22 physicians, but are actually performed by other clinicians

1 or nonphysician staff, even if the person who performs the  
2 service can bill Medicare directly.

3 For example, Part B drugs administered in a  
4 physician's office by a nurse or therapy exercises provided  
5 by a physical therapist in a physician's office can be  
6 billed by a physician as "incident to."

7 Under this policy option, any clinician who can  
8 bill Medicare directly would have to bill under their own  
9 billing number when they provide a telehealth service,  
10 instead of allowing a physician to bill for the services  
11 they perform.

12 Examples of clinicians who can bill Medicare  
13 directly include advanced practice registered nurses,  
14 physician assistants, and physical and occupational  
15 therapists.

16 By contrast, registered nurses and medical  
17 assistants are not allowed to bill Medicare directly.

18 In 2019, we recommended that the Congress  
19 eliminate "incident to" billing for services provided by  
20 APRNs and PAs.

21 This policy would expand this recommendation by  
22 applying it to other clinicians who can bill Medicare

1 directly when they perform telehealth services. It would  
2 give CMS more information about the clinicians who provide  
3 telehealth and enable CMS to better monitor the use of  
4 telehealth to prevent overuse.

5           The fourth safeguard would not allow clinicians  
6 to bill for "incident to" services if they provide direct  
7 supervision remotely instead of in person.

8           Under the rules for "incident to" billing, the  
9 billing clinician must provide direct supervision for the  
10 service in most cases, which means that they must be  
11 present in the office suite and immediately available to  
12 furnish assistance and direction.

13           During the PHE, however, CMS allows clinicians to  
14 provide direct supervision remotely through real-time audio  
15 and video technology instead of in person.

16           There is a concern that remote supervision could  
17 pose a safety risk to beneficiaries because clinicians are  
18 not physically present in the office suite to provide  
19 assistance and direction.

20           Allowing remote supervision could also enable a  
21 clinician to "supervise" multiple services in multiple  
22 locations at the same time, which could raise quality

1 issues and lead to higher spending.

2 I want to note that there are two key differences  
3 between the policy on this slide and the policy on the  
4 prior slide.

5 First, the policy on the previous slide would  
6 only apply to "incident to" services performed by  
7 clinicians who can bill Medicare directly; whereas, the  
8 policy on this slide would apply to "incident to" services  
9 performed by any individual, whether or not they can bill  
10 Medicare directly.

11 Second, the policy on the prior slide would only  
12 apply to telehealth services, but the policy on this slide  
13 would apply to both telehealth and in-person services.

14 For your discussion, we'd like to get your  
15 feedback on the policy option we discussed, which is  
16 summarized here, as well any additional information you'd  
17 like us to provide.

18 This concludes our presentation. We'd be happy  
19 to take any questions.

20 DR. CHERNEW: Great. Thank you.

21 Dana, I know you have a few people in Round 1. I  
22 think we're going to start with Paul.



1 MS. KELLEY: Yes, that's correct.

2 DR. PAUL GINSBURG: Great. I'll begin. I'm  
3 unmuted. This was a really valuable presentation and very  
4 well done.

5 I have two related questions, and they deal with  
6 the degree to which information we have to support these  
7 policy options, how it keeps flowing in. In the context of  
8 it, you know, people start thinking about making permanent  
9 changes to telehealth back in the spring when there was  
10 optimism that the COVID-19 pandemic was waning and maybe we  
11 wouldn't be in it that much longer. Of course, that hasn't  
12 come to pass. Despite the wonderful news this morning  
13 about the vaccine trial, it looks like we'll be in this for  
14 at least another six to nine months.

15 So the question is: Are recommendations in some  
16 areas -- you know, are we continuing to learn and the  
17 advice to Congress and CMS might be, you know, don't act  
18 prematurely, wait until we learn more, and then we can act  
19 in a better informed manner? On the other hand, there are  
20 maybe some of the policy options that are so obvious we  
21 want to do that we might even consider doing them now  
22 during the public health emergency because they're really

1 bad for the Medicare program and for beneficiaries.

2 MR. WINTER: Jim, do you want to take this on?

3 I think this is an issue for all of you to  
4 consider. I'm not sure that I can answer this on a  
5 technical basis.

6 DR. MATHEWS: Yeah. So, Paul, you are correct.  
7 The tension here is that we are, indeed, in the middle of  
8 the public health emergency, and by most accounts, it  
9 appears that it will continue for at least some months.

10 But the question is that even though that's the  
11 case, the Congress, CMS is under continuous, you know,  
12 substantial pressure to make many of these extensions  
13 permanent, and to the extent others are saying wait until  
14 things play out, that's all well and good and it's a very  
15 measured approach. But it might be helpful for a group  
16 like us to start to say of the expansions, these seem to  
17 make sense, these maybe not so much and should be pulled  
18 back, to counteract what is again a very strong pressure to  
19 make everything permanent.

20 DR. CHERNEW: If I can jump in, Paul, and give an  
21 answer much in that spirit, I think that the PHE pushed  
22 telemedicine very quickly, but the issue is much broader

1 than that. We would have had to have had this discussion  
2 following a health emergency or not, and so this discussion  
3 is to outline the policy options and the things we're  
4 thinking about. It is time sensitive, of course, depending  
5 when the PHE ends and as our thinking may evolve as we  
6 learn more during the PHE or other types of things. But I  
7 think we can do this discussion as how we envision  
8 eventually the world going, recognizing that more  
9 information may change that thinking.

10 Dana, do we have others in Round 1?

11 MS. KELLEY: I'm not sure if Bruce Pyenson had a  
12 Round 1 question.

13 MR. PYENSON: I do, and it's similar to Paul's  
14 question, that given how fast the technology of what we  
15 call telehealth is evolving, the decisions that are made  
16 now might be inappropriate for the telehealth of several  
17 years from now.

18 So my question is maybe a policy one. Does it  
19 make sense, is it practical to say here's some suggestions  
20 for a limited period of time, say, one year, two years, but  
21 not beyond that? Because as others have said in the past,  
22 once a policy is set, it's very hard to undo that.

1           So this is a policy question. Is it possible to  
2 put a time limit on some of these changes, not just in the  
3 context of the public health emergency, but really because  
4 the technology on the business side is changing so fast?

5           MR. WINTER: Bruce, are you suggesting -- by time  
6 limit, do you mean starting slowly and ramping things up,  
7 ramping up expansions as the evidence accumulates, or are  
8 you suggesting the opposite, that starting with a wide  
9 expansion and then narrowing it down over time, if  
10 necessary?

11           MR. PYENSON: I'm saying for the next two years,  
12 let's expand and we'll revisit a more permanent policy  
13 later.

14           MR. WINTER: That's certainly a policy option for  
15 you all to consider.

16           MR. PYENSON: Are there precedents for that? I  
17 think I've seen a precedent to various kinds of coverage  
18 precedents, but I can't recall.

19           MR. WINTER: Yeah. The first thing that came to  
20 mind was coverage with evidence development, which allows  
21 coverage as evidence is gathered. Nothing immediately  
22 occurs to my mind outside of the development of coverage,

1 but I'll keep thinking about that.

2 MR. PYENSON: Thank you.

3 MS. KELLEY: Okay. I think Dana Safran had a  
4 Round 1 question.

5 DR. SAFRAN: Yes. Thank you.

6 My question is about the recommendation related  
7 to physical therapy being one of the services that would be  
8 excluded from telehealth after the PHE, and in that  
9 chapter, you cite concerns about patient safety, you know,  
10 falls that happen without a physical therapist on-site.

11 I was looking for something that's maybe the  
12 balance of the pros and cons around physical therapy. Just  
13 curious whether it's a really open-and-shut case that  
14 physical therapy really is one of those services that  
15 should be excluded or whether it be increase to access  
16 that's afforded by allowing virtual PT, it merits  
17 consideration of maintaining it.

18 MS. TABOR: That's a good question. So I think  
19 we have heard from several clinicians, both during the  
20 focus groups and other kind of conversations about their  
21 concern with physical therapy for Medicare beneficiaries.  
22 I'm sure many of the clinicians on the Commission could

1 also weigh in on this.

2 I do think that there is an opportunity to learn  
3 more about through the public health emergency, kind of the  
4 pros and cons, as you said, of in-person versus remote.

5 One thing we could look at to help answer this  
6 question is how much physical therapy was actually done by  
7 telehealth over the public health emergency, which I think  
8 could help answer the question if patients and clinicians  
9 felt comfortable doing that. So we can come back to you  
10 with more information on that.

11 DR. SAFRAN: Thanks.

12 MS. KELLEY: Pat, did you have a Round --

13 MS. WANG: Hi. Thank you.

14 So I think it's great that you consulted with  
15 clinicians and did focus groups as you evaluated what other  
16 information was available at this point in time.

17 I'm curious whether you saw any differences in  
18 response on behavioral health for audio-only services. I  
19 understand the recommendation to sort of eliminate coverage  
20 of audio-only and where that is coming from. I just  
21 wondered whether there was anything that you might have  
22 learned in your focus groups in particular that makes

1 behavioral health perhaps a different category, especially  
2 if it's talk therapy. I don't know how much prescribing  
3 might have been going on, but is behavioral health a  
4 different kind of service that we should be aware of when  
5 it comes to evaluating audio-only?

6 Thank you.

7 MS. TABOR: During the focus groups, we didn't  
8 specifically ask about mental health, and we didn't  
9 actually include any mental health clinicians or behavioral  
10 health clinicians in the focus groups, but that's something  
11 that we can think about and perhaps look at some research  
12 to provide more background on this.

13 MS. KELLEY: Karen?

14 DR. DeSALVO: Thank you, Dana.

15 I actually have, as always, these are issues that  
16 are near and dear to my heart, and that was going to be one  
17 of my questions about whether there are some conditions for  
18 which, for privacy and other reasons, it may make sense to  
19 not make changes.

20 I also wondered about whether you all thought  
21 about this for geographic differences, whether there may  
22 need to be more of a tail for rural communities that are

1 likely to have more of a slow burn, even of virus and  
2 challenges of people getting into the office, even after  
3 the PHE might end, the way that we think that there may  
4 still be some viral spread in communities but also because  
5 of challenges around broadband and other access to video  
6 kinds of services.

7 MS. TABOR: Are you asking specifically about the  
8 audio-only visits?

9 DR. DeSALVO: I think just in general about  
10 flexibilities, but part of that is about audio-only.

11 MS. TABOR: I'd say that --

12 DR. DeSALVO: Just thinking about if there are  
13 going to be particular challenges for rural populations.  
14 This relevant for our next conversation. That may mean  
15 that even if the PHE ends, there still may be some tail of  
16 need that the rural communities might take a little longer  
17 to catch up and go back to, quote, "normal" or have kind of  
18 a more structured approach that you all are advocating for.

19 MS. TABOR: I guess I would say that this  
20 proposed policy option would actually expand access to  
21 those in rural communities compared to prior to the PHE  
22 because they would be able to do services from their home



1 as opposed to having to travel to an originating site. So  
2 that is improving access.

3           Although under, again, this proposed option,  
4 audio-only wouldn't be covered, that is going back to the  
5 previous calls where audio-only was not covered for rural  
6 beneficiaries or for any beneficiary.

7           MS. KELLEY: I think our last Round 1 question is  
8 from Sue.

9           MS. THOMPSON: Thank you, Dana. Thank you, Ledia  
10 and Ariel.

11           I have a question going back pre-pandemic. Did  
12 we define the access issues in some quantifiable way that  
13 caused us to say it made sense that telemedicine should be  
14 available to rural and should be available for behavioral  
15 health, or was that an assumption about rural access and an  
16 assumption about we don't have a lot of behavioral health  
17 providers? I'm curious if there was any quantifiable  
18 measurement around defining access that telemedicine  
19 answered.

20           MR. WINTER: Yeah. I don't think we developed  
21 any quantifiable measure of access in terms of what would  
22 be the threshold where, you know, for expanding telehealth.

1           I think you also asked about kind of the initial  
2 decision to cover telehealth in rural areas, which was a  
3 statutory provision, and I don't think that was a result of  
4 the Commission recommendation. This goes back many years.  
5 I assume the rationale related -- I assume the decision was  
6 related to concerns about access in rural areas, the need  
7 to give it another way to access clinicians, but it's not  
8 something that we initially -- it's not something the  
9 Commission weighed in on before Congress authorized it.

10           MS. THOMPSON: Thank you.

11           DR. CHERNEW: Great. Dana, I think that was the  
12 end of the Round 1. Am I following that correctly, and can  
13 you hear me?

14           MS. KELLEY: I can hear you, and that is correct.  
15 We have a number of Round 2 questions.

16           DR. CHERNEW: I have seen.

17           So I'm going to ask a Round 1 question, and  
18 actually, then we're going to jump into Round 2. And we're  
19 going to kick it off with Jon Perlin.

20           So my Round 1 question is you spoke about a cap  
21 on volume, and I was a little uncertain. One version was  
22 how much an individual patient might get. A person could

1 only get three visits, right? There's another version of a  
2 cap which is a physician could only have a certain number  
3 of -- the physician can only bill a certain amount of  
4 telemedicine, sort of an NPI-level cap or an NPI-level  
5 share cap. Were you talking about the beneficiary version  
6 or the physician-type cap to max the total amount of  
7 telemedicine that a given provider could provide?

8 MR. WINTER: We were talking about the former, a  
9 beneficiary-level cap, because that's -- before the PHE,  
10 there were some frequency of limits in place for telehealth  
11 services that apply to beneficiary level. For example, on  
12 a telehealth visit to a beneficiary in a nursing facility,  
13 they can only receive a telehealth visit, I think, once a  
14 month or once a week. I forget the exact frequency. So  
15 that applied to beneficiary level. So we were thinking  
16 about something similar, similar to that, rather than a cap  
17 at the provider level.

18 DR. CHERNEW: All right. Thank you.

19 So I will save any broader thoughts I have for  
20 after the Round 2 comments. I think my general point is  
21 what we are trying to do or what I believe we are trying to  
22 do is maximize the access to the value that telemedicine

1 can provide and minimize the concern about overuse of  
2 telemedicine, recognizing there's two potential ways in  
3 which that might happen.

4 One is sort of existing, the way we deliver case  
5 now, having too much or not enough telemedicine, and then  
6 concern that other organizations that we might not even be  
7 able to anticipate could identify loopholes in the rules  
8 and do things we're not so thrilled about.

9 And that's sort of where we are, but I'm going  
10 to, with that brief intro, turn it over to Jon Perlin for  
11 the beginning of Round 2.

12 Jon?

13 DR. PERLIN: Well, thank you, Michael. Good  
14 morning, everybody.

15 I want to thank Ariel and Ledia for just a  
16 terrific set of presentations and review materials. This  
17 is obviously a genie that's not going back in the bottle,  
18 and bottom line up front, I substantially agree with the  
19 recommendations on some areas of questions.

20 Just to sort of set the context -- and this is an  
21 area I've been working in for a while -- the positives are  
22 pretty clear-cut operationally. It increases access for

1 beneficiaries, potentially relieves travel burden for  
2 rural, for those with physical impairments, those with  
3 transportation difficulties, reduces infectious exposure.

4           For rural in particular as well as sort of urban  
5 deserts, it allows access to some specialists outside of  
6 what might be the region. It may at times, on the positive  
7 substitute for in-person care, especially for transactional  
8 activities or things that don't really require the laying  
9 on of hands, and it can increase access in order to get  
10 services, psychiatric, substance use, et cetera.

11           I think the negatives are challenging. It may  
12 not be a substitute for in-person care, and it may, in  
13 fact, induce demand for subsequent services. Too, by  
14 virtue of the virtualization, not only can it be abused,  
15 but it can be abused at scale. And that's particularly  
16 challenging in the areas that were noted, DME, pain, and  
17 expensive lab tests.

18           So, again, I want to come back to the point that  
19 I substantially agree, but here are a few points for  
20 considerations, I think, about our policy.

21           First, the reimbursements should reflect the  
22 resources used. There's probably more work that needs to

1 be determined to calibrate appropriately to whether it  
2 emanates from a doctor's office or a hospital or other  
3 areas, a critical fix or a technical fix that needs to  
4 occur for critical access hospitals.

5 I think the second is that we want to encourage,  
6 not suppress, innovation through our payment policy, and,  
7 Ariel, I'm glad you mentioned what I was thinking about,  
8 which was coverage with evidence determination for areas  
9 where we have more ambivalence.

10 I think the PHE has demonstrated utility of  
11 telehealth broadly, and I think I've had some technical  
12 challenges with our video teleconference this morning. And  
13 if my image dropped off, I hope this would still be a  
14 value-added engagement. I think we need to think carefully  
15 about whether we completely, out of hand, reject audio-only  
16 and certainly include those for areas with low bandwidth,  
17 like rural environments. I think we need to consider the  
18 implications for individuals with technology challenges and  
19 the like.

20 The one that's going to sound sort of strange, it  
21 feels like we want to absolutely support HIPAA, but in fact  
22 -- and, you know, I think the PHE may be one of the areas

1 where we want to use coverage with evidence development in  
2 terms of what are the real risks of someone who is  
3 proficient on Facetime with their family can extend to  
4 provider. Is this really the vehicle where the  
5 interception of information would occur in such a way that  
6 private information is really compromised?

7 In terms of some of the negative areas and  
8 limitations on abuse, perhaps one way of going at it is not  
9 to punish the patient in terms of access but to really  
10 punish abusers in terms of multiyear disbarment from the  
11 Medicare program.

12 On the table on page 12 of the reading material,  
13 I substantially support, but I wouldn't necessarily  
14 recommend relief of a waiver of cost sharing as the way.  
15 If you have a bad teacher, it doesn't make sense to punish  
16 the student. Here, I would put all of the sanctions on the  
17 abuse of the provider.

18 The concerns that some area require a laying on  
19 hands and are rejected categorically may be more of a  
20 reflection of how we've traditionally paid for services,  
21 particularly in the area of physical therapy, occupational  
22 therapy, and the like. As someone who's experiencing as we

1 speak, trochanteric bursitis, I personally am the  
2 beneficiary of virtualized physical therapy, and it's  
3 really the burden of a complex schedule and transportation.  
4 So I think we need to differentiate the idiosyncrasies of  
5 the prior payment and oversight mechanism from the capacity  
6 to reasonably virtualize services and PT, speech and  
7 language pathology, and the like.

8           Michael has raised that point that A-APM operates  
9 on the fee-for-service chassis and trying to delineate A-  
10 APM from fee-for-service may be fraught. They also have a  
11 consequence in that A-APMs are more prominent in more  
12 populous areas and might categorically disadvantage some of  
13 the individuals who might benefit most from telehealth, and  
14 that's our rural populations.

15           Let me just close with a comment. I think we  
16 also don't know the unintended consequences of certain  
17 policies. For example, a practice might organize that the  
18 vast majority of the practitioners are in person, but they  
19 designate someone as a telehealth expert. So that  
20 individual might actually accrue a large number of  
21 telehealth visits, and so arbitrarily limiting the number  
22 of visits may not be the best way, though coupling visits



1 with in person in the practice or something may be the  
2 piece. And that's why I come back to that bottom line up  
3 front.

4 I substantially agree with the recommendations  
5 with the caveats I've offered, some relief on HIPAA. Don't  
6 overly exclude audio. Don't overly try to delineate  
7 between A-APM and other, and for areas where we have  
8 ambivalence, use some tools that we have like coverage with  
9 evidence determination.

10 I look forward to a discussion in this area.  
11 Thanks for a great chapter.

12 DR. CHERNEW: Jon, that was great. In a moment  
13 we're going to go to Larry, but I am going to jump in  
14 because I am trying to -- I want to raise a few issues as  
15 we go around the rest of the discussion, to see where folks  
16 are.

17 Let me just start with one, but I think it fits  
18 into the scene of your remarks, which is the role of cost  
19 sharing. First let me say cost sharing is certainly not  
20 intended to be a penalty on beneficiaries in any way,  
21 shape, or form. As you know, much of my work suggests we  
22 want to lower that with this high value.

1           The challenge is in the absence of an efficient  
2 way to cap the providers, or monitor use of the provider  
3 level, cost sharing can prevent against some of the most  
4 egregious cases of fraud. And I think it would clearly  
5 have to be structured well, but I will go on record, in  
6 part to get people's reaction, that I think some role for  
7 consumer cost sharing, as distasteful as that is, might be  
8 useful at solving some of the problems until we can find  
9 some other way to find the right caps of provider level or  
10 whatever.

11           And that leads to my last point to get reaction  
12 on which is as Ariel mentioned, the caps we're talking  
13 about have been on a per-beneficiary level. It might be if  
14 one want to weed out providers that might not be providing  
15 the services with as pure a heart as most would be, that we  
16 have a cap at a provider level, in a particular way.  
17 Again, that is fraught with challenges. I won't claim to  
18 know how to structure that.

19           But I want to move on to Larry to get his  
20 thoughts, but those two types of paths are where at least  
21 part of my thinking is.

22           Larry?

1 DR. CASALINO: Yeah. Thanks, Mike. Ariel and  
2 Ledia, as always, a wonderful presentation. I agreed with  
3 almost all of the recommendations so I'm not going to waste  
4 time listing the ones I agreed with. But I will mention  
5 ones where I don't agree.

6 I felt what Jon had to say was excellent and I  
7 agreed with almost everything Jon said as well. I'm not  
8 sure about HIPAA, and I basically I'm with Mike about cost  
9 sharing. I think there has to be some. Although I will  
10 say that I think one principle we should use in our  
11 recommendations is we don't want to increase the  
12 administrative burden on physicians and their practices,  
13 and this is one place that cost sharing becomes tricky. If  
14 the patient's cost share is \$10 or \$12, for example, it can  
15 cost the practice more than that to try to collect the \$10  
16 or \$12 when you're not talking about an in-person visit.  
17 So that's not great. On the other hand, if you make the  
18 cost sharing a lot, you know, that doesn't seem right for a  
19 lot of reasons. So I think the details of that will be  
20 important.

21 The main thing I think I have to say, and this is  
22 going along with what Jonathan said, is I really strongly

1 do not support the idea to not pay for audio, for both  
2 equity and efficiency reasons. For equity reasons, Karen  
3 and Jonathan already mentioned some, and I won't reiterate  
4 them, except to say I did come up with some data. This is  
5 from Behavioral Risk Factor Surveillance System, that at  
6 least a few years ago 16 percent of people don't have  
7 internet access, and you can imagine kind of who they are  
8 or where they are.

9           And just to put a little bit of more detail on  
10 that, patients with diabetes or hypertension, 28 percent at  
11 the time they did this survey didn't have internet access,  
12 and for black patients with diabetes or hypertension, 38  
13 percent didn't have regular internet access, and 44 percent  
14 of Hispanics with diabetes or hypertension don't have it.

15           And then there are people with cognitive  
16 difficulties, and frankly, it isn't that easy to do a video  
17 visit. I've had trouble with it myself, and I've been  
18 scrambling around trying to get hooked up at the time the  
19 visit is supposed to start. And I think the staff report  
20 mentioned anecdotal evidence, at least, that it's not  
21 uncommon, to say the least, for what is supposed to be a  
22 video visit could turn into an audio visit because the

1 hookup, for whatever reason, doesn't work.

2           So that's the equity reason. But the efficiency  
3 reason, I think there's no question that face-to-face adds  
4 elements that you don't have when you're just talking on  
5 the telephone. But it's really important to notice, and I  
6 think the report does undervalue this, that a great many  
7 communications for patients do not involve the kind of  
8 things that would require video, or even be really enhanced  
9 very much by video.

10           For example, a very large proportion of follow-up  
11 in-person visits are for hypertension, diabetes, adjusting  
12 your blood pressure medication, adjusting your diabetes  
13 medication, talking about diet, whatever. That's a lot of  
14 visits. Those can be done very, very well by audio. There  
15 really is no need for video. It just adds costs and  
16 hassle. So to me that's really important, and in my 20  
17 years in practice not getting paid for this I spend an  
18 immense amount of time doing that. I think it's valuable,  
19 and to not pay for that I think would be a mistake.

20           Now I would make an exception. You would only do  
21 this if the patient has seen the physician. I would not  
22 have physicians managing chronic diseases when they've

1 never seen the patient in person. And I'm spending time on  
2 this, I think, because it is my main point. I'm not saying  
3 that everything that gets done via phone should be paid  
4 for. I know there's the virtual check-ins. Those could  
5 continue as they are. Physicians have always called  
6 patients with their test results, for example. Those are  
7 usually brief calls. I think it's a mistake to pay for  
8 those. Patients would legitimately say, "Why am I having  
9 to pay for this now? I never had to pay for this before."  
10 But if a call has a certain duration, for example, and  
11 really is substituting for a visit, I think it ought to be  
12 paid for.

13           So that's my main disagreement. My other one is  
14 more detailed and smaller, and Mike already brought it up.  
15 The materials we got are a little ambiguous, at least to  
16 the reader -- although less, now that you have clarified it  
17 -- about were there any limits or any search for outliers  
18 in use of telehealth services, outlier physicians with,  
19 well let me say, limits that the service would provide for  
20 a beneficiary or per beneficiary. To me, for a beneficiary  
21 says, okay, Larry Casalino has already had two visits this  
22 month. He can't have any more. That adds a huge

1 administrative burden to physicians. Physicians will go  
2 crazy about that. There's no easy way to track that.

3           Per physician would you mean you look at the NPI,  
4 as Mike was suggesting, and you try to set some guidelines  
5 for what seems to be an appropriate number of per-  
6 beneficiary telehealth visits per month, proportion of  
7 telehealth visits to in-person visits, although Jon  
8 mentioned a potential problem with that. It would be  
9 relatively easy to come up with per-beneficiary limits to  
10 try to set some guidelines and ways to look for outliers,  
11 but looking at it for individual beneficiaries I think is a  
12 mistake, and at least the language should be clarified  
13 about that.

14           And then I just want to mention a few concerns,  
15 that are not really about recommendations but I just would  
16 like to see more discussion from the Commission, and maybe  
17 in a report from the staff. One is what to do about the  
18 telehealth companies that only deliver telehealth. I mean,  
19 they can cherry-pick patients. They don't have expenses of  
20 brick and mortar or staff, and so on and so forth. And  
21 they could do real harm to practices. I think we want to  
22 have brick-and-mortar practices with staff and in-person

1 visits. We don't want them harmed by what might be unfair  
2 competition from companies that don't provide brick-and-  
3 mortar care. And then there are the concerns, as Ledia and  
4 Ariel mentioned, about continuity of care.

5           So what to do about those is the question I'd  
6 like to hear more about. I already mentioned not  
7 increasing administrative complexity. We're going to have  
8 to talk about attribution. I won't talk about that today.  
9 Maybe when we discuss it at a future meeting, advanced  
10 APMS.

11           And then a minor comment and then I'll conclude.  
12 A minor comment is the materials and the presentation  
13 talked about facility rates, and I'm used to thinking of  
14 facility rates as what the hospital gets paid when a  
15 physician delivers an outpatient service and the physician  
16 is delivering it, say, on the hospital campus. So then  
17 there's a payment to the physician, not payment to the  
18 hospital. And you guys meant by facility rates, I figured  
19 it out, the rate that gets paid to the physician who  
20 delivers a service on the hospital campus. But I think to  
21 a lot of readers, you're talking about the facility fee,  
22 what the hospital gets paid, and I would just clarify that



1 because it does make a difference.

2           And the last thing I would say, just to conclude,  
3 is I think that Jon mentioned the advantages and  
4 disadvantages of telehealth. We'd like to do things  
5 evidence based but there's real pressure to make policy, at  
6 least for the upcoming time period now. And frankly, we're  
7 going to wait a very long time before we get -- I'm not  
8 sure we'll ever get good rein amongst control trials now --  
9 expecting a really firm evidence base. It's not that we  
10 can't learn more, but expecting conclusive evidence on  
11 telehealth, I think we'd wait a very long time, if not  
12 forever.

13           And I would add that there's not that kind of  
14 evidence for the 95 percent of what physicians do, for  
15 example. For example, there's no generally accepted  
16 evidence on how often a patient with hypertension should  
17 come in for follow-up visits. How often should that  
18 happen? Some physicians do it twice a year. Some  
19 physicians do it every two weeks, and everything in  
20 between. Same thing for diabetes, congestive heart  
21 failure, and you could go on.

22           So I look at this as -- and Jon mentioned this in

1 terms of supporting innovation -- this is a new tool which  
2 we're just beginning to use. It's going to lead to a new  
3 way of thinking about how physicians spend their time that  
4 hasn't been thought about since time immemorial. It's just  
5 see as many patients as you can face to face in a day.  
6 This would open up a whole new way, I think, of thinking  
7 how can care be provided. I don't think we'd want to  
8 suppress that.

9           And I will just add, I did quite a bit of looking  
10 for evidence over the weekend, and there isn't really much  
11 good evidence. But what I did see, I was stunned by the  
12 variety of specialties that have been proving telehealth  
13 care and the variety of articles about individual  
14 specialties that are doing it.

15           So this is a major thing. It's a major  
16 innovation, and I think we want to be very careful about  
17 suppressing it. And I do think it's possible to put  
18 guardrails in place, looking for outliers to prevent abuse.  
19 That in-patient cost sharing I think would go a long way  
20 toward preventing abuse.

21           DR. CHERNEW: Larry, thank you. There's a  
22 reasonably long queue and about 35 minutes or so. Keep

1 that in mind. And Dana, I'm going to let you run through  
2 the queue.

3 MS. KELLEY: Okay. Paul, did you have something  
4 on point with Larry?

5 DR. PAUL GINSBURG: Yes, I do. It's about the  
6 issue of paying less for telehealth services and whether it  
7 actually makes it uneconomic for physicians to provide them  
8 because the rate would be lower.

9 I want to point out that whether it makes sense  
10 for physicians economically to provide them at a lower rate  
11 depends not on the average costs of billing a service but  
12 really the marginal costs of what it cost to bill an extra  
13 service. And it may very well be that still at the  
14 marginal level telehealth services are still worth being  
15 provided, even if they have lower rates, reflecting the  
16 resources involved. So let's not be too quick to dismiss  
17 that.

18 DR. CASALINO: No, Paul, if I may just respond  
19 very quickly, I think I misled you, I think. I agree that  
20 telehealth should be paid considerably less. It may be  
21 even that what the staff are calling the facility rate,  
22 that may be too much, I think. So I would totally agree

1 for paying a lot less for telehealth than for in-person  
2 visits.

3 I was just linking it to the problem with cost  
4 sharing, and I don't really see a solution here. So I  
5 would advocate paying physicians less for telehealth, or  
6 whoever less for telehealth. And I agree that there should  
7 be cost sharing. It's just a kind of a technical problem.  
8 If the cost sharing for the patient is lower than what it  
9 costs the physician to collect the cost share, that's a  
10 problem, and I'm not sure I see a solution to that. But I  
11 agree that substantially less should be paid for  
12 telehealth.

13 DR. PAUL GINSBURG: Thanks, Larry. You know, we  
14 shouldn't lose sight of the fact that I think we are going  
15 to have telehealth playing a bigger role in our delivery  
16 system permanently. And telehealth works better in a  
17 system that's not entirely fee-for-service. So, you know,  
18 we might see this as a motivation to move faster into more  
19 modern models for paying for primary care, in particular,  
20 as are being carried out right now.

21 DR. CHERNEW: We will be looking at how to do  
22 that, as you know, Paul, so thank you. And Larry, I agree

1 with your administrative comment on cost sharing. But Dana,  
2 do you want to run through the rest of the list?

3 MS. KELLEY: Sure. Brian, you're next.

4 DR. DeBUSK: First of all, thank you for a  
5 fantastic chapter. I really enjoyed the read.

6 I hope that we do go back and revisit this idea  
7 of ending the audio-only visits. To me, I do see some  
8 merit in audio-only, and obviously there are the access  
9 issues around who has access to, say, broadband, or who has  
10 access to some of these other technologies, seeing a merit  
11 there.

12 But the other thing I want to point out is audio,  
13 telephone calls, are still the most secure form of  
14 communication, and this where I get into this HIPAA issue  
15 just a little bit. For example, you know, I think our  
16 emphasis should shift away from securing point-to-point  
17 conversations. I'm not necessarily worried about a  
18 conversation I'm having over Facetime or over Skype. If  
19 you notice where the shift is going it's toward larger-  
20 scale data breaches and theft of other and ancillary  
21 personal information.

22 And let me just sort of explain how I'm pulling

1 audio-only and HIPAA into one issue. Imagine the links  
2 that we've clicked on simply to connect to this meeting.  
3 If you look at what's going on out there it's the phishing  
4 attacks, where people are clicking on links, it's malware.  
5 I don't know if you guys have looked up but malware is  
6 actually offered as a service. There are groups of people  
7 who will install just gateway malware on your machine, and  
8 then that opens you up to all sorts of other things that  
9 secondary waves of hackers can use.

10           So my concern is I see audio as a secure, safe  
11 medium for some of our less-sophisticated or lower-  
12 socioeconomic beneficiaries. I think it also mitigates  
13 some of the confusion that's in the market. So I hope we  
14 don't throw that away as we move toward these  
15 recommendations in telehealth.

16           The other thing I want to mention, I really like  
17 what you did with the "incident to" treatment. I think  
18 that's excellent work. And I really like where you're  
19 going with requiring some face-to-face visits, particularly  
20 on DME and lab tests and some of these other costly tests.  
21 So as a DME supplier I think that policy is very effective,  
22 and I hope that it makes it to the recommendations. Thank

1 you.

2 MS. KELLEY: David, you're next.

3 DR. GRABOWSKI: Great. Thanks for this super  
4 work. Like others I believe coverage of telehealth in  
5 traditional Medicare should continue post pandemic.  
6 Similar to Jon, I agree the genie is not going back in the  
7 bottle, and it really shouldn't. However, the key is how  
8 do we put up guardrails such that we really limit low-value  
9 telemedicine?

10 So I want to emphasize three such guardrails that  
11 were raised in the chapter and the presentation. Guardrail  
12 number one, I think following the PHE, I would really favor  
13 the policy option of covering many but not all telehealth  
14 services. As was discussed by Ledia, there's very little  
15 need to cover those telehealth services where there are no  
16 quality or access concerns. I worried that fraud coverage  
17 for certain services really raises the potential of opening  
18 the floodgates for low-value care.

19 The key, of course, is what services belong on  
20 that list and which services don't. Larry, your point  
21 about the lack of data on what works and what doesn't is  
22 really well taken. We've already heard some back-and-forth

1 from Dana and Jon on physical therapy and occupational  
2 therapy. However, I still think we need to do the work to  
3 figure out which services aren't adding quality or access  
4 and are really just duplicative of what we're already doing  
5 in person.

6           Guardrail number two, others have already said  
7 this but I just want to echo it, Medicare should really pay  
8 for telemedicine visits at a lower rate than in-person  
9 visits, and I believe we once again want to avoid any  
10 telemedicine parity laws. I get that implementing  
11 telemedicine does require some costs for physicians, but in  
12 the longer term a provider's marginal cost for telemedicine  
13 visits should be lower than in-person visits, and Medicare  
14 payments should reflect that.

15           Guardrail number three, you know, I agree with  
16 others that telemedicine should be subject to some cost  
17 sharing. At least for some patients, out-of-pocket costs  
18 could be increased for some forms of telemedicine. And the  
19 key, once again, is what form does that take? I think we  
20 should try to match cost-sharing to value. I know Mike  
21 knows something about value-based insurance design. I  
22 would love to see us go down that route. Once again, to



1 Larry's point, what works and what doesn't and what's high  
2 value and what's low value, we're going to need more work  
3 there. But I really think we want to implement some form  
4 of cost-sharing on these services.

5 I'll stop there and look forward to future work  
6 on this issue. Thanks.

7 MS. KELLEY: Dana.

8 DR. SAFRAN: Great, thanks. Echoing the comments  
9 and compliments about a great piece of work, you know, it's  
10 hard to overemphasize the importance of this issue, not  
11 just the changes that have happened during the PHE, which  
12 have been momentous, but the potential for the role and the  
13 increasing role over the indefinite future that telehealth  
14 can play in health care delivery in this country. It  
15 relates, I think, importantly to a conversation we're going  
16 to have later about rural care, but not just that.

17 So I think I wanted to just emphasize two points,  
18 one of which has already been mentioned, but just I really  
19 agree with the comments that have been made questioning a  
20 recommendation around limiting phone-only use, just, you  
21 know, as has been mentioned, my concerns, as I read about  
22 that, were exacerbating access and access disparities

1 because of who does and doesn't have Internet access, and I  
2 think Larry had some good data points on that. And also  
3 someone has already mentioned the known problems with  
4 technology during the PHE that has resulted in a large  
5 share of visits getting converted. So I do think we have  
6 to look at that.

7 I really applaud the recommendation related to  
8 "incident to" and ending that. To me that seems like an  
9 absolute must because giving Medicare complete data on  
10 which clinicians are providing services seems really  
11 critical.

12 And I think that relates to the broader point I  
13 would make and sort of back to where I opened of the truly  
14 momentous changes this can -- already has, but in the  
15 future can continue to create in the way health care gets  
16 delivered. I think we really must find ways to evaluate  
17 the impact and the comparisons of care being provided with  
18 virtual technologies versus care being provided in person,  
19 how that -- you know, and who's providing the services and  
20 so forth, because, you know, there were some comments in  
21 the chapter that I would urge us to take a look at tone  
22 that suggested that, you know, there might be inferior

1 quality that occurs with telehealth visits. We really do  
2 not know. We don't know that for physical therapy, but we  
3 don't know it broadly. And it could be that the access to  
4 -- you know, the sort of stimulation of a home visit, so to  
5 speak, actually is a tremendous enhancer of quality and  
6 potentially safety.

7           So I think we really need to be studying what  
8 results we're getting and how it compares as we're doing  
9 this, and that that should inform the policy of how broadly  
10 we continue to adopt these services. I really liked  
11 Bruce's idea about the possibility of kind of time-limited  
12 approvals and then a kind of coverage with evidence  
13 approach.

14           And then I think the last point I'll make -- and,  
15 you know, I liked David's reference to avoiding low-value  
16 telehealth. You know, we've talked in previous meetings  
17 about the concern for the inflationary impact that  
18 telehealth could have on Medicare payment. And so there  
19 are a number of things you mentioned in the chapter that I  
20 think aim to address that. I think we've accepted the fact  
21 that to try to limit this to ACO situations is terribly  
22 complex because it's not been a provider as uniformly, an

1 ACO provider, but they are for certain patients. So I am  
2 not recommending that we do that, but I am recommending  
3 that we need to be eyes wide open about the potential  
4 inflationary effects here.

5           On the other hand -- and this is my last point --  
6 I think it was mentioned in the chapter; I know it was  
7 mentioned in the oral presentation -- that providing these  
8 services actually is lower cost and ultimately virtual  
9 services can help us to get to reduced infrastructure costs  
10 for health care delivery. And I do believe that needs to  
11 be our spot on the wall. I absolutely agree that we have  
12 to be careful getting there because we can reduce access to  
13 virtual care by making the compensation for it too low  
14 right now. But we ultimately have to have payment policies  
15 that acknowledge that these services cost less to deliver,  
16 ultimately require less infrastructure, and that that's a  
17 good thing, and that we would expect, as we develop the  
18 evidence, that we should be trying to move the whole system  
19 in that direction in cases where it's appropriate,  
20 effective, and safe.

21           Thank you.

22           MS. KELLEY: Amol.

1 DR. NAVATHE: Great, thanks, Dana. So great work  
2 as usual, Ariel and Ledia. I agree a lot with much of what  
3 has been said by the Commissioners, so I'll try to build on  
4 that. In fact, I found much of what the chapter said and  
5 what everybody has said so compelling that I find myself  
6 changing positions each somebody spoke, and so that made me  
7 kind of reconsider and say, okay, what is the approach that  
8 one might take here? And it seems to me that we could have  
9 one of two kind of base approaches.

10 One approach could be let's value preference and  
11 access, and only when safeguards don't work or we have real  
12 concerns that there could be overuse and abuse, that we  
13 really figure out that we should carve something out and  
14 say we don't cover it. The other option would be a more  
15 restrictive, if you will, view, which would be to say,  
16 well, we're going to not cover unless there's evidence  
17 against it. Right? And I think that leads us in two  
18 pretty different directions, in fact, and I think Larry  
19 pointed out that we don't actually have a lot of evidence  
20 to go on here, further making this, you know, quite  
21 challenging.

22 So then I thought, how does MedPAC do things?

1 MedPAC does things oftentimes by setting out some  
2 principles. So what are the principles we might have? So  
3 if we think about that, I kind of laid out five not  
4 completely exhaustive ones, but one is generally speaking I  
5 think we would all probably agree that we want to support  
6 beneficiary choice and beneficiary access. Another is we  
7 want to protect beneficiaries in terms of privacy, a la  
8 HIPAA. We generally want things to be -- credible things  
9 to be aligned with a shift toward value longer term. We  
10 want to try to create -- Larry's point -- we want to keep  
11 practice administrative costs as simple and easy as  
12 possible. The last one is we certainly want safeguards  
13 around abuse of the program.

14           And so I think when I started to think through  
15 this using this framework, perhaps espousing the idea that  
16 the benefit here of lower-cost access and perhaps lower  
17 dollar cost itself for access, and the idea here that  
18 beneficiaries are going to have different preferences,  
19 right? So some people are going to want to do in-person.  
20 Some people may have very strong preferences for telehealth  
21 types of access, and this may be because they live in rural  
22 areas, as Karen and others have pointed out, or for other

1 reasons.

2           So I thought, well, if that's the case, then  
3 maybe we need to think about, you know, I think Larry and  
4 others have kind of -- building upon what they said, we  
5 could mention that there's actually two tiers of things  
6 here. There's one where we know there's strong benefit.  
7 This could be in the behavioral health type areas or people  
8 who have physical disabilities. Or we could have another  
9 level of payment which could be lower or cost sharing would  
10 be higher for a group that is more preference-sensitive, if  
11 you will, in terms of people -- some people just want to  
12 consume their care that way, and why would we a priori  
13 restrict that?

14           So I submit that for consideration that we  
15 consider something like that where we actually have  
16 multiple tiers of payment or multiple -- you know, two  
17 tiers of payment, say, or two tiers of cost sharing to  
18 allow a balance between allowing people choice and  
19 preference, but still supporting the idea that we want to  
20 emphasize, if you will, the program towards areas where  
21 there is more evidence of benefit.

22           A couple other points along that. I think to the

1 extent that we need safeguards, I think I support every  
2 safeguard that you guys have put in the chapter thus far.  
3 And I would also say, you know, Jon's point around using  
4 participation in the Medicare program itself as a stake, if  
5 you will, to induce better behavior, also is something that  
6 potentially we should consider, and I would support  
7 considering something like that.

8           The last point I have is thinking forward. So,  
9 you know, there's innovation, there's going to be evolution  
10 of evidence. Ideally -- I know that this chapter probably  
11 will get too long, but ideally we should not only talk  
12 about the current state immediately post-pandemic here, but  
13 also what happens as evidence evolves? What happens as we  
14 get more evidence that chatbox, or whatever, are actually  
15 delivering great care? And do we need to have some  
16 flexibility? Do we need to have an approach, most  
17 importantly, to support that evidence will change and there  
18 will be innovation in the sector, and I think somebody said  
19 it earlier that we want to support innovation rather than  
20 stifle it?

21           And so I would submit here again that as part of  
22 this, perhaps as a parenthetical, end the chapter, you



1 know, we talked about what some ideas should be around how  
2 we would evolve this benefit to the extent that -- or, you  
3 know, coverage of services, to the extent that evidence and  
4 innovation make that important.

5 Thanks.

6 MS. KELLEY: Jonathan Jaffery.

7 DR. JAFFERY: Thanks, Dana, and thanks, Ariel and  
8 Ledia. This has been a great discussion. I'll be brief.

9 I broadly agree with the points put forth on the  
10 slide, but also have a few concerns that really largely  
11 echo what others have said. The physical therapy, for  
12 example, as a coverage issue, I think it's important that  
13 we don't just sort of carve these things out whole cloth.  
14 In addition to the comments people have made, there are --  
15 while there may be -- broadly may not be huge access issues  
16 for things like physical therapy, there's a big range of  
17 services. So Jon used a personal example. I'll use one.  
18 Many Commissioners know I had Bell's palsy about a year ago  
19 and continue to receive some physical therapy that's very  
20 specialized for that. For one thing, that's actually, I  
21 think, our video services are -- if anything, may actually  
22 be more valuable than in-person in some ways. But even

1 beyond that, that's not a physical therapy service that  
2 necessarily is broadly available, and so for beneficiaries  
3 who don't live near a big center where that might be  
4 available, it could be valuable to be able to have that  
5 service because it may be something they need to get  
6 frequently.

7           The other thing I really want to emphasize is  
8 also the audio-only services, sort of piling on to what  
9 others have said. I don't think we have the evidence here  
10 to suggest that the quality is necessarily lower or that  
11 there are consistent reasons to think that services are  
12 better when you can lay hands on people and/or see them.  
13 And so this -- and, actually, you know, Jon had mentioned  
14 the opportunity to reduce infectious exposure. You know,  
15 next fall we're not going to have the same issue for COVID,  
16 hopefully, but we will have a flu season, and that actually  
17 impacts Medicare beneficiaries a lot each year, too.

18           So not limiting the ability to keep people out of  
19 our waiting rooms if necessary when at this point I don't  
20 think we have evidence that the care is less good is  
21 important, which I think lends credence to Bruce's idea of  
22 maybe a period of time where we can think through how to

1 get -- expand coverage with evidence development.

2           And then a final comment I'll make sort of builds  
3 on something Dana had said about -- that I think is sort of  
4 a long game notion of instilling within the health care  
5 delivery system the opportunity to decrease some of our  
6 fixed costs over time and some of our brick and mortar  
7 needs. We've talked a fair bit in the Commission at  
8 different times about this larger movement to home-based --  
9 more and more home-based care, and I think the ability to  
10 use the innovations that we're already getting and  
11 continuing to get with telehealth will facilitate that and  
12 be sort of foundational for that, as will this longer-term  
13 movement towards health systems not continuing to put more  
14 and more capital investments into all these brick and  
15 mortar buildings that then just propagates the need to keep  
16 seeing people in those buildings.

17           Thank you.

18           MS. KELLEY: Marge?

19           MS. MARJORIE GINSBURG: Great, thank you. I  
20 think previously I've registered my curmudgeonly views  
21 about this topic, and it hasn't change, though I must say  
22 that many of your comments today have made me modify my

1 curmudgeonly instincts. But I still am very concerned.  
2 Someone made a reference to we can't put the genie back in  
3 the bottle. Well, actually, you know, I think we can. And  
4 because there was this opportunity to do telehealth and  
5 everybody geared up really fast and really well does not  
6 say to me, therefore, we should continue to do this in the  
7 future. I think the Commission's emphasis has always been  
8 on evidence-based, value-based practices, and that's what  
9 we focus on. And I'm not convinced that we have either one  
10 of those elements in place now for universal telehealth  
11 across all avenues of fee-for-service medicine.

12           Having said that, I actually propose what I think  
13 was the Commission's recommendation in its congressionally  
14 mandated report in 2018, which is that we start with  
15 particularly two-sided APMs, that we let the fee-for-  
16 service world that is accustomed to trying to do things  
17 better in order to assure higher income would be the place  
18 to test this out, not in the general world.

19           So, anyway, I'll stop there. I think my views on  
20 this subject are established. Thank you.

21           MS. KELLEY: I have Bruce next.

22           MR. PYENSON: Thank you, and thank you, Ariel and

1 Ledia, for a terrific chapter.

2 Marge, I'm sympathetic to your view. I think one  
3 of the most interesting sessions we had a month ago was on  
4 private equity's role in health care and Medicare. And  
5 private equity is certainly very interested in telehealth,  
6 and they're not probably particularly interested in the  
7 kind of telehealth that we've been mostly talking about  
8 today, which involve individual physicians and their  
9 patients. So I think the term "telehealth" means a bunch  
10 of different things. There's at least two or three  
11 different major kinds of telehealth, and one is the  
12 extension of the services that we've seen with the public  
13 health emergency, but there's other forms of telehealth,  
14 and my concern is that making some of what we're talking  
15 about permanent will result in payments that are far too  
16 high for telehealth enterprises. And I think it was Larry  
17 that mentioned the telehealth-only organizations. And let  
18 me describe what I see as emerging in these organizations.  
19 I think they can do a terrific amount of good, but it's  
20 very different from the sorts of things we've been talking  
21 about, but it would be swept in under some of the fee  
22 schedules we're talking about.

1           So a telehealth company would recognize the  
2 caller based on their phone number, will use AI systems to  
3 collect data from the patient before the patient is  
4 directed to a physician or a PA or an NP in a phone pool.  
5 It will sweep in information perhaps from Blue Button or  
6 data from their EMR or relevant data from their Internet  
7 searches. This is perhaps very different than what we  
8 normally consider physician services, so perhaps this type  
9 of telehealth that I'm describing should be a different  
10 kind of Medicare benefit and not a physician service. And  
11 that's growing very rapidly. As I said, it can bring an  
12 enormous amount of efficiency to the health care system,  
13 and we need to think about that. But because of that  
14 potential, which is happening very rapidly, I want to  
15 suggest that any of the continuation that we are talking  
16 about -- and I think there's terrific ideas for that, but  
17 any of those continuations, extensions, be temporary while  
18 we work out the broader view of how to handle what I'd call  
19 "stand-alone telehealth enterprises."

20           I do want to also recognize Brian's comment that  
21 HIPAA protection of protected -- individually identifiable  
22 protected health information is just the tip of the

1 iceberg, and the broader issues companies are adopting high  
2 HITRUST or SOC 2 or other higher types of security because  
3 the patient's Social Security number and their credit card  
4 information is worth a heck of a lot more to bad actors  
5 than what their diagnoses are.

6           So just in short, I think the changes we're  
7 seeing are going to -- potentially could, as Larry said,  
8 threaten the existing physician practices and roles of  
9 physicians, so I think we have to proceed very carefully  
10 and think about those other types of telehealth that are  
11 based on an individual physician and individual patient  
12 with whom they have a relationship.

13           Thank you.

14           MS. KELLEY: Jaewon?

15           DR. RYU: Yeah. I think, like many others, I  
16 like the balance that's been struck with all the policy  
17 ideas and suggestions here, basically the ones covered in  
18 Slide 4 through 12. I think it strikes a good balance  
19 between the benefits of this modality of care but also the  
20 potential for unintended consequences.

21           I do think, though, that whether it's rural or  
22 with the A-APMs, I think those scenarios merit even greater

1 flexibility, and some of the examples, a lot of folks  
2 talked about the audio-only. I would agree with that.  
3 Some folks mentioned the cost share, especially with A-APM  
4 models. I think creating some flexibility there makes  
5 sense, acknowledging that the A-APMs carry with it some  
6 administrative and logistical complexity around how that  
7 would be administered.

8           But the other one that I wanted to throw in there  
9 is actually the second of the "incident to" suggestion, so  
10 the one around supervision. I think the first "incident  
11 to" suggestion that any clinician who can bill directly  
12 should do so. I agree with that.

13           On the second "incident to" suggestion around  
14 direct supervision, again, I think if you're in one of  
15 these other environments, whether it's rural or A-APM, I'd  
16 be in favor of creating additional flexibility there.

17           Lastly, I want to just touch on something that  
18 Larry mentioned because I think the other nuance that might  
19 make sense is to split scenarios between things that are  
20 truly chronic disease management versus services that are  
21 more episodic or urgent convenient care in nature, because  
22 I think for the chronic disease management bucket of



1 services, however those could be defined, I think  
2 familiarity of visit and continuity need to be taken into  
3 account versus the episodic stuff where a fragmented  
4 experience with an unfamiliar provider may not be as big of  
5 a deal.

6 I think in the chronic care, the continuity to me  
7 would speak in favor of making sure that the provider is  
8 someone who is an established provider with the patient.

9 MS. KELLEY: Pat.

10 DR. CHERNEW: Dana, I think we have -- yeah. I  
11 think we have Pat and Wayne left. Is that right?

12 MS. KELLEY: And Betty also.

13 DR. CHERNEW: And Betty. Okay.

14 And then we have five minutes left, and I have  
15 something I need to sum up at the end.

16 Pat, thanks for your comment.

17 MS. WANG: Okay. I'll make this quick. I just  
18 want to observe that the discussion that we've been having  
19 sort of points out how the fee-for-service system limits  
20 innovation because everything that we have been talking  
21 about are new modalities and care, which will continue to  
22 evolve, but because it's in the context of the fee-for-

1 service system, we are desperately trying to put up walls  
2 and safeguards and so forth to limit the eventuality, the  
3 certainty of low-value care and outright fraud, waste, and  
4 abuse.

5 I appreciate what folks have said about being  
6 tough on providers and really catching the outliers.  
7 Medicare already does this. They have cases that they are  
8 prosecuting that predated the public health emergency.  
9 They have to prosecute them to the end. They can exclude  
10 people from the Medicare program. This exists today. I  
11 don't think that we should underestimate the risk, that as  
12 attractive as these new modalities are for people, that  
13 within the fee-for-service system, it's just the portal to  
14 access, inappropriate spending is unbelievable.

15 And so I wanted to suggest that one of the things  
16 that perhaps we should be thinking about going forward --  
17 because right now, this is the list of what the telehealth  
18 innovation that is available. Tomorrow there will be  
19 something different. That we focus more on the safeguards  
20 and also maybe form of payment.

21 Jaewon mentioned something about established  
22 providers. Maybe there is such a thing as a telehealth

1 bundle that can be paid to the primary care physician who  
2 will have the most flexibility on the amount of telehealth  
3 that somebody can have. The idea that a beneficiary can  
4 have all of these disjointed telehealth providers giving  
5 all kinds of services, I think, is not anything that we  
6 would want, whether it was in person or virtual.

7           So I like the idea of kind of focusing more about  
8 the payment wrapper and who will be responsible for  
9 administering those services, whatever they may be going  
10 forward.

11           And the final thing that I will say about audio-  
12 only, which I think is particularly valuable in talk  
13 therapy, behavioral health, I struggle with audio-only  
14 because I think that there really is a big health equity  
15 gap that gets solved by audio-only. But I think the  
16 potential for fraud, waste, and abuse with audio-only is  
17 immense, and so I kind of hope that where we get is to a  
18 point where even folks who don't have easy access to video  
19 capability have a helper in the home that at least once a  
20 month that they can have a video chat with somebody as  
21 opposed to just rely on the telephone.

22           I think the telephone really is an open door to a

1 lot of abuse. As attractive as it is, I think the downside  
2 is pretty big.

3 That's all. Thank you.

4 MS. KELLEY: Wayne?

5 DR. RILEY: Yeah. Great discussion,  
6 Commissioners.

7 I just want to underscore a couple things. One,  
8 Dr. Perlin mentioned the issue with critical access  
9 hospitals and access to behavioral health services in a  
10 group context. They already struggled with access to  
11 psychiatrists and clinical psychologists and licensed  
12 social workers, psychiatric social workers, et cetera, who  
13 can provide this type of service to critical access  
14 hospitals and in rural areas as well. So I would not want  
15 to see us embrace anything that makes it harder for that  
16 key aspect of our health care system to operate and to  
17 provide good mental health services.

18 Secondly, Pat just mentioned telephone. I can  
19 tell you here in Brooklyn, during the height of the  
20 pandemic, in central Brooklyn where we had the highest  
21 incidence in prevalence in black and brown communities, we  
22 pivoted to, quote/unquote, "telehealth." And Pat is right,

1 45 -- 48 percent of the visits were telephone exclusively.  
2 So, again, the access to broadband and to a family member  
3 in a household for some of our inner-city neighborhoods is  
4 not all that good or it's uneven.

5 I understand we have to put some guardrails  
6 around telephone, but I would not want to embrace an idea  
7 where we totally discontinue telephonic access,  
8 particularly for vulnerable communities.

9 MS. KELLEY: And Betty.

10 DR. RAMBUR: Well, thank you all. I'll be very  
11 brief.

12 I just wanted to comment that the ideas up around  
13 non-physician chronic care management is really exciting  
14 and interesting to me. I'm thinking about whether or not  
15 these should be different lines.

16 I actually had the experience as a nurse  
17 practitioner of flying in small planes to rural areas, and  
18 also, in the early 1990s, PT was being delivered. And I  
19 can't even think of the technology, and I think of the  
20 enormous opportunities now for service that can really be  
21 thought about differently.

22 So how do we package the payment to make that

1 happen? I have to say I don't fully know, but here are the  
2 things that I do support.

3 I think the reimbursement has to reflect the  
4 resources used, and as Dana and others have said over time,  
5 this actually, hopefully, creates some of the right  
6 structuring of our infrastructure.

7 I do support cost sharing. I think it's  
8 essential, and yet are there certain types of services we  
9 want to incentivize using virtual care and telehealth and  
10 have different cost-sharing strategies?

11 It's really hard for me to imagine not including  
12 audio. So where are the guardrails around that? Because  
13 for all the reasons that you have said.

14 Then I strongly support the elimination of the  
15 first "incident to" billing for the reasons discussed here  
16 as well as for many other reasons.

17 So thank you. Thank you all so much for the  
18 great ideas.

19 DR. CHERNEW: Terrific. Thank you, everybody.

20 We are a minute over, and we're about to be three  
21 minutes over before we jump into the next session on rural  
22 health. But I think it's important that I give you all a

1 sense of where we're going.

2           We are going to review the transcript, think  
3 about where there's consensus, where there's not, where we  
4 need some more thinking, and come back again in January.

5           I'm going to give you a quick summary of my  
6 takeaways so we can get some sense if I got this right or  
7 wrong. Everybody look into the camera and smile or  
8 grimace, and we'll do a quick count. We're not voting.  
9 We're just smiling and grimacing. That was a joke.

10           So a few things. I think there's reason to  
11 believe that whatever we do, some sub-setting or  
12 reexamination is important. It's not how much evidence  
13 will or how or can be generated, though obviously that  
14 matters.

15           I think there was a fair bit of support for the  
16 notion of paying less. Obviously, that comes with the  
17 notion of understanding a better cost measurement, but  
18 there seems to be support there.

19           There was some support, I think, for requiring  
20 face-to-face, certainly for ordering certain types of  
21 services, but perhaps more broadly, face-to-face to prevent  
22 broad expansion of services.

1 I think there was general support, a few  
2 questions about the general support for some reforms of the  
3 "incident to" billing, at least parts of the "incident to"  
4 billing things we've discussed.

5 I think cost sharing was very interesting because  
6 I think there was general support for cost sharing.  
7 There's recognition. I agree with your point, Larry, that  
8 the administrative aspect of how to do cost sharing, if  
9 we're sending everybody a bill for 36 cents or \$2.20, it's  
10 probably not important. And trying to figure out how to  
11 interact with supplemental coverage and administer costs is  
12 important, so we will think about cost sharing.

13 Generally speaking, I found a lot of support for  
14 maintaining access to audio-only, and we will give that  
15 some thought, although I don't think that was necessarily a  
16 universal view per what Pat and some others said.

17 There's a question, of course, about what people  
18 can do versus what we will pay for them to do, and we'll  
19 give some thought there.

20 There were a few other areas of interest that I  
21 think are important. One is if we could use some other  
22 types of guardrails. A good example would be some aspect



1 of participation in the Medicare program or booting you out  
2 if you're found to be abusing the telehealth privileges,  
3 potential caps on a doctor as opposed to particular  
4 beneficiary level, to identify people that might really be  
5 churning through in a range of ways.

6 I think Amol's point about maybe doing this by  
7 service or even having multiple tiers is something that we  
8 can explore a little bit more.

9 My overarching view is, unfortunately -- and I  
10 want to emphasize the word "unfortunately" -- we're going  
11 to have to throw out some of the good to protect ourselves  
12 against some of the bad, and we will continue to think  
13 about that. And so the argument that there's a lot of good  
14 there, I do not dispute, and I agree we want to harvest it.  
15 But every time we do, we have to ask how much of the bad  
16 are we letting under the tent when we support the good. If  
17 we could observe perfectly, this would be a lot easier job,  
18 but we can't. So we have to find an administratively  
19 feasible way to get as much good as possible and still  
20 protect the program integrity, and some of that is work  
21 that we are going to get you to do, recognizing Bruce's  
22 distinction between traditional and I'll call it

1 telemedicine-only companies and try and make sure we can  
2 get to the future, as Dana said the spot on the wall, where  
3 we have more efficient care delivery without way  
4 overpaying.

5           So that's my -- it was going to be quick. Now it  
6 was intermediate summary, but that said, we will continue  
7 this discussion over the course of our meeting. And for  
8 now, we're going to move on to -- I think it's Brian,  
9 Carolyn, or Jeff. One of those is going to go first, and  
10 we're going to talk about another super, super important  
11 issue, which is access to care in rural areas.

12           So am I turning it over to Brian whose name is  
13 first on the slide or someone else?

14           MR. O'DONNELL: Yep. This is Brian. I'll start.

15           DR. CHERNEW: Thanks, Brian.

16           MR. O'DONNELL: Good afternoon. In this  
17 presentation, we'll discuss our work towards fulfilling a  
18 congressional request to study rural beneficiaries' access  
19 to care. Before I give an overview of the congressional  
20 request, I'd like to thank Alison Binkowski for her  
21 assistance with this work.

22           Also, the audience can download a PDF version of

1 these slides in the handout section of the control panel on  
2 the right-hand of the screen.

3           The House Committee on Ways and Means submitted a  
4 bipartisan request for the Commission to update its June  
5 2012 report on rural beneficiaries' access to care.

6           The committee also requested information on  
7 beneficiaries who are dually eligible for Medicare and  
8 Medicaid, reside in a medically underserved area, or have  
9 multiple chronic conditions. We'll come back to you in the  
10 spring with more information on these groups of  
11 beneficiaries.

12           And, finally, the committee requested that the  
13 Commission analyze emerging issues that could affect  
14 beneficiaries' access to care.

15           An interim report is due in June 2021, and a  
16 final report is due in June 2022.

17           We have three parts to our presentation today.  
18 In the first part, we begin to update the Commission's 2012  
19 work by comparing rural and urban beneficiaries' use of  
20 clinician and hospital services.

21           Just a quick methodology note before we get into  
22 the results. In the 2012 report, the Commission examined

1 ambulatory volume by combining clinician office visits and  
2 hospital outpatient department visits. In our current  
3 work, we disaggregate ambulatory services into detailed  
4 categories to provide more granular results.

5 To measure clinician use, we focused on  
6 encounters beneficiaries had with clinicians that involved  
7 an E&M service. E&M services represent about half of all  
8 Medicare physician fee schedule spending and are billed by  
9 many types of clinicians in a wide variety of settings.

10 To ensure we got a complete view of service use,  
11 we tracked utilization across multiple billing pathways,  
12 which are listed on the slide.

13 We found that rural beneficiaries had fewer E&M  
14 encounters than urban beneficiaries in both 2010 and 2018.  
15 For example, in 2018, urban beneficiaries averaged 13.4 E&M  
16 encounters and our two categories of rural beneficiaries  
17 averaged 11.5 and 11.0 encounters per beneficiary.

18 While we found modest differences between urban  
19 and rural beneficiaries, differences in utilization across  
20 geographic regions of the country were larger than  
21 differences between urban and rural beneficiaries within  
22 the same region.

1           Rural beneficiaries' lower E&M utilization was  
2 mainly attributable to fewer encounters with specialist  
3 physicians. In 2018, urban beneficiaries averaged 7.1  
4 encounters with specialists compared with an average of  
5 about five for rural beneficiaries.

6           The difference in specialist utilization between  
7 rural and urban beneficiaries was much larger than the  
8 differences in the use of primary care physicians or APRNs  
9 and PAs.

10           While our claims analysis suggests lower  
11 specialist use among rural beneficiaries, the Commission's  
12 annual beneficiary survey has consistently found that rural  
13 beneficiaries have no more difficulty obtaining specialist  
14 appointments than urban beneficiaries. The combination of  
15 these two analyses suggest that rural beneficiaries can get  
16 appointments with specialists but might visit them less  
17 often, perhaps because rural beneficiaries travel farther  
18 to access specialists.

19           To better understand how beneficiaries access  
20 care, I'll next discuss the location where beneficiaries  
21 received their care.

22           We found that rural beneficiaries increasingly

1 received their clinician care in urban areas, suggesting  
2 increasing travel times.

3 We also found that rural beneficiaries are more  
4 dependent on hospitals to access clinician care, and that  
5 this dependence is growing.

6 In 2018, urban beneficiaries had 29 percent of  
7 their E&M encounters in hospitals, compared with 34 percent  
8 to 40 percent for rural beneficiaries. In addition, while  
9 the shift to hospitals occurred among all beneficiaries,  
10 the shift was more than twice as rapid for rural  
11 beneficiaries from 2010 to 2018.

12 DR. STENSLAND: After examining clinician use, we  
13 shifted to examining differences in rural and urban  
14 hospital uses. We found that, on average, inpatient  
15 admissions per capita were very similar in rural and urban  
16 areas. There are large regional differences across states,  
17 but within states, the rates tend to be similar. For  
18 example, there is a low admission rate in Hawaii in both  
19 rural and urban areas. In contrast, there is a high  
20 admission rate in West Virginia in both rural and urban  
21 areas. The admission rate differences we found were  
22 regional, and they weren't a rural/urban phenomenon.

1           On the outpatient side, there tends to be  
2 slightly higher use in rural areas, but this may reflect  
3 where beneficiaries receive care as opposed to how much  
4 care they receive. For example, urban beneficiaries may be  
5 more likely to get an imaging services at free-standing  
6 imaging center, but in a small rural town, the hospital may  
7 be the only provider of a CT scan.

8           As was the case with inpatient care, we find that  
9 regional differences in outpatient service use were much  
10 larger than rural/urban differences.

11           After reviewing how care is delivered in rural  
12 and urban areas, we found that rural ambulatory care,  
13 including primary care, was increasingly dependent on  
14 having an institutional site for that care. Currently,  
15 that institution is often the rural hospital. That raises  
16 questions about how many rural hospitals have been closing  
17 and what options are there for either preserving the  
18 hospital or providing other sources of ambulatory care in  
19 the rural communities.

20           We found that rural hospital closures have been  
21 increasing modestly in recent years, and we wanted to  
22 examine what changes in hospital use may have led to the

1 closures. We identified 40 closed hospitals that met our  
2 criteria for analysis. The 40 were all open from 2005 to  
3 2014. They were the only hospital in town, and then they  
4 all closed between 2015 and 2019. We do not have full data  
5 for 2020, but it appears that after a spike up in closures  
6 in 2019, the rate of rural closures in 2020 has declined  
7 back to a similar level that we saw in 2013 to 2018.

8           In addition to examining claims data, we  
9 conducted interviews to better understand how rural  
10 beneficiaries in those towns obtained their health care  
11 prior to closure and after the hospital closed.

12           When we examine claims data from closed  
13 hospitals, we find that the closed hospitals were more  
14 important as a source of outpatient care than inpatient  
15 care.

16           With respect to inpatient services, we found  
17 large declines in inpatient use prior to the closure. From  
18 2005 to 2014, all-payer discharges fell by 53 percent and  
19 Medicare discharges fell by 61 percent.

20           With respect to Medicare, about two-thirds of  
21 that decline was due to the hospital's loss of market  
22 share. This means beneficiaries living in the 40 rural



1 hospitals' markets were increasingly bypassing their local  
2 hospital and going elsewhere for inpatient services. The  
3 remaining one-third of the decline in admissions reflects a  
4 shrinking of the market for inpatient services, meaning  
5 people living in the hospital's market area were receiving  
6 less inpatient care overall.

7           In contrast with inpatient care, we see  
8 relatively constant use of the ED, and overall outpatient  
9 volume only declined slightly prior to closure. On  
10 average, the closed hospitals had provided over 1,000 ED  
11 visits per year and over 5,000 outpatient visits per year  
12 in 2014. This level of services had remained fairly level  
13 for the prior decade.

14           Therefore, prior to closure, it appears the 40  
15 hospitals were more important sources of outpatient care,  
16 including emergency care, than they were for inpatient  
17 care. Carolyn is now going to discuss some of the  
18 information we gained from interviews with stakeholders in  
19 some of those communities where a hospital closed.

20           MS. SAN SOUCIE: To supplement our quantitative  
21 analysis, we conducted three virtual site visits to rural  
22 communities with a recent hospital closure. We interviewed

1 several key stakeholders in each town, including hospital  
2 executives, city and county government officials, hospital  
3 board members, FQHC leaders, and EMS staff. The focus of  
4 these interviews was how access to care in a community  
5 changed after the local hospital closed.

6           In all three communities, the rural hospitals had  
7 furnished little inpatient care before they closed.  
8 Stakeholders suggested that the decline in admissions was  
9 partly due to patients bypassing their local hospitals in  
10 favor of larger, regional hospitals. Local leaders in all  
11 three communities said that ensuring timely access to  
12 emergency and other outpatient care, including urgent care,  
13 was their first priority after their local hospital closed

14           The three communities we visited approached  
15 access to care differently after their hospitals closed.  
16 In the first town, the hospital was converted to an off-  
17 campus emergency department of another hospital 30 miles  
18 away. The 24/7 ED was accompanied by wraparound outpatient  
19 services. The local FQHC provides primary care services on  
20 the same campus. In the second town, the FQHC is the only  
21 healthcare provider in the entire county. The FQHC runs a  
22 primary care clinic and an urgent care center, run by an

1 emergency medicine physician. The state where the second  
2 town is located does not allow for standalone EDs.

3           Since the closure of the hospital in the third  
4 town, there is only one physician practicing regularly in  
5 the entire county. The doctor has a primary care clinic  
6 and recently opened an urgent care center at the same  
7 facility that he and his nurse practitioners staff. An  
8 FQHC located in a neighboring county is working to open a  
9 mobile FQHC site to service the county in which the  
10 hospital closed. The mobile unit will be a bus with an  
11 exam room, laboratory space, and check-in area.

12           Now, I will turn to broad policy options that  
13 policymakers have identified to address the recent increase  
14 in rural hospital closures.

15           Since the inpatient prospective payment system  
16 was implemented, Medicare's primary response to rural  
17 hospital closures has been to increase payment rates  
18 through mechanisms such as an inpatient add-on and cost-  
19 based payments. Rural hospitals can be designated as  
20 critical access hospitals, Medicare-dependent hospitals,  
21 sole community hospitals, and low-volume hospitals to  
22 receive special payments. Over 95 percent of rural

1 hospitals received higher payments under one of these  
2 programs in 2018. Nonetheless, rural hospitals continue to  
3 close.

4           Policymakers have suggested other options for  
5 preventing rural closures through alternative payment  
6 mechanisms. One such policy involves payment through a  
7 global budget. A global budget is an overall limit on  
8 health care expenditures. Hospital global budgets have  
9 been used extensively in Europe and on a more limited basis  
10 in the United States. All of the hospitals in Maryland are  
11 paid through a global budget and recently some rural  
12 hospitals in Pennsylvania have been paid through such a  
13 mechanism.

14           Global budgets for rural hospitals are  
15 predominantly tools to provide revenue stability, and they  
16 remove the volume incentives inherent in fee-for-service.

17           While global budgets could help support access in  
18 rural areas, administering them requires claims data or  
19 analogous sources of information, such as encounter data.  
20 Claims data allows global budgets to be adjusted based on  
21 the providers who actually furnish care to beneficiaries.  
22 Without such adjustments, Medicare payments to hospitals

1 would become inequitable and poorly targeted if  
2 beneficiaries seek care from different providers over time.  
3 Such adjustments require enhanced administrative authority  
4 beyond what CMS needs to implement fee-for-service payment  
5 systems.

6           Policymakers have also proposed alternative  
7 delivery models in communities facing hospital closures.  
8 In June 2018, the Commission recommended that Medicare  
9 allow isolated standalone EDs, those that are more than 35  
10 miles from another ED, to bill standard outpatient  
11 prospective payment system facility fees and provide such  
12 EDs with annual payments to assist with fixed costs. The  
13 standalone ED could retain other services such as ambulance  
14 services and outpatient clinics, a combination which the  
15 Commission referred to as an outpatient-only hospital.

16           Standalone EDs may not be appropriate for all  
17 communities. Some may choose to retain a full inpatient  
18 hospital, while others cannot support an ED either because  
19 of low volumes or state laws that prohibit them. In these  
20 cases, we found that FQHCs played an important role in  
21 maintaining access to clinician services, including urgent  
22 care services. The federal government already makes

1 substantial investments in FQHCs through grant funding and  
2 enhanced Medicare payment rates, but there might be a role  
3 for additional, targeted funding that is directed  
4 specifically at communities that lose their local hospital  
5 but cannot support a standalone ED.

6           To meet the congressional request, over the next  
7 year and a half, we plan to expand our utilization analyses  
8 to include additional beneficiary stratifications. With  
9 regard to rural hospital closures, we would like feedback  
10 from the Commission on their level of interest in exploring  
11 policies, beyond the Commission's recommendation on  
12 standalone EDs, to address potential access issues rural  
13 beneficiaries may face.

14           With that I will turn it back over to Mike.

15           DR. CHERNEW: Great. Thank you so much, and I  
16 think Jonathan Jaffery is the first person in the Round 1  
17 queue. Is that right, Dana?

18           MS. KELLEY: That's correct.

19           DR. JAFFERY: Great. Thank you. Thanks for the  
20 great presentation and I really this we appreciate sort of  
21 tying back to our 2018 recommendations around some of the  
22 standalone ideas.

1           But a quick question. On Slide 6 you showed the  
2 difference in E&M utilization between rural and urban in  
3 2018. Do you have any data about how that may or may not  
4 have changed over time?

5           MR. O'DONNELL: We only did that breakdown by  
6 specialist and PCPs in this one year, but having said that,  
7 when you look at the total E&M kind of difference between  
8 urban and rural beneficiaries, it has stayed fairly  
9 consistent from 2010 to 2018. So we haven't run this  
10 particular analysis in every year, but my suspicion is that  
11 it would probably look pretty similar, given the total kind  
12 of difference has been pretty static.

13          DR. JAFFERY: Thank you.

14          MS. KELLEY: Dana, did you have a Round 1  
15 question?

16          DR. SAFRAN: Yes, a couple of them. Thank you.

17                 First question is -- I didn't see this and I  
18 apologize if it was in the chapter -- are the utilization  
19 comparisons risk adjusted?

20          MR. O'DONNELL: They are not. They are raw  
21 numbers.

22          DR. SAFRAN: Hmm. Okay. Second question, in

1 talking about global budgets, and, you know, as a policy  
2 option and revenue stability for rural hospitals, you  
3 talked about challenges related to claims data, and I was  
4 confused by that, just because Medicare does have access to  
5 claims data. So can you just explain, or did I  
6 misunderstand?

7 MR. O'DONNELL: Sure. So I think what we are  
8 trying to say there -- and just to be clear, there could be  
9 a whole presentation on global budgets -- but I think the  
10 thumbnail sketch that we were trying to provide is that a  
11 global budget is not just kind of you give a hospital a  
12 chunk of money and kind of set it and forget it. In all  
13 the models that we've seen, what happens is you give a  
14 hospital a global budget and then the money follows the  
15 person, so to speak. So if benes choose to go to a  
16 different hospital, maybe an urban hospital or another  
17 rural hospital, you need a fairly robust claims  
18 infrastructure to adjust the global budgets.

19 And I agree with you the current fee-for-service  
20 payment infrastructure is already there, and I think one of  
21 our points was that you'd need to maintain something akin  
22 to that to adjust the global budgets over time.



1 DR. SAFRAN: Got it. Yeah, I think it would be  
2 good to clarify that in the writing, and, you know, I think  
3 maybe part of what you're thinking about is a kind of  
4 conflating of global budgets and global payments. Right?  
5 So if you make a global payment to the hospital, then yes,  
6 the issue around maintaining the fee-for-service  
7 infrastructure is important. But if it's a global budget  
8 and it's still riding on top of fee-for-service, that was  
9 what I was confused about. So just to clarify that.

10 Two final questions. One, is there anything that  
11 you have available that would let you provide some  
12 information about the distances and drive times for rural  
13 beneficiaries to the closest, next closest facility if  
14 further rural hospitals close? I didn't see anything like  
15 that in the chapter. It seemed like it would be valuable.

16 DR. STENSLAND: Yeah. That's in the appendix.  
17 If you look at the 40 closures, I think there should be a  
18 statement of how far they are from the next hospital.

19 DR. SAFRAN: Right. I did see it. That's part  
20 of what got me thinking about it, was for the existing, for  
21 the continuing, functioning rural hospitals, just  
22 understanding, you know, this issue of bypassing these

1 facilities to go to other ones is important, and just  
2 having some understanding of what kind of distances and  
3 drive times are we talking about. And I understand that's  
4 probably quite different for different rural areas, but  
5 even understanding the ranges I think would be helpful.

6 DR. STENSLAND: Yeah. We can get you a  
7 distribution.

8 DR. SAFRAN: Okay. And then final question, do  
9 you have any information on comparison of quality and  
10 outcomes for beneficiaries residing in rural markets where  
11 this bypassing and going to urban hospitals is now  
12 happening? Because there is some information in the  
13 chapter, and that we all understand, about the relationship  
14 between volume and quality and outcomes that can occur, and  
15 some inferences that you could make from some of the  
16 writings that enrollees maybe have the perspective that  
17 they will get better quality care if they go someplace  
18 else, et cetera. So I just wondered if there are data  
19 available that would allow any actual analysis of  
20 differences in quality and outcomes once beneficiaries  
21 started to use facilities that have greater volume than the  
22 rural hospitals that they had been going to.

1 DR. STENSLAND: I don't know if we have the  
2 differences in outcomes for people who switched locations.  
3 In our last rural report we had a separate discussion of  
4 the literature in our own analysis of risk-adjusted  
5 mortality rates for the smaller rural hospitals versus  
6 larger hospitals, and the smaller rural hospitals tended to  
7 have slightly higher mortality rates 30 days post  
8 discharge, compared both to larger rural hospitals and  
9 there was also a rural-urban differential there.

10 If we decided to do that again there might be  
11 some choices made, because it actually takes a lot of time  
12 to go through that analysis. We could discuss the  
13 literature, but if we did our own analysis again it takes a  
14 lot of time, just because it's a very sensitive topic.

15 DR. SAFRAN: Yeah. Okay. I'm happy to take it  
16 offline, and just to be clear, what you're just describing,  
17 population level was what I meant. I didn't mean for the  
18 individual beneficiaries who made a decision to go  
19 somewhere else.

20 MS. KELLEY: Bruce, did you have a question?

21 MR. PYENSON: Oh, I did. Thank you. Terrific  
22 chapter. I want to compliment the authors.

1           My question is whether there is information that  
2 might be useful from the international studies. Certainly  
3 the United States is not the only country that has rural  
4 versus urban health care issues -- it's been an issue in  
5 Canada, Australia, perhaps other places -- and whether it  
6 would be useful to affix some information from some of  
7 those studies and include it in the report, for  
8 perspective. I would be curious what the authors think  
9 about that.

10           DR. STENSLAND: We can look into that and get  
11 back to you. There have been some studies in Canada and  
12 Norway. They have different payment models than we do, but  
13 we could look into that.

14           MS. KELLEY: Amol?

15           DR. NAVATHE: I had a similar question, I guess,  
16 as Jonathan and Dana, on Slide 6, where you have the  
17 differences in the specialist utilization, the rural benes.  
18 And I guess what I was trying to understand, and I wonder  
19 if what Dana pointed out about the raw versus risk-adjusted  
20 accounts for this, I was trying to get a sense of if we  
21 have any hypothesis for why we would see such differences  
22 in utilization of specialists with the survey that's also

1 telling us that there's no differences in ability to access  
2 services. So how would we account for those differences?

3 MR. O'DONNELL: Sure, and I don't think we have  
4 kind of a great explanation for it. I think just  
5 anecdotally, when you say, you know, a lot of these  
6 communities they cannot support a specialist locally, so  
7 that in all likelihood they do have to travel. So I think  
8 that's our leading hypothesis is that there's a travel  
9 distance issue. But having said that, we don't have any  
10 firm data on what exactly explains that delta.

11 DR. STENSLAND: And risk adjustment, we didn't  
12 risk-adjust these data. We looked into it last time, and  
13 you find two different things. One, if you look at HCC  
14 scores, the rural beneficiaries tend to have lower HCC  
15 scores, indicating that they would be healthier. If you  
16 look at mortality, they have higher mortality. Their life  
17 expectancy is a little bit lower at 65 than the urban  
18 individuals.

19 And I think part of the problem is if you look at  
20 our payment models that we have in rural areas, whether  
21 it's the rural health clinic or the critical access  
22 hospital, you're often getting paid a fixed overall rate

1 per visit or based on your costs. So your incentive to  
2 code is much lower than it is in urban areas. So we're  
3 somewhat skeptical that just to look at the claims data and  
4 then come to the conclusion that rural people are  
5 healthier, I think that would be somewhat of a dangerous  
6 assumption. And if we're not going to use claims data for  
7 risk adjustment, then it comes down to what would we use,  
8 that's, at this point, where we decided not to do at least  
9 the risk adjustment, at least at this point.

10 DR. NAVATHE: That's very helpful, Jeff. I mean,  
11 I think it's interesting that the surveys turn out what  
12 they do turn out, because I think if it is indeed true that  
13 they have higher mortality and therefore we might insert  
14 that they are equivalent, or at least equivalent risks.  
15 Say, if it's a coding thing, then the ability to  
16 consolidates visits because of distance, as you're  
17 implying, Brian, it would be impressive if that's actually  
18 what was happening. And I would kind of wonder if there's  
19 lower expectations or there's something else kind of  
20 underlying here. Not that we need to go adjudicate all  
21 this, but I found that in the chapter, the way that we  
22 described it was kind of accepting of that as fact and then

1 just moving on. And I wonder if we should maybe at least  
2 soften that a little bit and say that that's worthy of more  
3 investigation, or something like that.

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

5 MS. THOMPSON: Yes, thank you, Dana. I have  
6 three questions, and, again, thank you for this great  
7 report. And I really appreciate this conversation.

8 When you interviewed the three communities who  
9 lost their hospitals, my first question is: Related to,  
10 you know, the implication that there appeared to become a  
11 more integrated relationship between the hospital and the  
12 FQHC, can you talk about anything you learned from maybe  
13 reducing overhead, reducing infrastructure, that might have  
14 occurred in those two communities?

15 MR. O'DONNELL: Go ahead, Jeff.

16 DR. STENSLAND: You know, in two places the  
17 hospital closed, so you have all that general  
18 infrastructure with the hospital is gone. And then they  
19 souped up the FQHC to a degree, to have more of an urgent  
20 care center, including with a physician in one place  
21 trained in emergency medicine. But that infrastructure is  
22 going to be much smaller than the hospital's

1 infrastructure. And when we talked to these places -- and  
2 probably over the years I've talked to maybe 20 different  
3 communities where a hospital was closed, and it's very  
4 common that what you see is, you know, the patients still  
5 live in that town, but now often they travel to the next  
6 county over, which is 25 miles, to get their care. And  
7 some of the people that used to work in that town now go  
8 work 25 miles away in the other town where the hospital is,  
9 where now the patients are going. You kind of think of the  
10 shift of employees and patients over to the town that's 25  
11 miles away. But the overall level of employment to take  
12 care of those people is probably a little bit lower because  
13 you're just consolidating things into one facility.

14 MS. THOMPSON: Okay. And then in relation to the  
15 funding to FQHCs, did you learn anything about the FQHC's  
16 ability to recruit providers, physicians, to the community  
17 that was an advantage over what the now-closed hospital  
18 had?

19 DR. STENSLAND: I could take that too, I guess,  
20 but I think they definitely have some advantages. First,  
21 there's the FQHC grant funds. Second, there's a loan  
22 forgiveness program which attracts a lot of people. And



1 then there's some liability protections. But I think the  
2 main point, which Sue is probably very familiar with, is  
3 that in these communities we think you need some entity to  
4 be doing the recruiting given the current nature of  
5 residents not necessarily wanting to hang out their own  
6 shingle. So you're going to need either a hospital or an  
7 FQHC or something that's going to say, okay, we're going to  
8 bring you into this small town. But there are some  
9 advantages of the FQHC, including a higher payment rate  
10 compared to just a physician billing off the fee schedule.

11 MS. THOMPSON: And then my final question relates  
12 to telehealth, kind of reflecting back on our last  
13 conversation. Did you learn anything about the use of  
14 telehealth by any of these three communities in accessing  
15 specialty services prior to their decision to close?

16 MR. O'DONNELL: So my colleagues can jump in  
17 here, but, you know, even before -- you know, so we talked  
18 to them while the pandemic was happening. But even before  
19 the pandemic was happening, you know, there really weren't  
20 specialists in the town. So the extent you were getting a  
21 specialist visit, you were either driving, which is the  
22 predominant modality pre-pandemic, or doing telehealth, so

1 driving to, you know, let's say your local RHC and then  
2 getting a specialist visit that way.

3 MS. THOMPSON: And did these three organizations  
4 use that technology, or any of them? Do you recall, Brian?

5 MR. O'DONNELL: I'd have to check my notes. I do  
6 believe some of them were doing telehealth visits. Some of  
7 the FQHCs were definitely engaged in telehealth visits. I  
8 can't remember the exact breakdown of whether it was video  
9 or audio, but they certainly were.

10 MS. THOMPSON: Okay. Thank you very much.

11 MS. KELLEY: Jon Perlin, did you have a Round 1  
12 question?

13 DR. PERLIN: Yes, thank you. Again, thank you  
14 for this chapter. My question is this -- behind it is  
15 really a concern that the average rural patient believes  
16 multiple truths across the spectrum of reality. You know,  
17 I guess behind that is the question whether hospital  
18 closure is really the key determinant of those patient  
19 outcomes. So my question really on this chapter is: Are  
20 there other sources of data that might help us understand  
21 or inform what the ideal set of resources are for  
22 supporting rural beneficiaries?

1 DR. STENSLAND: I'm going to say when we -- I  
2 don't know if you were here when we had our freestanding ED  
3 recommendation. I think you were here. But the take there  
4 was we would give the small community a fixed block of  
5 dollars. They would get the regular outpatient per visit  
6 fee-for-service payment if they were able to be deemed  
7 desirable enough by the patient to get their outpatient  
8 emergency care there. But they would also get a fixed  
9 dollar amount, and they could use that fixed dollar amount  
10 in whatever way they thought was most important for their  
11 community. And I think there's a feeling that there's a  
12 lot of diversity amongst rural communities, and what they  
13 might decide to do with that fixed dollar amount might  
14 vary, and rather than us prescribe what we think is best,  
15 they could decide whether that goes into EMS or does it  
16 really go into supporting on-call coverage for an urgent  
17 care center 24/7. We would kind of allow some flexibility  
18 for the community to decide what's best for itself.

19 MS. KELLEY: Mike, that's it for Round 1. Do you  
20 want to jump in?

21 DR. CHERNEW: Great, Dana. Yes, thank you.  
22 We're about to move to Round 2. We'll have about 35

1 minutes. I just want to make a few very quick points.

2           The first one is the importance of this issue is  
3 remarkably high, and I just want to go on the record in  
4 emphasizing, I think, how much I and I think how much my  
5 fellow Commissioners care about preserving access to care  
6 for individuals in rural communities.

7           The second thing I want to say is at least this  
8 chapter is really in response to a congressional request,  
9 and our primary goal right now is to provide the evidence  
10 that was asked of us about access as opposed to solve the  
11 very complicated problems, although it's useful to have the  
12 types of discussions we've been having.

13           The last thing I'll say relates to some of the  
14 issues like global budgeting. Because we are the Medicare  
15 program, not all-payer systems, we are in a somewhat  
16 different position for certain types of solution than one  
17 might otherwise have. For example, the critical access  
18 program is very helpful, I believe, to a lot of hospitals  
19 in rural communities, except it's only dealing with the  
20 Medicare portion of payment. There's other payers. In  
21 places like Maryland, which are hospital global budget  
22 models, they're all-payer models. And so we have to think

1 through the role that Medicare itself is playing as opposed  
2 to the entire delivery system, which, again, I think is  
3 worth doing.

4 But right now, I think you should move through  
5 the Round 2 questions, and I think, Betty, you're going to  
6 be first, followed by Sue. And then we'll go on to the  
7 rest of the queue.

8 DR. RAMBUR: Okay. Thank you very much. Just by  
9 way of full disclosure, this issue is extraordinarily  
10 important to me. I've spent most of my time living in the  
11 State of North Dakota and the State of Vermont and did my  
12 dissertation on the delivery of home health services to  
13 rural areas, the barriers. So I have a few thoughts that  
14 are both sort of shorter-term and longer-term.

15 One is the principle of quality of nonemergency  
16 services that rural hospitals choose to deliver needing to  
17 be equal to urban. That is a really important principle.  
18 And I also know from my former role regulating rural  
19 hospital budgets that that's actually really complicated,  
20 more complicated than it seems, because organizations often  
21 choose high-margin services, and I'll just give you two  
22 examples that were in public budget hearings. One small

1 rural hospital said they would love to do more in the area  
2 of substance abuse, mental health, but they really needed  
3 to keep doing orthopedic surgery even though there was just  
4 a place up the road that was a center of excellence;  
5 another one considering bariatric procedures.

6           So this also creates problems because often  
7 there's one physician deep doing this, and it's not just --  
8 or maybe two. It's not just the volume that the surgeon  
9 does, or the physician. It's the whole team.

10           So it ends up being a very precarious situation.  
11 So I don't understand how we can't be thinking more  
12 seriously about global budgets in this country for this  
13 setting, and I know there's the all-payer issue, et cetera.  
14 But it seems like it's one strategy towards a more  
15 sustainable revenue stream.

16           So I'm curious if we know early lessons from  
17 Pennsylvania. Is there over the next year an opportunity  
18 to learn something from that? Vermont just adopted a  
19 sustainability planning model in which they are using the  
20 American Hospital Association's essential services for  
21 vulnerable populations to help places divest of some of  
22 these things that they're doing to chase after revenue.

1           My apologies. I just ran out of computer power,  
2 so let me move here.

3           So I think that it would be really interesting to  
4 see some of the things that emerge, especially as  
5 telehealth continues to emerge and creates new  
6 opportunities and fresh opportunities.

7           Our document talked a little bit about our  
8 frontier counties, and I would just underscore my hope that  
9 we continue to look at population density. Vermont and  
10 North Dakota, as just one example, have the same amount of  
11 people but North Dakota has nine times the land mass, so if  
12 you think about the differences of what that means.  
13 There's a county right by where I grew up that's about the  
14 size of Rhode Island and has 0.7 population density. So  
15 the point in bringing this up is that I think it's  
16 important that we think about services and quality, but  
17 equity won't mean the exact same kinds of things, and  
18 certainly different health beliefs, different systems of  
19 emergency transportation, et cetera, really means that  
20 there needs to be the capacity for somewhat of a local  
21 solution.

22           Some of you brought this up in different kinds of

1 ways and with a different way of thinking about this, but I  
2 was really curious what the less use of specialists really  
3 means. We're in a country where we're trying -- where many  
4 of us are trying to think about more primary care and have  
5 these populations really been harmed through the lack of  
6 specialists? I don't know if we know that.

7 Nurse practitioners and PAs are more common in  
8 these areas, and having educated many people who went off  
9 to work in frontier counties, they're often from these  
10 areas and are getting more education to return to them. So  
11 some states still have not lifted the regulatory barriers  
12 to nurse practitioners and PAs. I know that's not within  
13 our wheelhouse, but I think it's interesting and it  
14 certainly impacts delivery in less populated areas.

15 We've talked about removal of the "incident to"  
16 in the last section, but I think it's also very important  
17 to consider, as it is in this chapter as well.

18 And the only other thing I wanted to mention is  
19 the freestanding emergency, at least in my view, also --  
20 it's implemented, and it also has to be incorporated with  
21 the whole system of how do we make sure people are able to  
22 get where they need to be when they need to be. Some parts



1 of the country are very happy with paramedics, and others  
2 that's been absolutely not something they're interested in.

3 So thank you so much for the work you did in  
4 putting this thing, and I'm real excited to hear how it  
5 evolves over the next little bit as we're working on it.

6 MS. KELLEY: Sue?

7 MS. THOMPSON: Thank you, Dana, and thank you,  
8 Betty. Great comments. I would echo everything I heard  
9 Betty say. And I just want to call out I, too, have lived  
10 my entire life in a very rural state and am quite  
11 passionate about this work, and I'm delighted for today's  
12 discussion and what I understand to be our work going  
13 forward.

14 I just want to comment on the focus on the  
15 closures of -- the closure of rural hospitals, and while  
16 there was mention in the narrative of the chapter that, you  
17 know, typically there's a connection between a closure and  
18 the loss of a physician, the workforce issues in rural  
19 America cannot be overstated in this discussion. The  
20 difficulty recruiting providers is immense, especially for  
21 a small rural hospital. No physician, there's no hospital.

22 The beneficiaries that live in rural America are

1 not bypassing their small-town hospital to go to the big  
2 city because they just want to drive into the big city.  
3 There's no doctor that's providing the care they need in  
4 their local hospital. So the workforce issue seems to me  
5 to be a part of this discussion that connects so well to  
6 other chapters we work on. I mean, it's not like we have  
7 to take on a whole lot of other work. We've talked about  
8 the shortage of primary care. We've talked about the need  
9 for telehealth, and all that work integrates I think so  
10 well in making this particular chapter so rich. So I just  
11 want to make sure we don't silo our thinking there and  
12 understand the connection between workforce and what's  
13 going on with these rural hospitals.

14 I was really quite delighted to see in the  
15 interview of these three communities, of the connection to  
16 the FQHCs typically in the communities that I've worked in  
17 where there is an FQHC, they do -- the FQHC does have  
18 additional monies that the not-for-profit hospital does not  
19 when it comes to recruiting providers, and that works well  
20 if you have good cooperation between the FQHC and the rural  
21 hospital. It works very badly if you do not. So I'm very  
22 interested in more discussion around promoting the

1 integration of not only the FQHC and the rural hospital,  
2 but also the public health agency of that rural community,  
3 for those three to come together, and the opportunity of  
4 reducing administrative overhead and, frankly, working  
5 together more collectively. And I think in this pandemic,  
6 by virtue of the fact that we've had to work together,  
7 we've seen more of that. I think that's, again, a piece of  
8 work that I would very much support.

9           And this is old news, but I want to restate. I  
10 think the support for reducing the requirement for  
11 inpatient remains important, remains something that we  
12 should continue to support in order that these small health  
13 care entities can continue to provide outpatient services  
14 and emergency services to rural beneficiaries. And in the  
15 vein of emergency medicine, I think it's really important  
16 that we support EMS as an essential service. In this  
17 pandemic, I've learned in the State of Iowa EMS is not an  
18 essential service, and I understand there's a variability  
19 about whether or not states recognize EMS as an essential  
20 service. But the quality, when we talk about assuring that  
21 quality is the same standard and rural beneficiaries have  
22 access to the same quality, that must apply, I believe, to

1 the pre-hospitalization component of the continuum of care.

2 I want to underscore Betty's comments about nurse  
3 practitioners. Were it not for nurse practitioners in  
4 rural America, our care would be greatly diminished? So,  
5 again, that's a chapter of work that we, I believe, again  
6 need to integrate a great deal into this conversation.

7 Thank you for the opportunity to make comments.

8 MS. KELLEY: Brian, I have you next.

9 DR. DeBUSK: First of all, thank you for this  
10 chapter, and thank you for exploring this topic.

11 Sue, I could not agree more with your comments  
12 about physicians and recruiting and availability. So I  
13 want to make that point first.

14 The struggle there is to recruit and retain  
15 physicians in these rural areas, and I would argue that the  
16 geographic mix of how we train physicians is not correct  
17 right now. The struggle -- we're not going to get a  
18 physician who grew up in New York or grew up in Los Angeles  
19 to be excited about practicing medicine in a small rural  
20 area. And I know I'm speaking in generalities, but I just  
21 think it's very difficult. So, Sue, thank you. I really  
22 appreciated your comments. Betty, I enjoyed yours as well.

1 Thank you.

2           One thing I want to mention -- I've got a list of  
3 items I would like to cover. One is this whole method of  
4 comparing rural areas to urban areas. I'm not sure that  
5 our traditional methods of phone surveys and measuring E&M  
6 visits is going to be adequate. I was really interested in  
7 what you mentioned on pages 6 and 7 of the reading  
8 materials that talked about the HCC scores. And my  
9 question -- and this could have been a Round 1 question,  
10 but I'm trying to keep it in Round 2 -- is: Could we do  
11 some audits and look at the measured or documented HCC  
12 scores versus the actual HCC scores of urban versus rural  
13 beneficiaries? And this is really a question to staff.  
14 I'm wondering if we could, by capturing the systematic  
15 differentials in HCC coding of these fee-for-service  
16 beneficiaries, I wonder if that could serve as a proxy for  
17 how much health care they're receiving or how much health  
18 care they have access to. So, anyway, just curious about  
19 that.

20           The next thing I want to talk about is the  
21 hospital wage index. We sometimes overlook the impact that  
22 the hospital wage index has on hospitals, but a tremendous

1 part of their OPPS and IPPS fee schedules are adjusted  
2 based on that. And the wage index reflects increases in  
3 pay, in gross pay, but the other aspect of labor cost that  
4 it doesn't capture is the efficiency of that labor.

5           As you would expect, a hospital with 200, 300  
6 nurses in it is going to have much more efficient  
7 deployment and utilization of those nurses than a small  
8 rural hospital with six nurses or four nurses. They just  
9 don't have the flexibility. They don't have the large  
10 numbers. So I would argue right now the hospital wage  
11 index graph is a straight line, simply increases with wage  
12 expense, with wage rates. I would argue it's really U-  
13 shaped because in high-wage areas with large workforces,  
14 yes, the wage effect is the principal effect on the  
15 hospital's cost. But I would argue as you move into rural  
16 areas, where labor is less expensive but due to scale is  
17 less efficient, you actually pick up a utilization effect.

18           So instead of having this perfectly linear  
19 hospital wage index scale, I would tell you I believe that  
20 it's actual somewhat U-shaped. It's not a symmetric U, but  
21 it is somewhat U-shaped.

22           And just to give you a feel for the numbers, this

1 little back-of-the-envelope calculation. Let's say a rural  
2 hospital has a 0.8 hospital wage index, but it's a sole  
3 community hospital so it receives the extra 7.1 percent  
4 reimbursement for its outpatient services. Well, at 0.8  
5 wage index for outpatient services, apply 60 percent of the  
6 fee schedule with a 7.1 percent add-on payment, takes them  
7 to 92.4 percent of the national OPPS.

8           Now, compare that, say, to a metropolitan area  
9 that has a large, a very large hospital wage index, like  
10 2.4. Well, applying a 2.4 multiplier to 60 percent of  
11 their fee schedule takes them to 184 percent of the  
12 national rate. So while we look at some of these  
13 incremental payments that we make, say, to sole community  
14 hospitals, Medicare-dependent hospitals, in the grand  
15 scheme of adjustments these are very, very tiny adjustments  
16 when you're looking at something that's varying by, say,  
17 over 100 percent or over 150 percent in extreme cases.

18           The other thing I want to mention is I have been  
19 part of or witnessed a number of affiliations where urban  
20 hospitals reach out to rural hospitals, and I think these  
21 are very well intended attempts to try to save these rural  
22 hospitals. But I'm concerned that what we might

1 inadvertently have is a mechanism for those hospitals to  
2 ultimately fail, and here's why: Initially, it makes a lot  
3 of sense for that urban hospital to reach out to that rural  
4 hospital because they can infuse them with capital, they  
5 can -- it's beneficial to the hospital because they can get  
6 the specialist referrals. The entire arrangement just  
7 makes sense.

8           I think one of the problems, though, is that some  
9 of the outpatient procedures, some of the more profitable  
10 procedures, also start bypassing that rural hospital. So  
11 in an ideal scenario you would still have the emergency  
12 care done in the rural setting and you would have some of  
13 the outpatient care done, the appropriate outpatient care  
14 done staying in that rural setting. And sometimes I'm  
15 concerned that very well-intended, very well-planned  
16 affiliations between urban hospitals and rural hospitals  
17 actually net in a mechanism to continue to siphon off  
18 patients into those more urban areas.

19           So here is my proposal. I think for rural  
20 hospitals you've really got a four-faceted approach.  
21 Number one, looking at the hospital wage index and  
22 acknowledging the fact that it is somewhat U-shaped. I



1 think addressing the recruiting challenges that we have, to  
2 Sue's point, I think we need to train the right geographic  
3 mix of physicians so that they want to practice medicine in  
4 these areas.

5 I also think we should expand on our 2016  
6 publication on converting some of these hospitals to  
7 freestanding EDs. I think there's some real innovation in  
8 that report, because what it basically suggests is some  
9 form of global payment to help offset some of the fixed  
10 costs of these hospitals, and I think it's an important  
11 step toward global budgeting, or at least providing some of  
12 these services through global budgeting.

13 And then, to the final point, I do think we need  
14 to look at global budgeting overall as a way to help some  
15 of these hospitals stay afloat.

16 So thank you. I appreciate the opportunity to  
17 comment.

18 DR. CHERNEW: Great. Thank you, Brian. We have,  
19 I think, David, Paul, Dana, and Jaewon. We have about 15  
20 minutes. So David.

21 DR. GRABOWSKI: Great. Thanks, Mike, and thanks  
22 to the staff for this great work. I'm really excited we're

1 focusing on rural health and I look forward to the future  
2 work that was described that's going to examine the duals.

3           We had a great discussion earlier today on  
4 telemedicine, and I think a key takeaway of that discussion  
5 was the need for Medicare to be more innovative in  
6 considering the best mode of care delivery. I would  
7 encourage us to continue that spirit of innovation here.  
8 Jon Perlin raised this in Round 1, but it's an open  
9 question as to what the right mix of inpatient, outpatient,  
10 and ED services are for our rural communities.

11           My sense is that it's not a one-size-fits-all  
12 solution. Similar to Sue, I was really struck by the  
13 experience from the visits the staff made to the three  
14 communities that experienced hospital closures. All three  
15 towns embarked on very different paths to encouraging ED  
16 and outpatient care. Jeff mentioned flexibility earlier,  
17 and I think that's a really important principle. How does  
18 Medicare give local areas the flexibility to best structure  
19 services? Betty raised global budgets. That might be  
20 obviously one possible way to go about that objective.

21           So I'm really excited we're working on this and  
22 would love to see us kind of -- encourage the kind of

1 flexibility that rural areas can best meet the health needs  
2 of the population.

3           And my last remark, I wanted to flag one possible  
4 area in terms of the staff's future analyses. I'm really  
5 curious about access to Medicare post-acute care services  
6 in rural areas. Betty mentioned her dissertation was on  
7 home health. I'm particularly concerned about skilled  
8 nursing facility services. Back in the spring of 2019,  
9 there was a New York Times story on closures of skilled  
10 nursing facilities in rural areas. Given the pandemic, I  
11 think we may even see further SNF consolidation. I would  
12 love to see what kind of utilization declines we might be  
13 observing during the pandemic, and sort of is that  
14 happening disproportionately in rural areas.

15           I'll stop there and look forward to future work  
16 on these topics. Thanks.

17           DR. PAUL GINSBURG: Thanks. I guess I'm next.  
18 I'm very glad that your report brought up the issue of  
19 rural residents bypassing the closest hospital to go to a  
20 larger regional hospital. I had occasion to look very  
21 closely at a rural hospital which had joined the system,  
22 and in conjunction with that had closed its inpatient

1 services and expanded its emergency department and its  
2 outpatient services.

3           And there are two things I learned. I was able  
4 to see, in hospital association data, the dramatic degree  
5 of bypassing that hospital that was going on in the years  
6 prior to closure. The other thing I learned was in  
7 interviews with medical and nursing executives, how  
8 concerned they were before the closure with the quality of  
9 care, just because the volume was not enough to enable the  
10 nursing staff to maintain its skills. And so, you know,  
11 that's another issue, the quality dimension.

12           I've long been enthusiastic about the  
13 Commission's 2018 recommendations to facilitate the  
14 expansion of ED and outpatient services in conjunction with  
15 inpatient closings.

16           MS. KELLEY: Dana, I think you're next.

17           DR. SAFRAN: Thank you. I'll be really brief.  
18 Just three quick points.

19           One is on your answer to my question about  
20 utilization comparisons not being risk-adjusted,  
21 understanding that risk adjustment is going to be tricky,  
22 given the differences in HCC coding that are very likely

1 going on, I think we have to at least do a sensitivity  
2 check of what we know about utilization differences in  
3 rural versus urban with some risk adjustment. We've got, I  
4 think, some clear evidence that there are health  
5 differences, and so to ignore those in comparing  
6 utilization just seems like it really undercuts our ability  
7 to do justice to this topic. So I'd really urge us to  
8 consider how to do that, even in spite of some steep  
9 methodological challenges that we'll face.

10           Second is, like other Commissioners, I really  
11 support the 2018 work around freestanding ED, and this  
12 chapter, you know, some of what you shared in it really  
13 suggested that we should be thinking about the role that  
14 FQHCs might play in that, if funded properly, for  
15 infrastructure.

16           On global budgets I think the opportunity there  
17 is really an important one, notwithstanding the issue you  
18 raised about potential for double payment. To me, that  
19 raised -- and maybe this won't surprise you, that I'm  
20 suggesting it here -- that we should not just be thinking  
21 about global budgets as a tool for payment of rural  
22 hospitals but also of urban hospitals, and maybe start at

1 the urban hospitals where patients are going to bypass  
2 rural, bringing them into the global budget model as well.

3 I think you make a strong case in the chapter --  
4 and it hasn't been mentioned so I'll just mention it -- for  
5 avoiding cost-based reimbursement because of the  
6 disparities issues with respect to costs and how that  
7 exacerbates disparities.

8 And my final thought is just that, you know,  
9 apropos of our previous conversation around telehealth, and  
10 to what you shared from the first of your three site  
11 visits, I think it's very interesting to consider policy  
12 options that might encourage a partnering between urban  
13 hospitals and rural hospitals, to leverage telehealth care  
14 and specialists in urban settings for patients in rural  
15 settings, even without driving to the urban setting. So  
16 formal partnership between these two to help support the  
17 rural hospitals just seems like something we should  
18 explore.

19 Thank you very much.

20 MS. KELLEY: Jaewon.

21 DR. RYU: Yeah. I'm also supportive of the  
22 standalone ED and the global budget work. I think those

1 are two models that do make sense and could help here  
2 tremendously.

3           One thing that I think might also be helpful is  
4 if there was some measure of, you know, whether it's  
5 ambulatory sensitive conditions, that is there a higher  
6 prevalence in rural markets of things like that landing as  
7 admissions or in the ER, other indications of progression  
8 of disease. Because I feel like, as has been mentioned by  
9 others, there's probably more than just counting the actual  
10 visits, or, for that matter, even just the beneficiary's  
11 perception of whether or not there's access. I think there  
12 may be other ways to get at is there actually an access  
13 issue, even though on the surface it may appear as though  
14 there may not be.

15           I think the other is I just wanted to get back to  
16 Sue's comments around the workforce, just to try to paint  
17 the picture around what this I think looks like. And we  
18 obviously operate in many rural areas as well. But it's  
19 not just the matter of hiring the neurosurgeon oftentimes.  
20 It's also you've got to hire an intensivist. It's growing  
21 the program together, and it's not just one physician. If  
22 you need both of those different specialties you can't hire

1 just one, because to other people's point, they are less  
2 likely to want to come to a place where they're on call  
3 every night. Right? So now you've got to hire three or  
4 four to have a call pool that really works.

5 I think those are some of the practical kind of  
6 considerations and challenges, and it leads me to my last  
7 point. I do think there's something around the regulatory  
8 environment and the framework that may need to be  
9 approached differently for some of these rural markets.  
10 And I don't know if we have information from the 40 or so  
11 places that have closed, but I would be curious to see if  
12 there were any "in-market" or "near market" affiliations  
13 that may have been possible but may have been precluded as  
14 a result of antitrust review and so forth. Because, you  
15 know, if you take the ground rules of an antitrust approach  
16 from an urban market and try to apply them to the rural  
17 market, with all the complexities and challenges that we're  
18 talking about, I don't know if those same considerations  
19 and rules or framework apply, or should apply. And so I do  
20 think that's another dynamic to take into consideration.

21 DR. CHERNEW: Great. Dana, if I understand  
22 correctly that was the last person in the Round 2 queue,



1 which is good, because we're coming to the bottom of the  
2 hour. I will summarize until I see a message from Dana  
3 that someone else wants to chat.

4           Here's my summary. First, I think there's  
5 universal passion about this issue overall. I think I can  
6 hear it in the voices of those people speaking. Second of  
7 all, I believe there's consensus on the real workforce  
8 challenges and the need to think about workforce, because  
9 the workforce is more important than the brick-and-mortar  
10 building, in a whole variety of ways. It has to be thought  
11 of holistically, because it's not just having one person.  
12 It depends on the services you're offering and how they  
13 interact.

14           That relates to a number of issues, including  
15 things like DME and telemedicine, that we discussed in a  
16 whole series of other contexts. So while this is sometimes  
17 treated as the rural chapter, and it will be, understand  
18 that the issue of health care in rural America transcends  
19 vast amounts of the work that we do.

20           What is unique about the rural chapter, in  
21 general, are the scale issues, which you hear in  
22 everybody's voice, about how to deal with them, and I think

1 we're going to have to continue to deal with. Betty, your  
2 comments on density, for example, very much appreciated,  
3 and I think it matters a lot when we think about scale.

4 I will close by making a comment about global  
5 budgeting, which may draw the ire of my fellow  
6 Commissioners, and so I welcome the comments. But I  
7 wouldn't push this as global budgeting per se as much as  
8 the broader issue of how to think about alternative payment  
9 models in rural America and what they can be used by. I am  
10 skeptical that we will be able to do a lot under at least  
11 my understanding of what a global budget is, while we  
12 remain just one payer in a particular efficient way. I can  
13 see it much easier, even in Maryland, for example. They  
14 had a different rural global budget model that was much  
15 cleaner in some ways than when they moved it to their urban  
16 global budgeting model.

17 But nevertheless, there are obviously things that  
18 are worth exploring about those types of alternative  
19 payment models. We have some already. The AIM program,  
20 for example, in ACOs, for which there is work, moving  
21 forward about what's going on in rural areas matters. My  
22 general sense is that until we deal with the workforce

1 issues we're going to have a really hard time doing a whole  
2 bunch of other things, and so we will continue to think  
3 through that.

4           For now, I take to heart the comments about  
5 access, and some of you mentioned, Dana and others, what  
6 I'll call, for lack of a better word, risk adjustment  
7 issues, and we'll have to continue to think through that.  
8 But for those that are listening at home, I guess I'm just  
9 going to close with repeating my main point, that we  
10 certainly believe this is a very important area, and this  
11 will not be our last bite at this apple.

12           So that's my summary. I'm going to pause for a  
13 second to see if Jim or any other Commissioners want to add  
14 something. Otherwise, we will be taking a break for lunch  
15 until -- I think we're going to come back at 2:15. Jim?

16           DR. MATHEWS: I was just going to say 2:15.

17           DR. CHERNEW: There you go. All right then.

18 Everybody, stretch your legs, have some lunch, and we will  
19 see everyone back at our 2:15 session. And again, thank  
20 you guys so much for a really rich discussion on both  
21 topics this morning, and thanks to the staff. I know how  
22 much work all of this took, and you guys all did a

1 terrific, terrific job.

2 So see you all soon.

3 [Whereupon, at 1:28 p.m., the meeting was  
4 recessed, to reconvene at 2:15 p.m. this same day.]

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## 1 AFTERNOON SESSION

2 [2:16 p.m.]

3 DR. CHERNEW: Welcome back, everybody. I hope  
4 you had a terrific break. We are now going to start our  
5 afternoon session with two topics on Medicare Part D. The  
6 first one, I'm going to turn over to Shinobu to discuss the  
7 issue of rebates and risk adjustment.

8 Shinobu, you're up.

9 MS. SUZUKI: Good afternoon.

10 In this session, we are going to talk about how  
11 the growth in manufacturer rebates may be affecting the  
12 effectiveness of Part D's risk adjustment.

13 Before we begin, I'd like to thank Rachel  
14 Schmidt, Any Johnson, Eric Rollins, and Dan Zabinski for  
15 their help.

16 As a reminder to the audience, a PDF version of  
17 these slides can be downloaded from the handout section of  
18 the control panel on the right side of the screen.

19 I'll start with a quick summary of why we did  
20 this analysis.

21 The goal of a risk adjustment is to pay  
22 accurately across groups of beneficiaries based on expected

1 average costs of each of these groups. However, the rapid  
2 growth in post-sale rebates and discounts may have reduced  
3 the accuracy of Part D's risk adjustment across disease  
4 conditions.

5 Rebates and discounts obtained by Part D plan  
6 sponsors have grown by nearly 20 percent per year since  
7 2007. They are estimated to account for about 28 percent  
8 of total Part D spending in 2020, up from less than 10  
9 percent in 2007.

10 As the manufacturer rebates continue to grow, we  
11 need a better understanding of how rebates affect Part D's  
12 risk adjustment and their implications for the program.

13 The RxHCC model is similar to the hierarchical  
14 condition -- oh, I'm sorry.

15 Before we talk about the analysis, I'd like to  
16 spend the next few slides on some background information  
17 about Part D's risk adjustment system.

18 In Part D, plans are paid capitated payments,  
19 called the "direct subsidy," to cover their benefit  
20 liability. They are based on plans' estimates of expected  
21 benefit costs for an enrollee of average health.

22 To counter plan incentives to avoid high-cost

1 enrollees, CMS uses prescription drug hierarchical  
2 condition category, or RxHCC model, to adjust payments so  
3 that they reflect the expected costliness of each enrollee.

4           In 2018, risk adjustment was applied to 40  
5 percent of plan's revenue to cover Part D's basic benefit  
6 costs. The remainder of the benefit costs were covered by  
7 Medicare's cost-based reinsurance.

8           The RxHCC model is similar to the hierarchical  
9 condition category model used to adjust payments to  
10 Medicare Advantage plans. The model is based on age, sex,  
11 disability status, and medical diagnoses. CMS uses a  
12 regression analysis to estimate coefficients that reflect  
13 expected additional drug costs for each variable.

14           The model predicts plan's basic benefit costs,  
15 which are based on prices paid at the pharmacy. In other  
16 words, the model predicts costs for which plans bear  
17 insurance risk. It excludes reinsurance because that risk  
18 is borne by Medicare.

19           Since pharmacy claims do not reflect post-sale  
20 rebates or discounts, the model also does not account for  
21 rebates and discounts. As you see in a few slides, when  
22 Part D began in 2006, rebates and discounts offset a

1 relatively small share of spending so that the model  
2 provided a reasonable adjustment for the relative  
3 costliness of disease conditions. But this is no longer  
4 true.

5           Here is an example of how CMS calculates Part D's  
6 risk scores. The key thing to note here is the relative  
7 factors that are assigned to each variable. This is what  
8 we will be looking at in the analysis to see how rebates  
9 affect the RxHCC model.

10           Coefficients from the regression analysis are  
11 divided by average drug costs, before rebates and  
12 discounts, to arrive at the relative factors.

13           I've listed here examples of relative factors for  
14 community beneficiaries, not receiving Part D's low-income  
15 subsidy. For a 65-year-old female with no history of  
16 medical diagnosis, the risk score would be equal to the  
17 relative factor for her demographic category, or 0.239. If  
18 that person had diabetes with complications and diabetic  
19 retinopathy, the risk score for that person is the sum of  
20 all of the relative factors shown, or 0.971. That means  
21 this person is expected to be slightly less costly than an  
22 average enrollee with a risk score of 1.0.



1           The aggregate amount of rebates and discounts  
2 obtained by Part D plan sponsors, referred to collectively  
3 as direct and indirect remuneration, has grown rapidly.

4           In the figure on the right, the gray bars show  
5 aggregate gross plan liability. This is the portion of the  
6 benefit for which plans bear insurance risk. It has grown  
7 from about \$25 billion in 2007 to \$53 billion in 2018.

8           The red bars show the portion of the aggregate  
9 DIR retained by plan sponsors, which grew from about \$5  
10 billion to \$28 billion during the same period.

11           The red line shows how the DIR as a share of plan  
12 liability has increased over time. In 2018, DIR offset  
13 more than 50 percent of gross plan liability, up from about  
14 20 percent in 2007.

15           Manufacturer rebates account for the vast  
16 majority of DIR, and that raises a concern because rebates  
17 vary widely across therapies. And large differences in the  
18 availability and the magnitude of rebates could potentially  
19 undermine the accuracy of risk adjustment across the  
20 condition categories.

21           Our analysis focused on the following questions.  
22 How do rebates affect the RxHCC model's risk adjustment

1 factors?

2 Are there systematic over- or under-estimation of costs  
3 across condition categories? And, finally, what are the  
4 potential implications of rebates for plan incentives and  
5 payments?

6 To examine how rebates affect Part D's risk  
7 adjustment, we compared risk adjusters estimated with and  
8 without rebates. As the base case, we estimated a single  
9 community model calibrated using 2017 diagnoses to predict  
10 2018 gross plan liability. We used estimated rebates to  
11 calculate plan liability net of rebates for two categories  
12 of drugs -- insulins used for the treatment of diabetes  
13 and tumor necrosis factor inhibitors used to treat  
14 inflammatory conditions such as rheumatoid arthritis. I'll  
15 come back to this net plan liability calculation in just a  
16 minute.

17 We've re-estimated three versions of the model  
18 using plan liability net of rebates: one version using net  
19 plan liability for insulins, another version using net plan  
20 liability for TNF inhibitors, and a version using net plan  
21 liability for both insulins and TNF inhibitors. All models  
22 used the identical set of RxHCCs and demographic variables.

1 These are the same explanatory variables included in the  
2 current version of the RxHCC model.

3 For our analysis, we chose to calculate net plan  
4 liability for insulins and TNF inhibitors because rebate  
5 information was available in published studies and reports  
6 and because they represented drugs with very different use  
7 and costs.

8 The table shows selected data comparing these two  
9 drugs. In 2018, insulin was used by more than 3 million  
10 beneficiaries, with an average annual cost of about \$4,400  
11 per user.

12 TNF inhibitors, on the other hand, is a specialty  
13 drug used by a small number of beneficiaries, about 100,000  
14 in 2018, with an annual cost averaging more than 10 times  
15 that of insulins.

16 Plan's share of the benefit costs, labeled "plan  
17 liability" in the table, averaged about \$1,500 per user for  
18 insulins and \$7,600 for TNF inhibitors.

19 Estimated rebate per user that plans retained  
20 averaged about \$1,257 for insulins and about \$5,200 for TNF  
21 inhibitors.

22 As noted on the right, we used conservative

1 assumptions about rebates, starting with the lower bound of  
2 the range of estimates and further adjusting them downwards  
3 to account for manufacturer's coverage gap discount  
4 liability. More detail is in your mailing material, and I  
5 would be happy to discuss them on question.

6 Net plan liability is then calculated by  
7 subtracting estimated rebates from plan liability. For  
8 insulins, the average net plan liability was \$270 compared  
9 with the gross liability of about \$1,500. For TNF  
10 inhibitors, the average net plan liability was \$2,438  
11 compared with gross plan liability of about \$7,600.

12 What this means is plan's actual liability is a  
13 fraction of the gross plan liability used in the risk  
14 adjustment model. \$1,500 and \$7,600 is basically what is  
15 included in the current model. Our analysis compared the  
16 risk adjusters estimated using the gross plan liability  
17 with those estimated using net plan liability, which are  
18 \$270 and \$2,438, listed on the table.

19 In interpreting the regression results, it's  
20 important to keep in mind that the results are specific to  
21 two categories of drugs we examined -- insulins and TNF  
22 inhibitors -- and are based on estimated rebates. Impacts

1 would vary if rebates for other categories of drugs were  
2 reflected in the model.

3           However, there are insights that may help  
4 policymakers think about how to balance the need to improve  
5 the accuracy of risk adjusters and the administrative  
6 complexity involved in incorporating rebates in the risk-  
7 adjustment model.

8           The first set of findings show that using plan  
9 liability net of rebates for insulins and TNF inhibitor  
10 lowers the relative factors for condition categories  
11 affected by these therapies by as much as 75 percent.

12           The table shows the relative factors in base case  
13 and in the net plan liability model for diabetes and  
14 related condition categories.

15           For example, the relative factor for RxHCC30,  
16 diabetes with complications, was 0.612 in the base case  
17 using gross prices. Re-estimating the model using net plan  
18 liability for insulins resulted in a lower relative factor,  
19 0.395, or a 35 percent reduction.

20           The largest reduction was for RxHCC241, diabetic  
21 retinopathy. Relative factors decreased from 0.412 to  
22 0.102, or by 75 percent.

1           Using net plan liability for TNF inhibitors  
2 reduced relative factors for inflammatory condition  
3 categories by between 20 percent and 39 percent. The  
4 results were similar in the combined model using net plan  
5 liability for both insulins and TNF inhibitors.

6           The second set of findings is that changes in the  
7 relative costs for specific conditions affect risk scores  
8 for all beneficiaries. This is because a decrease in the  
9 relative costliness of a specific condition, such as  
10 diabetes, means that other conditions, not affected by the  
11 change in costs, are more costly relative to that  
12 condition.

13           To illustrate this, we compared the changes in  
14 the average risk scores for beneficiaries with diabetes to  
15 those without diabetes. The first row in the table shows  
16 that using net plan liability reduced the risk scores for  
17 beneficiaries with diabetes from 1.53 to 1.39, or by 9  
18 percent. The risk scores for beneficiaries without  
19 diabetes, on the other hand, increased by 8 percent, on  
20 average.

21           Similarly, using net plan liability for TNF  
22 inhibitors reduced the risk scores of beneficiaries with

1 inflammatory conditions by 7 percent. However, the effects  
2 on other beneficiaries, without inflammatory conditions,  
3 were relatively small, an increase in the average risk  
4 scores by 1 percent. This is because only a small share of  
5 Part D enrollees have inflammatory conditions affected by  
6 the change in plan costs.

7           These are average effects, and effects for  
8 individual beneficiaries will vary depending on the RxHCCs  
9 indicated. For example, while the risk scores for  
10 beneficiaries with diabetes decreased by 9 percent on  
11 average, for about 10 percent of those beneficiaries, the  
12 risk scores actually increased.

13           While using net, rather than gross, plan  
14 liability can result in large changes in risk scores for  
15 individual beneficiaries, the impact on plan-level average  
16 risk scores would tend to be smaller because of averaging  
17 across enrollees.

18           Whether risk scores would be higher or lower  
19 would depend on the mix of RxHCCs indicated for each plan's  
20 enrollees.

21           In our example using net plan liability for both  
22 insulins and TNF inhibitors, we found that the plan-level

1 average risk scores increased by 0.7 percent on average for  
2 PDPs and decrease by 1.5 percent for MA-PDs. The results  
3 were mostly driven by effects of rebates on insulins. This  
4 makes sense since inflammatory conditions affect a much  
5 smaller share of Part D enrollees compared with diabetes.

6           The differential impact reflects differences in  
7 RxHCCs indicated for their enrollees. For example, a  
8 higher share of MA-PD enrollees had diabetes with  
9 complications, a condition category that would see a  
10 relatively large reduction in payments if the model was  
11 estimated using plan liability net of rebates.

12           Your mailing material included more details on  
13 the findings, but here are some of the key takeaways.  
14 First, rebates affect the accuracy of the entire risk  
15 adjustment system. CMS currently uses gross, not net  
16 prices. The rapid and uneven growth in rebates across  
17 therapies has reduced the accuracy of a model based on  
18 gross prices. To improve payment accuracy, policymakers  
19 may want to initially focus on drugs with the largest  
20 impact, meaning therapies with large rebates that are used  
21 to treat conditions that are highly prevalent.

22           There are several policy implications for you to



1 consider. Given the findings, the current approach to risk  
2 adjustment based on pharmacy prices could create or worsen  
3 misaligned incentives; that is, the systematic bias in the  
4 risk adjusters could increase plan sponsors' incentives to  
5 engage in risk selection.

6 In addition, a relatively high compensation for  
7 certain drugs with rebates may further encourage the use of  
8 formularies that prefer high-price, highly rebated drugs.

9 Using net rather than gross costs in the risk-  
10 adjustment model would improve the accuracy of payments,  
11 and finally, accurate risk adjustment would be particularly  
12 important under the Commission's recommendations to  
13 restructure the Part D benefit.

14 In your discussion, we are looking for your  
15 feedback on the future direction of this work. We plan to  
16 include this material in the Part D chapter of the March  
17 2021 report to the Congress. If there is Commissioner  
18 interest, as the next step, we could look into what  
19 administrative changes may be required; for example, data  
20 submission requirements or agency resources needed and  
21 potential unintended consequences. We would also be  
22 interested in hearing about any other angles you would like

1 us to pursue on this topic.

2 With that, I'll turn things back over to Mike.

3 DR. CHERNEW: Shinobu, thank you so much. I  
4 think that was a really interesting talk. We have a few  
5 people in Round 1, and I think, Paul, you are number one.

6 DR. PAUL GINSBURG: I think I'm the lead for  
7 Round 2, Mike.

8 DR. CHERNEW: That's also true.

9 MS. KELLEY: Mike, I think Dana was first.

10 DR. CHERNEW: Oh, excuse me? Dana? Yes, I'm  
11 sorry. I've got it. Dana.

12 DR. SAFRAN: Okay. Am I on? Can you hear me?

13 DR. CHERNEW: Yes.

14 DR. SAFRAN: Okay, good. Thanks. You know, this  
15 is a really incredibly informative and well-written piece  
16 of work, so really congrats, Shinobu. Really terrific.

17 I have two questions. One is on page 15 of the  
18 chapter, you talk about the higher percent of Medicare  
19 Advantage members with complex diabetes compared with Part  
20 D plan enrollees, and I wonder if we know how much of this  
21 is likely due to coding intensity in the MA plans versus  
22 true differences in case mix between MA and Part D?

1 MS. SUZUKI: We did not look into, for example,  
2 utilization of certain medications by the beneficiaries who  
3 are coded differently, between PDPs and MA-PDs, to  
4 determine whether they code differently. However, I think  
5 CMS has at least mentioned coding diabetes beneficiaries as  
6 having complications, maybe some of the upcoding that may  
7 be occurring in MA.

8 DR. SAFRAN: Yeah. Okay. I think that's the  
9 point underneath my question, then. It doesn't really  
10 relate just to diabetes. But we can come back to it.  
11 Yeah, I'll come back to that.

12 My second question is maybe a bit of a naïve  
13 question, but hopefully one that will be informative to the  
14 other Commissioners as well. Can you help us understand,  
15 from a manufacturer's perspective, why it's beneficial to  
16 have inflated prices that they then go and give back, by  
17 way of rebates, on the other end? Why does this serve  
18 manufacturers or, you know, others well in the pharmacy  
19 side of the industry?

20 MS. SUZUKI: I think there is definitely market  
21 segmentation that pharmaceutical manufacturers engage in,  
22 by pricing things differently depending on the leverage in

1 terms of the contracts that they negotiate. The prices are  
2 confidential, so some purchasers with leverage likely  
3 obtain a significantly lower net price compared to someone  
4 who is paying cash at the pharmacy.

5 In Part D we have talked about the benefit  
6 structure provides plan sponsors financial gains when there  
7 is the difference between the pharmacy prices and prices  
8 net of rebates, and we sort of show this in how we  
9 estimated the net plan liability the plan sponsors retain a  
10 substantial portion of the rebate to offset their benefit  
11 cost.

12 So I think manufacturers are aware of these  
13 financial gains that plan sponsors gain from having rebates  
14 be the way they lower the prices for the purchasers, and  
15 manufacturers also obtain preferential formulary treatment,  
16 usually on a preferred brand tier rather than a non-  
17 preferred tier, with higher cost sharing. So that gives  
18 them more market share, typically.

19 DR. SAFRAN: Thank you.

20 MS. KELLEY: I have Pat next with a Round 1  
21 question.

22 MS. WANG: Thank you. Shinobu, can you just

1 clarify. Do the risk scores always rebalance to 1.0? So  
2 what you're talking about in this chapter is the  
3 distribution of risk scores around 1.0. Is there any  
4 change in the net, I guess, value, I guess, of recognizing  
5 sort of the spend on drug and how it gets distributed? I  
6 think the answer is yes but I just wanted to confirm.

7 MS. SUZUKI: It is normalized to average 1.0  
8 across all Part D enrollees. So regardless of whether  
9 you're using gross price or net price to estimate the  
10 model, it would average to 1.0.

11 MS. WANG: Okay. Got it. Thank you. But, you  
12 know, I should have started by saying it's really great to  
13 be undertaking the work around risk adjustment accuracy,  
14 particularly given the significance of the Commission's  
15 Part D restructuring recommendations.

16 I did wonder whether you think that the work on  
17 risk adjustment accuracy should focus on this one specific  
18 thing of cost gross or net of rebates, because, you know, I  
19 really don't understand this whole world very well, but it  
20 seems like there's at least a step that comes before the  
21 use of cost, which is the development of the coefficients,  
22 I think.

1           And so I guess the question is, does this issue  
2 also have an impact on the coefficients that are used  
3 before we get to dividing by cost, whether it's gross or  
4 net? Is there a relationship there? Are the development  
5 of coefficients, which seems like a very critical step in  
6 accuracy of risk scores, is that affected by the issue that  
7 you've written about, or is that still separate?

8           MS. SUZUKI: It directly affects the coefficient.  
9 So current model would be estimating -- for example, in the  
10 case of insulins, they would be using the \$1,500, which is  
11 the average cost before rebates are accounted for. In the  
12 model that accounts for rebates, in our example, we are  
13 replacing that \$1,500 essentially with the \$270, which is  
14 the net cost for the plans. And what that does is once you  
15 convert the coefficients to the relative factors, condition  
16 categories that were inflated because of the gross costs  
17 that were higher than the net costs are lowered, relative  
18 to other conditions.

19           But your first question asked about whether it  
20 equals 1.0 across everyone. It still does. It just  
21 changes the relative cost to more accurately reflect the  
22 net cost of the plans.

1 MS. WANG: Okay. And it works backwards, too.  
2 It kind of will reshuffle the coefficients, so it loops  
3 around somehow? Okay. I see.

4 DR. CHERNEW: Pat? I'm sorry. Shinobu, that was  
5 an answer that was spot on, so thank you. And Pat, I  
6 understood and grappled with your question so let me just  
7 say, sort of more directly, this is all about the  
8 coefficient. Everything else is an adjustment, that gets  
9 netted out so the net dollars aren't changing. But the  
10 entire approach that Shinobu did is all about the  
11 coefficient.

12 MS. WANG: Got it. Okay. If I could just ask  
13 one more question. Shinobu, you said on one of these  
14 slides and in the paper that probably the most significant  
15 impact on the risk scores was the size of the rebate. Was  
16 there anything in your analysis that would suggest sort of  
17 the speed or, you know, the release of new specialty drugs  
18 ever year, very, very high cost, the rapidity and sort of  
19 the concurrence of those new releases with the actual plan  
20 year versus development of coefficients, et cetera, using  
21 the base information that may be a couple of years old.  
22 How significant is that?

1 MS. SUZUKI: So that's a good question. When CMS  
2 estimates these models they are inevitably relying on  
3 lagged years of data. So for hepatitis C, for example,  
4 their model did not reflect the Sovaldis and other  
5 hepatitis C drugs that were extremely expensive but were  
6 not reflected in the data that they used to estimate the  
7 model. And for that specific case they ended up making  
8 retroactive adjustments, to make sure that plans were not  
9 losing an enormous amount of money because the risk  
10 adjustment did not account for those new drugs.

11 But generally, the risk adjustors apply to the  
12 plan's bid, which would account for some of the knowable  
13 future launches. So it's trying to adjust for the relative  
14 cost to the beneficiaries but it doesn't have to  
15 necessarily account for all the new launches, specifically  
16 for each of the condition categories that would be  
17 affected. But it would do a better of adjusting if it used  
18 some more accurate prices. So in our case we were trying  
19 to look at the net prices versus gross prices.

20 MS. WANG: Given the amount that you've thought  
21 about this issue, do you think that this net versus gross  
22 price is the most significant issue in getting to better



1 risk score accuracy for Part D? Is this the linchpin issue  
2 or are there other issues?

3 MS. SUZUKI: So the reason we focused on this  
4 particular issue is when we recommended the change to the  
5 benefit structure back in June we were going to expand the  
6 amount of payment that plans received through the capitated  
7 payments. And that's the payment that's going to be risk  
8 adjusted. And as you extend the payment that's paid  
9 through capitated payments it would be more important for  
10 the payment to be accurately adjusted for individuals'  
11 health status. So that's one reason we were looking into  
12 this issue.

13 MS. WANG: Okay. Thank you.

14 MS. KELLEY: Okay. I have David with a Round 1  
15 question.

16 DR. GRABOWSKI: Great. Thanks, Shinobu. This is  
17 an incredibly complicated part of the program, and you did  
18 a great job of kind of, I think, really explaining it and  
19 putting some of the pieces together. And I just wanted to  
20 ask about one other piece.

21 It's obvious that we have some real distortions  
22 here with this manufacturer rebates. We've talked in the

1 past, in previous cycles, about individuals getting into  
2 the catastrophic phase more quickly. This is about  
3 distorting the risk adjustment. The other piece I'm just  
4 trying to put together in my head are the risk corridors.  
5 Do those also end up playing a role here, interacting in  
6 any way, and could you just help me think about that,  
7 because that's the one piece I'm confused on. Thanks.

8 MS. SUZUKI: Well, the way it works is plans are  
9 paid a risk-adjusted payment, and rebates are going to  
10 allow them to, on average, lower their liability relative  
11 to what they get paid for that condition categories. So we  
12 show this with insulin and TNF inhibitors.

13 That allows them to potentially have lower cost  
14 relative to the capitated payments they receive, but those  
15 are now part of the risk corridor reconciliation. So, as  
16 you know, you get to keep the first 5 percent. You do a  
17 50/50 split for the next 5 percent. The larger your  
18 profit, I guess, the difference between the capitated  
19 payment versus what your actual costs were is going to  
20 contribute to the amount you are able to keep in the  
21 corridors.

22 DR. GRABOWSKI: So do the corridors then buffer

1 this issue? I'm just trying to think about -- I guess by  
2 definition they should bound this, to some degree, right?

3 MS. SUZUKI: It does. There's a 50/50 from 5  
4 percent to 10 percent difference, and then beyond that it's  
5 80/20, so Medicare keeps 80 percent. So there is some  
6 limitation on how much the plans are able to keep if they  
7 make a profit beyond 5 percent.

8 MS. KELLEY: Does that answer it, David?

9 DR. GRABOWSKI: Yeah. Sorry. Thanks.

10 DR. CHERNEW: David, my take is what's going on,  
11 and again I'll look at Shinobu because she knows this  
12 intimately and in much more detail than I. Because things  
13 are rebalancing to one, the way Pat was asking about, the  
14 net dollars aren't changing that much. They are just  
15 moving them across plans. So what matters is whether the  
16 movement across plans spreads things out to where the  
17 corridors bite or moves things in a way where the corridors  
18 don't bite.

19 I don't know the exact answer, but basically  
20 what's happening is we're shifting money away from plans  
21 that are serving -- if one were to do this, one would move  
22 money away from plans that are serving patients that are

1 using a lot of high-rebate drugs, towards other plans. So  
2 if you had a lot of patients with diabetes, meaning they're  
3 using a lot of drugs that have a lot of rebate, you would  
4 be getting less money, but that money wouldn't be taken out  
5 of the system. That money would be spread around to all  
6 the other plans, one way or another.

7 Shinobu, I can't see you because your face is so  
8 small on my little screen. I see you smiling, so I'm going  
9 to take that as loosely right.

10 DR. GRABOWSKI: Thanks, Mike. That's helpful.  
11 It's redistributed, I guess, in that way, and not about  
12 program wins and losses but rather redistributed across  
13 plans. Understood.

14 DR. CHERNEW: So, Dana, how are we on the Round 1  
15 queue?

16 MS. KELLEY: We have two more, Bruce and then  
17 Larry.

18 DR. CHERNEW: Okay. Then we'll move on to Round  
19 2 with Paul at the kickoff. But Bruce.

20 MR. PYENSON: Thank you very much, and Shinobu, a  
21 terrific chapter. I have a question on page 11 of the  
22 slides, which is to sort of bring out what the scale we're

1 talking about is and what, on a back-of-the-envelope basis  
2 of looking at the biggest change here, the dramatic number  
3 of minus 75 percent, is about 0.3 on the risk score. I  
4 believe that gets applied to the sum of premium and direct  
5 subsidy, which I think is perhaps \$45 PMPM, something like  
6 that. And I'm wondering if you could compare the total  
7 dollars we're talking about here to the total estimated  
8 rebate for insulin in a month. I think the numbers to do  
9 that are all in the paper.

10 MS. SUZUKI: I'm afraid to do the math on the  
11 fly, but what we have looked at is average cost of -- well,  
12 we use an example in the paper of a plan with bid equal to  
13 the national average, and I'm sorry to use an annual number  
14 but it's roughly \$700 for a year. And so when we were  
15 looking at a change of about 0.3 reduction for diabetic  
16 retinopathy, if a plan were bidding at the national  
17 average, annual reduction in payment we estimated to be  
18 around \$200. This is going to vary across plans, depending  
19 on their bid, but it is a pretty substantial reduction off  
20 of \$700 for national with an average bid.

21 MR. PYENSON: I'm sorry. It was how many  
22 hundreds?

1 MS. SUZUKI: \$200.

2 MR. PYENSON: So \$200 out of \$700, you know. So  
3 that was just from insulin?

4 MS. SUZUKI: Mm-hmm.

5 MR. PYENSON: That's on an annual basis. Now I  
6 think -- and folks can correct me -- a script of insulin  
7 gross might be \$500, or \$100, and I think you were -- and  
8 that might be in a month? And I think you were identifying  
9 the 50 percent rebate. So one month of rebate is worth  
10 more than the shift in risk score. Is that right, for the  
11 --

12 MS. SUZUKI: Yes.

13 MR. PYENSON: The annual income is worth less  
14 than one month of rebate.

15 MS. SUZUKI: And this is based on a regression  
16 model, so there's that piece. But we also lowered the  
17 rebate further from the 50 percent that we initially  
18 assumed to account for the fact that manufacturers would be  
19 paying coverage gap discount. So we ended up lowering it  
20 to a little over 40 percent after accounting for the amount  
21 they would have paid in coverage gap discount.

22 MR. PYENSON: So is your proposal then to use net

1 of both rebate and coverage gap discount?

2 MS. SUZUKI: No, this is not a proposal. This  
3 was just to illustrate what -- the kinds of change you  
4 would see in the risk adjustment model by using net  
5 liability rather than gross plan liability. And so for a  
6 medication like insulin that has large rebate, the effects  
7 on payment could be fairly substantial.

8 MR. PYENSON: So let me ask the question again.  
9 I think what you're describing as net plan liability is net  
10 of both rebate and coverage gap discount.

11 MS. SUZUKI: Net plan liability is actually the  
12 gross plan liability reduced by our estimated rebate. Plan  
13 liability does not include the manufacturer coverage gap  
14 discount payment, so it's actually not related to the  
15 coverage gap discount. We were just trying to come up with  
16 a conservative estimate of what manufacturers may be paying  
17 plan sponsors in rebate for insulin. And so this is just  
18 our trying to be very conservative in our estimate of the  
19 magnitude of the effect, and so if they were actually  
20 getting 50 percent or higher rebate, the effect would have  
21 been larger.

22 DR. CHERNEW: Can we sort that out off-line? We

1 will have a lot of time to discuss how the manufacturer  
2 discount is playing into this, whether it's coming off  
3 before we do any of the regressions or after. But I think  
4 we've past the point of clarifying in a concise way, I  
5 think, on that topic.

6 MR. PYENSON: Went over two minutes. Sorry.

7 MS. KELLEY: Larry, I think you're next.

8 DR. CASALINO: Yeah, my question is a follow-up  
9 to Dana. You know, Dana generously characterized her  
10 question as naive, which probably wasn't naive for most of  
11 us, but giving permission to ask more naive questions, so I  
12 have one. Shinobu, presumably the manufacturers and the  
13 plans can figure out and have figured out the risk  
14 adjustment and not only related to the rebates that you've  
15 pointed out. What, if anything, are they doing  
16 strategically to try to benefit from that? Do you have any  
17 sense of that?

18 MS. SUZUKI: I think that's a really good  
19 question but difficult to measure. We do think there is an  
20 incentive in the program for plan sponsors to benefit from  
21 highly rebated drugs, particularly if the prices are going  
22 to be high and fall into the catastrophic phase of the



1 benefit, as you saw with the TNF inhibitors. Much of the  
2 spending occurs in the catastrophic phase, so plan  
3 liability is a fraction of the actual cost of the drug.

4           However, the way the rebates are allocated  
5 currently, there is a substantial portion of the rebates  
6 that are accruing to the plans, which reduces their  
7 liability by a significant amount. So given that benefit,  
8 it's possible that there are some formulary incentives that  
9 are misaligned, and we talked about this when we discussed  
10 the benefit restructure.

11           DR. CASALINO: Thank you.

12           MS. KELLEY: Okay. I think we're on to Round 2  
13 then, and Paul is going first.

14           DR. PAUL GINSBURG: Oh, thanks. Shinobu, you've  
15 done an excellent job in explaining this both in your  
16 presentation and in the chapter you sent. And, you know,  
17 it's very convincing to me. This issue is important. It's  
18 worth MedPAC's time on developing recommendations on. In  
19 fact, it's interesting that you were able to make a  
20 convincing case without access to the detailed CMS data,  
21 which MedPAC does not have. You were able to base it on  
22 the public data for at least these two drugs.

1           But what I want to focus our attention on is that  
2 the problem with the risk adjustment is really kind of a  
3 side effect of a much bigger problem with the way rebates  
4 are handled in Medicare Part D. The big problem to me is  
5 that Medicare beneficiaries are paying too much cost  
6 sharing when they use drugs that are highly rebated. And  
7 so in a sense, what this has done is it's really hollowed  
8 out the Medicare Part D benefit, and this has happened over  
9 time as rebates have grown. And if you ever wondered about  
10 why the Part D premiums have increased so slowly over time,  
11 this is probably a key reason. The benefit has been  
12 hollowed out.

13           Now, the solution to this, which has been used in  
14 the employer-based sector to some extent, is to at the  
15 pharmacy counter charge beneficiary cost sharing based on  
16 an approximation of what the rebate is likely to be. And  
17 United Healthcare has been a pioneer in its employer-based  
18 plans of doing just that. You know, a difficulty is that  
19 it means that the coverage has become more valuable again  
20 and the premium will have to go up, and that becomes a  
21 difficult payment issue.

22           So I would like to say that along with doing the

1 improvements in the risk adjustment, which, you know, would  
2 be easier to get through, that the Commission ought to be  
3 turning its attention to solving the broader problem with  
4 rebates in Medicare Part D.

5 MS. KELLEY: Bruce, I think you're next.

6 MR. PYENSON: Oh, thank you. I agree with Paul's  
7 comment about what we should be focusing on. However, I  
8 think moving in the direction that's proposed is actually  
9 helpful because it identifies the -- it sheds some light on  
10 the nature and magnitude of rebates and would set up the  
11 data reporting to get that right. So I think the issues  
12 are less about a material change or the risk of plans using  
13 distortions for a selection which I think are not huge, but  
14 more as part of a process of recognizing what -- how the  
15 set of rebates and part of the process, as Paul calls for  
16 really fixing that destructive process.

17 I think looking at the magnitude of changes, what  
18 we could probably comfortably conclude is that the risk  
19 scores for patients who don't take brand drugs, who have  
20 conditions that are today predominantly treated by  
21 generics, the risk scores for those people would increase a  
22 little bit. But I think the issues of selection are

1 dwarfed by the role of rebate in selecting formulary and  
2 using formulary to select patients. So I support this  
3 direction, but I also support the broader goal that Paul  
4 just stated.

5 Thank you.

6 MS. KELLEY: Brian?

7 DR. DeBUSK: First of all, thank you for  
8 revisiting this again. And to the staff, I thought the  
9 quality of the analytic work in this report was just  
10 fantastic. So, again, thank you.

11 This chapter is just yet another reason for why  
12 we should be skeptical and wary of rebates. There's a lot  
13 to not like about rebates, and I think this chapter is  
14 another reason for why we should pursue getting the  
15 underlying data and winding it.

16 But I have noticed something, because each time  
17 some facet of rebate comes up, we always wind up in the  
18 same somewhat degenerate argument around, well, we need the  
19 data, well, we don't have the data, or we only have pieces  
20 of the data, and it would be administratively complex.  
21 And, you know, we start talking about burden. First of  
22 all, I still want to unwind the rebates and get to the

1 bottom number. But here's an alternative that I would  
2 propose, and actually I didn't propose it, the staff did,  
3 back in August 2017 in a public presentation.

4 Shinobu, do you have the not-so-secret slide?  
5 Great. This is a chart from 2017. Actually, Shinobu and  
6 Rachel presented it. I was in the meeting when they did  
7 it. But this is one of the underpinnings of why rebates  
8 are so important and why they drive this misallocation of -  
9 - or how they're misallocated back between plans and the  
10 Medicare reinsurance program.

11 If you notice the gross spending level, you've  
12 got about \$42 billion both in reinsurance and in plan  
13 liability. But you have one other kind of spending there,  
14 and that's the cost sharing, which includes things like  
15 LIS. I mean, these were big-ticket items here. If you  
16 notice, it's more than the gross spending at the plan or  
17 the Medicare insurance level. That sum is used in the  
18 denominator to calculate the ratio of how this direct and  
19 indirect remuneration goes back to the plans and to  
20 taxpayers.

21 So if you notice, you're always using a ratio;  
22 that cost-sharing component is always going to dilute that

1 denominator. So whoever gets paid first is always going to  
2 be underpaid. And if you notice the Medicare reinsurance  
3 fund is underpaid systematically; whereas, their gross  
4 spending was about 50/50. They only get about 30 percent  
5 of the DIR, and then the remainder goes to the plan.

6           Now, the staff had an excellent idea back in  
7 2017, which was to basically just take the cost sharing out  
8 of the denominator and make the distribution of DIR more  
9 equitable. But today I want to take that one step further.  
10 If you look at Medicare reinsurance and if you look at cost  
11 sharing, that's still ultimately -- those are just taxpayer  
12 and beneficiary dollars. I mean, the way they're  
13 collected, the way they're distributed is different, but  
14 these are both ultimately -- taxpayers are where this money  
15 comes from.

16           My argument would be leave that denominator in  
17 place. Leave that \$136.9 billion in this example, leave  
18 that number in place, but allocate the DIR such that the  
19 Medicare -- that the plan -- I'm sorry -- that the plan  
20 gets the first allocation, and then the Medicare  
21 reinsurance fund gets the balance. So what I'm really  
22 proposing is swapping the order that the DIR is

1 distributed.

2           Now, what that will do is create a tremendous  
3 drag on rebates, and what I would predict is that we're  
4 going to have a sudden administrative breakthrough that's  
5 suddenly going to make all of these numbers feasible, and  
6 we're going to have no problems getting to these net  
7 rebated values once the rebate starts working against the  
8 manufacturers and against the plans in how this DIR is  
9 allocated.

10           So, again, you know, Paul and Bruce, I completely  
11 agree with your comments. The right answer is to have this  
12 data, but I think that in the absence of having this data  
13 provided, I think we should err on the side of the taxpayer  
14 and put the taxpayers and beneficiaries first in how we  
15 allocate this DIR.

16           Thank you.

17           DR. CHERNEW: Can I just -- I just want to say  
18 one thing before we move on. I think maybe Amol is next.  
19 I'm not sure. But let me just say something first.

20           I think I understand that, Brian. That will be a  
21 longer conversation to make sure that I fully do. I wasn't  
22 around when this was all presented. But I think one of the

1 things to think through this entire discussion -- right now  
2 we're just illustrating an issue, and it sounds like we'll  
3 have some passion for moving forward one way or another.  
4 But at least on this particular topic, I think the  
5 challenge is that the DIR is not some fixed amount of  
6 money. The amount of money in there depends on the  
7 incentives or who gets it and what happens. And so while  
8 we -- we don't have a pot of DIR to allocate. If we change  
9 the way it gets allocated, we may change the amount of  
10 money that's in that pot, and we'll have to sort through  
11 how the incentives for all of that plays out, and I think  
12 that's sort of one of the big challenges. I think that may  
13 have been exactly where you were going, Brian. We can  
14 reduce the incentives for DIR in particular ways, but it's  
15 not clear how that plays out in terms of premiums or other  
16 types of money for folks, and that's what would have to be  
17 thought through.

18           So I guess I'll just be quiet there, and is Amol  
19 next, Dana?

20           MS. KELLEY: Amol is next.

21           DR. NAVATHE: Great, thank you. So, Shinobu,  
22 fantastic write-up, very clear, I think, always distilling



1 complex things into understandable ways.

2           So I just wanted to take a few minutes -- not  
3 minutes -- a few moments here to voice support for the  
4 work. I think, you know, clearly very important -- I would  
5 say, you know, even under the current structure we're  
6 looking at 40 percent, not more, we're seeing that there's  
7 pending pretty meaningful impact here, and that's with the  
8 inferred rebates, if you will, from some of the other  
9 literature. So I think what we're seeing here is  
10 important.

11           What I would say is I think it's really important  
12 that we -- and, you know, this kind of builds on other  
13 Commissioners' comments, including Paul's and Brian's and  
14 others' -- is this connects very directly to prior work  
15 that we at MedPAC have been doing around Part D, and as far  
16 as I see it, the importance of this risk factor or risk  
17 adjustment will only amplify considerably if you think  
18 about the alternative structures that we're proposing. So  
19 that only, I think, kind of makes me want to double down  
20 and say this is going to only become more important as the  
21 Part D program evolves going forward. And for that, the  
22 integrity of the data, actual rebate data for MedPAC to

1 both do this work and recommend a program that functionally  
2 actually improves, you know, considerably how things work  
3 for the taxpayers, beneficiaries, et cetera, and plans, I  
4 think that's really important.

5 I think that aligns with the general principle  
6 around trying to get toward more transparency in health  
7 care as well, and I think it will allow us also to more  
8 effectively communicate how this will impact every  
9 stakeholder and sector, and David in his Round 1  
10 questioning highlighted that this could bite, if you will,  
11 in different ways or the margin effectively, it depends,  
12 based on the heterogeneity of your mix of beneficiaries for  
13 a specific plan. And I think we want to have the clarity  
14 to be able to see where those shifts are happening, even if  
15 they're, you know, budget neutral in a sense.

16 So I just wanted to voice that support and make a  
17 plug here, if we can, for explicitly tying not only the  
18 importance but also the impact of this work to the broader  
19 work around Part D that we've been doing.

20 Thanks.

21 MS. KELLEY: Dana, did you have a Round 2  
22 comment?

1 DR. SAFRAN: Yes, just very brief. So one is  
2 understanding that MedPAC does not have access to these  
3 data and that's why, Shinobu, you needed to do the really  
4 creative and sophisticated analyses that you did on two  
5 classes of medicines, I wonder if we could consider adding  
6 information to this chapter about the potential impact of  
7 accounting for rebates and risk adjustment on Medicare  
8 spending overall. I realize that would take some even more  
9 sophisticated modeling and assumptions, but that's just a  
10 thought to put out there.

11 Second is to, you know, underscore the point that  
12 has been made that, you know, the inaccessibility of these  
13 data to MedPAC is in my mind nothing short of outrageous.  
14 You know, it is important to understand that CMS does have  
15 access to these data, but the fact that MedPAC does not and  
16 that this is one of the few exceptions of information for  
17 modeling cost and payment policy recommendations that, you  
18 know, we have to do with duct tape and other creative  
19 methods is really just outrageous and a testament to the,  
20 you know, lack of transparency in the industry that really  
21 I think has to be addressed.

22 The third point is that, you know, I think Paul

1 made the point that employers are doing some really  
2 important and creative things to try to address rebates,  
3 and one of the things I've seen in my work with employers  
4 is having rebates flow through to the employee at the point  
5 of sale, and so that seems, I think, a really important  
6 thing for us to consider as well.

7           And then, finally, just to endorse the point  
8 that's been made by several others about the value of a  
9 broader piece of work on the impact of rebates on Medicare  
10 spending, on utilization, formulary, you know, design, not  
11 just on risk adjustment, you know, I think it is critically  
12 important because of what rebates are doing both in the  
13 commercial sector and in Medicare that we take that broader  
14 lens and write about it, but that's not to denigrate at all  
15 the importance of this piece of work I think is very  
16 important to show the impact on risk adjustment as well,  
17 because you're clearly showing that risk adjustment no  
18 longer is worth its salt because the high percentage of  
19 spending that's happening in medications where there are  
20 rebates and, therefore, you know, the spending side of what  
21 we're trying to model is just completely inaccurate.

22           Thank you.

1 MS. KELLEY: David, you're next.

2 DR. GRABOWSKI: Great. Thanks. I'll be brief.

3 I agree with others on the value of this work.  
4 These manufacturer rebates have to start at risk  
5 adjustment. We need the rebate data. Dana just used the  
6 word "outrageous" that we don't have these data. I think  
7 that's exactly correct. So I think if I could just -- the  
8 headline here is get us the data.

9 One other point similar to the point that Amol  
10 made, I wonder if this work could be framed a little bit  
11 differently, and I guess Dana made this point as well. We  
12 currently framed the chapter about risk adjustment. I  
13 think this could be much broader about the distortionary  
14 impacts of rebates and the need for greater transparency.

15 I understand the importance, and this is a great  
16 illustration of just the issue with these rebates, but I  
17 think it's one of several issues. And I wonder if we  
18 package these together it makes a stronger case for greater  
19 transparency.

20 Thanks.

21 MS. KELLEY: And, Pat, I have you as the last  
22 Round 2.

1 MS. WANG: Thank you.

2 Let me just pick up where David ended, which is  
3 the paper is focused on two incredibly important subjects.  
4 One is rebates, and the other is risk score accuracy. I  
5 hope that we don't lose sight of either one because we're  
6 putting them together.

7 I agree with comments that have been made prior  
8 to this. I agree that MedPAC should have access to the  
9 information on rebates.

10 On the topic of risk score accuracy, because I do  
11 think that that is deserving of its own special attention -  
12 - and I'm very appreciative, Shinobu, that you took this up  
13 -- it is really critical, particularly with the  
14 recommendations that we made around restructuring the part  
15 D benefit, to put more liability in capitated payments.  
16 It's critically important that the risk adjustment be  
17 accurate.

18 And I see it last as an issue of avoiding plans  
19 from cherry-picking people with certain characteristics  
20 because I personally think that that is actually a really  
21 hard thing to do in the real world, at least in the MA  
22 world, and it really is just more about payment accuracy.

1 I think that that is a worthy enough goal without sort of  
2 ascribing magical powers to people.

3 So I would very much encourage that in addition  
4 to this work, which is obviously very important, that we  
5 continue to look for ways to improve risk score accuracy.

6 And I go back to the comment -- or the question,  
7 I guess, that I raised in Round 1, which was around the  
8 currency of the analysis and the data that CMS uses. I  
9 appreciate, Shinobu, you pointing out the example of  
10 Sovaldi and sort of CMS kind of pivoting quickly to make  
11 adjustments within the year. I just think that every  
12 single year there are new launches of new high-cost drugs  
13 that are substituting for other drugs, and they're like  
14 wow.

15 The predictability of the spend in Part D is  
16 unlike medical. Medical is stable. You can really do a  
17 projection and a risk score model that I think has  
18 integrity as you go forward, and I just think it's less  
19 stable in Part D because of all the new releases.

20 I also just want to put something on the radar  
21 screen that I have a little concern about. Focusing on net  
22 cost may affect the way that people structure rebates, and

1 if you're using two-year-old data and rebates that existed  
2 two years ago to project risk scores for today, I just  
3 wonder whether there's going to be another kind of time  
4 mismatch as you go on. I do think it's possible that if  
5 the system shifts using net cost versus gross cost that  
6 rebate strategies may also shift. So I would urge again  
7 for the new high-cost drug launches as well as this  
8 additional time-lag issue that we continue to look at  
9 whether or not it's possible to make the analysis and  
10 projection of coefficients and actual risk score factors  
11 more current with the actual service year or to adjust that  
12 way.

13 So it's great work. I really hope that we can  
14 continue an independent focus on risk score accuracy at the  
15 same time that we continue digging deeper on how drug  
16 rebates work.

17 Thank you.

18 MS. KELLEY: That's the end of the queue, Mike.

19 DR. CHERNEW: Yeah. Great.

20 So I will summarize, and then we'll move straight  
21 away to Eric and the LIS benchmark work that we've been  
22 doing. But my summary is essentially as follows.



1           First, I think there's a lot of enthusiasm for  
2 moving forward on this work broadly and a lot of desire to  
3 get payment accurate in the -- Pat's portion of her  
4 comments and all the rest of yours which was on getting  
5 risk adjustment right.

6           Second, I hear two broad levels of frustration  
7 with the rebate system that extended beyond the fact that  
8 it screws up risk adjustment.

9           The first one is that beneficiaries face a lot of  
10 liability because they're often paying based on gross price  
11 when actually the amount of money that's being paid is net  
12 priced, much lower than that. So, in some sense,  
13 beneficiaries are overpaying, and I think there's a lot of  
14 desire to broaden our concern about distortion that rebates  
15 place inside the Medicare program. And I think doing so  
16 requires to think of all the pathways by which that happens  
17 and what we might be making sure we understand, any  
18 intended and unintended consequences, different policy  
19 options.

20           The second, which is somewhat separate from any  
21 substantive recommendation, is we think it's important to  
22 have the data so we understand what's actually going on

1 here and how it's going on and a whole range of other  
2 things that might be happening.

3           It is obviously very complicated when you add in  
4 the earlier comment that David made about how it's affected  
5 by risk corridors and other types of things like the  
6 manufacturer discount and stuff. All of that makes this an  
7 incredibly complex topic. It's complex because it's an  
8 interaction in MA Plan. It doesn't happen in Part D plan.

9           I think we will ponder all of that, but first --  
10 well, we're going to move on, but before we do now, I think  
11 there's a question from Larry that he wants to ask before  
12 we move on. So we have a few minutes.

13           Larry, I can't see you, but you're up. Oh, there  
14 you are.

15           DR. CASALINO: My quick question may be putting  
16 you on the spot too much, but following up on what some  
17 other people seem to suggest, are you proposing a potential  
18 chapter specifically on rebates and their effects and ways  
19 to deal with them that would bring together information on  
20 rebates that we've already discussed at various meetings?

21           DR. CHERNEW: To be honest, I'm not sure. It  
22 depends on how much is there and how far we can go, what

1 Jim thinks, and how it fits best in a coherent chapter. So  
2 I'm not sure a stand-alone chapter on rebates is what I  
3 would propose.

4 This was going to be integrated into another  
5 chapter, anyway, and so I think we have to think about how  
6 we integrate it into broader activities. I don't know  
7 exactly the answer, Larry. I wish I did.

8 Jim, do you have any comments on that?

9 DR. MATHEWS: Yeah.

10 DR. CASALINO: I think that's a good response.

11 I guess my only recommendation would be that at  
12 some point, an explicit decision up or down is made about  
13 whether to do that or not, have kind of a summary chapter  
14 about rebates.

15 And I'm not necessarily advocating it. Honestly,  
16 I'm not, but I think at some point, an explicit decision  
17 about it.

18 Jim is shaking his head, I think, negative.

19 DR. MATHEWS: No, we will make an explicit  
20 decision. Recall that this material that we've just  
21 presented is very much at a developmental stage. It is a  
22 new issue related to rebates that we as a Commission have

1 not discussed in detail previously, but as Brian has  
2 extremely helpfully pointed out, we do have some history  
3 here. To the extent the Commission wants to evaluate  
4 several lawyers of the effects of rebates, we can do that  
5 in a comprehensive chapter, but it will not be this cycle.  
6 So we would be talking about a potential 2022 chapter in  
7 March or June in that year.

8 DR. CASALINO: Okay.

9 MS. KELLEY: Bruce, did you have a question?

10 MR. PYENSON: Just to follow up on that, Jim, I'm  
11 wondering if there's more interest -- maybe to Paul's first  
12 point -- in not pursuing these details but going into the  
13 broader direction.

14 [Audio difficulties.]

15 DR. CHERNEW: I'm not sure who's talking.  
16 Whoever is talking, we're not hearing you very well at all.

17 MS. KELLEY: I think -- I think I muted everyone  
18 here. Can you try again, Bruce? I'm sorry.

19 MR. PYENSON: I'm sorry. My question was to Jim  
20 on whether given the discussion, there might be more  
21 interest in going to the broader issue rather than spending  
22 the effort to complete this technical discussion, and I'm

1 wondering if that's on the table, Jim.

2 DR. MATHEWS: So just to be clear, you are  
3 putting me on the spot here in making a decision as to  
4 whether or not MedPAC is going to weigh in on the broader  
5 proprietary of rebates in the free market. Is that what's  
6 happening here?

7 DR. CHERNEW: Jim, I can take this. I'm not sure  
8 I'll take it accurately.

9 I do not think that MedPAC is going to weigh in  
10 on the broader role of rebates across all markets. I do  
11 think MedPAC can weigh in on the ramifications to the  
12 rebates on things that clearly affect Medicare  
13 beneficiaries like their out-of-pocket cost sharing, for  
14 example.

15 So my personal view -- and, again, it would be  
16 nice to be able to be there in person and see you all face-  
17 to-face, but I'll go on record as saying this is a Chernew,  
18 not a MedPAC Commission direction. I would like to  
19 continue this because I think it fits into the spirit of  
20 getting payment accuracy right, and I don't see this as an  
21 either/or kind of question.

22 In fact, I'm not sure, depending on data, how

1 much more effort there is beyond this work. I think we've  
2 done a lot of the work already.

3           That being said, per Paul's initial comment, an  
4 expansion to understand some of the other ways in which the  
5 rebate system causes untoward consequences to the Medicare  
6 program or the Medicare beneficiaries is something that I  
7 think we should entertain doing once we understand what  
8 that involved, although in the spirit of what Jim said, it  
9 is not likely -- by that, I mean unlikely -- to happen this  
10 cycle.

11           I'll say one other thing. It is in the spirit  
12 both of our session tomorrow and some of these comments  
13 that Pat made about new products. The issue of new  
14 products, be they pharmaceutical products or not, is a  
15 continual challenge in the Medicare program in a range of  
16 ways, certainly not just risk adjustment. It's a challenge  
17 for benchmarking, a challenge for bundling, and there's a  
18 series of systems that Medicare has put in place to deal  
19 with new products. In the drug case, for example, separate  
20 passthrough drugs and a range of things like that.

21           We will be discussing them tomorrow and continue  
22 to discuss them, and I think we will spend more time in

1 future cycles, spending a lot of time thinking about the  
2 process by which the Medicare program incorporates new  
3 products, writ large.

4           Again, I think risk adjustment is only a small  
5 portion of the challenges that that creates, and I'm  
6 particularly interested in the bundling issues, which again  
7 we're going to talk about some tomorrow.

8           Go on, Paul.

9           DR. PAUL GINSBURG: I've thought a lot about the  
10 issue that Bruce raised, and my thinking is that improving  
11 the risk adjustment is something that is much more doable.  
12 It's easier politically than taking on a broader rebate  
13 issue. So I don't think I'd want to give it up to wait for  
14 something bigger. I would want to pursue this risk  
15 adjustment issue but mentioning there are bigger issues and  
16 the Commission will get to them later.

17           MS. KELLEY: Betty, did you have something you  
18 wanted to say?

19           DR. RAMBUR: Very briefly. I will just say  
20 tuning into this conversation and really being part of this  
21 conversation as a new person on MedPAC, the one thing that  
22 the conversation sort of screams to me is greater

1 transparency and greater understanding. Just to understand  
2 these different pieces and how they come together, even  
3 describing that, and then greater transparency, I think,  
4 would be a tremendous -- the need for greater transparency  
5 and our argument for that would be a great contribution.

6 DR. CHERNEW: Thank you, Betty.

7 I'm pausing just for a second.

8 [Pause.]

9 DR. CHERNEW: Seeing no one jumping in, we are  
10 now going to move to a different Part D question. I'm  
11 going to turn it over to Eric, and we're going to talk  
12 about competition among Part D's benchmark plans.

13 So, Eric, you have the floor or the video or  
14 whatever you have.

15 MR. ROLLINS: Thank you.

16 Good afternoon. I'm going to conclude today's  
17 presentations with another session on the Part D drug  
18 benefit.

19 Earlier this year, the Commission made several  
20 recommendations to restructure Part D and restore its  
21 market-based structure. We recommended reducing the use of  
22 cost-based reinsurance, making plans bear more financial



1 risk for drug spending, and giving plans greater ability to  
2 manage drug spending.

3           During this presentation, I'm going to discuss  
4 another area where we think the program's market-based  
5 structure could be improved -- the stand-alone drug plans  
6 that largely serve low-income beneficiaries and are known  
7 as benchmark plans. Our goal today is to assess your  
8 interest in doing more work on this area in the future.

9           Before I begin, I'd like to remind the audience  
10 that they can download a PDF version of these slides in the  
11 handout section of the control panel on the right-hand side  
12 of the screen.

13           Let me start by giving you a little bit of  
14 background. Part D's low-income subsidy, or LIS, was  
15 created to ensure that low-income Medicare beneficiaries  
16 have access to drug coverage by helping them pay their  
17 premiums and out-of-pocket costs.

18           As of April 2020, almost 13 million people  
19 received the LIS, and they account for 27 percent of  
20 overall Part D enrollment.

21           Today I'm going to focus on how the LIS  
22 subsidizes premiums and the stand-alone prescription drug

1 plans, or PDPs, that largely serve LIS beneficiaries. The  
2 premium subsidy has two key features -- a dollar limit  
3 known as the benchmark and an auto-enrollment process. And  
4 I'll now go into those in more detail.

5           The benchmark is designed to encourage LIS  
6 beneficiaries to enroll in lower-cost plans. Under Part D,  
7 each plan offers either basic coverage, which consists of  
8 the standard Part D benefit or its actuarial equivalent, or  
9 enhanced coverage, which is basic coverage plus some type  
10 of additional benefits. The benchmark equals the average  
11 premium for basic coverage across all PDPs and Medicare  
12 Advantage prescription drug plans, or MA-PDs, in a region.

13           The benchmark is the maximum amount that the LIS  
14 will pay for basic coverage. LIS beneficiaries who enroll  
15 in basic plans that are less expensive do not have to pay a  
16 premium, and these plans are thus known as benchmark plans.

17           In contrast, LIS beneficiaries who enroll in  
18 basic plans that are more expensive must pay the difference  
19 between their plan's premium and the benchmark. In  
20 addition, since the LIS only subsidizes basic coverage, any  
21 beneficiaries who enroll in enhanced plans must pay the  
22 extra premium that those plans charge to finance their

1 richer benefits.

2           The Part D program relies on beneficiaries to  
3 voluntarily select a drug plan, but policymakers also  
4 wanted to ensure that LIS beneficiaries had drug coverage.  
5 They decided to balance these goals by automatically  
6 enrolling these beneficiaries in a benchmark plan if they  
7 did not choose a plan on their own. Using benchmark plans  
8 in the auto-enrollment process helps ensure access to  
9 coverage because the LIS covers the entire beneficiary  
10 premium. This approach also gives plan sponsors an  
11 incentive to offer benchmark plans because auto-enrollment  
12 enables them to generate enrollment without incurring  
13 expenses such as marketing costs.

14           CMS auto-enrolls beneficiaries by randomly  
15 assigning them to a benchmark plan, and each benchmark plan  
16 in a region usually receives the same number of auto-  
17 enrollees. CMS also gives beneficiaries who have been  
18 auto-enrolled and do not like their plan several chances to  
19 switch to another plan.

20           Auto-enrollment is also used in situations  
21 besides a beneficiary's initial enrollment in Part D. The  
22 most notable instance applies to PDPs that lose their

1 benchmark status when CMS calculates Part D premiums and  
2 benchmarks for a new plan year. CMS reassigns the  
3 beneficiaries in these losing plans to other benchmark  
4 plans to ensure that they do not have to start paying  
5 premiums.

6           However, there is also a de minimis exception  
7 that allows plans that narrowly miss the benchmark to waive  
8 the remaining premium for their LIS enrollees and avoid  
9 having them reassigned to other plans. CMS has used \$2 as  
10 the de minimis threshold since 2011. Plans that take this  
11 option avoid the reassignment process but do not receive  
12 any new auto-enrollments.

13           Since LIS beneficiaries can enroll without paying  
14 a premium, benchmark plans and de minimis plans are  
15 collectively referred to as zero-premium plans. Given the  
16 emphasis that Part D places on beneficiary choice, CMS does  
17 not reassign LIS beneficiaries who have chosen a plan on  
18 their own. These people are often referred to as  
19 "choosers."

20           The LIS has led to the creation of a distinct  
21 subset of PDPs that focus heavily on low-income  
22 beneficiaries and have relatively little overlap with the

1 plans that serve the rest of the Part D population. This  
2 year, 88 percent of LIS beneficiaries are enrolled in zero-  
3 premium plans, compared to only 21 percent of non-LIS  
4 beneficiaries

5 LIS beneficiaries also account for more than half  
6 of the overall enrollment in zero-premium plans, but  
7 represent only a small share of the enrollment in other  
8 PDPs, such as enhanced plans or employer-sponsored plans.

9 In 2020, there are a total of 244 zero-premium  
10 plans -- 191 benchmark plans and 53 de minimis plans. Like  
11 the broader Part D market, this sector is highly  
12 concentrated, and almost 85 percent of all zero-premium  
13 plans are offered by just six national plan sponsors. The  
14 number of zero-premium plans varies from region to region  
15 and changes from year to year along with plan bids and  
16 benchmarks. This year, most regions have between five and  
17 nine plans.

18 Turning now to the effects of auto-enrollment, we  
19 analyzed Part D enrollment data and found that most LIS  
20 beneficiaries in PDPs are auto-enrollees. In 2019, we  
21 found that 62 percent of the LIS beneficiaries in PDPs, or  
22 4.5 million people, were current auto-enrollees, meaning

1 they had been auto-enrolled and had not yet chosen a plan  
2 on their own. Another 16 percent were former auto-  
3 enrollees.

4           There is also significant turnover within the  
5 auto-enrolled population. Between 2015 and 2019, we found  
6 that an average of about 875,000 beneficiaries were auto-  
7 enrolled each year. Roughly 85 percent of them were new  
8 Part D enrollees. Many auto-enrollees later select a PDP  
9 or MA-PD on their own. We found that about half select a  
10 plan within 5 years, and that the share who later select a  
11 plan has been going up over time, likely due to growing  
12 participation in MA.

13           Moving now to Slide 8, the paper has information  
14 on the overall number of LIS beneficiaries who have been  
15 reassigned to new plans. However, we think the impact of  
16 reassignment is best measured by the subset of people who  
17 are randomly reassigned to other PDPs because the premium  
18 for their current plan is rising above the benchmark.  
19 Using this metric, the number of reassignments has declined  
20 from about 498,000 at the end of 2015 to 100,000 at the end  
21 of 2019.

22           I would also like to highlight that the benchmark

1 PDP market was much more unstable in Part D's early years.  
2 There was a high level of turnover in the lineup of zero-  
3 premium plans and the number of reassignments was sometimes  
4 significant, which generated concerns that many  
5 beneficiaries might be switched to plans that didn't cover  
6 all of their medications. Policymakers reacted by making a  
7 series of changes that stabilized the market by increasing  
8 benchmarks and reducing reassignments.

9           Although benchmarks and auto-enrollment have been  
10 very effective at enrolling LIS beneficiaries in zero-  
11 premium plans, they also create incentives that limit the  
12 amount of competition among those plans and result in  
13 higher Part D spending.

14           The Part D program relies on competition among  
15 private insurers to encourage the development of plans that  
16 beneficiaries find attractive and to control overall  
17 program spending. Plans that want to serve LIS  
18 beneficiaries have an incentive to keep their premiums  
19 below the benchmark. These plans don't know exactly what  
20 the benchmark will be when they submit their bids, but they  
21 can often make a reasonable estimate based on the current  
22 benchmark, their share of LIS enrollment in the region, and

1 projected spending growth.

2           However, once a plan qualifies as a benchmark  
3 plan, it has no marginal incentive to lower its premium any  
4 further. If the plan does lower its premium, it won't  
5 receive any more auto-enrollees, since every benchmark plan  
6 in a region receives an equal number. The plan also won't  
7 become any more attractive to LIS choosers compared to  
8 other benchmark plans, because the choosers pay no premium  
9 in either case. As a result, a benchmark plan that lowers  
10 its premium receives less Medicare revenue for the same  
11 number of enrollees. Like contestants on The Price Is  
12 Right, these plans want to set their premiums as close to  
13 the benchmark as they can without going over.

14           This graphic illustrates how the premiums for  
15 benchmark plans tend to cluster around the benchmark. It  
16 shows the distribution of PDP premiums in 2020, based on  
17 the difference between the plan's premium and the  
18 benchmark. In the top half, you can see that the premiums  
19 for most benchmark plans are very close to the benchmark  
20 and that there are a significant number of plans in the de  
21 minimis range. In contrast, you can see in the bottom half  
22 that there is more variation in the premiums for enhanced



1 PDPs, and that some plans have premiums that are lower than  
2 the benchmark.

3           So why do we think that benchmark plans are not  
4 bidding as low as they could? We don't have a lot of  
5 direct evidence, since the premiums for those plans cluster  
6 in such a narrow range, but there are other indicators that  
7 are suggestive.

8           The first indicator is the contrast between the  
9 premiums for basic plans and enhanced plans. As we just  
10 saw, some enhanced plans have premiums that are well below  
11 the benchmark, even when you include the extra premium that  
12 they charge for their richer coverage. The comparison  
13 isn't perfect, since basic and enhanced plans serve  
14 different types of beneficiaries, but the differences are  
15 large enough to suggest that basic plans could reduce their  
16 premiums to some extent.

17           The second indicator is that the vast majority of  
18 the plans that qualify for the de minimis option, 88  
19 percent over the past decade, agree to participate. The  
20 fact that so many plans agree to waive the extra premium  
21 when they miss the benchmark indicates they were willing to  
22 serve LIS beneficiaries for less revenue than they stated

1 in their bid.

2           The third indicator are some findings from a 2014  
3 study of benchmark plans by the Congressional Budget  
4 Office. CBO found that benchmark plans were less  
5 responsive than other basic plans to greater competition,  
6 and that plans with premiums that were farther below the  
7 benchmark were more likely to increase their bids the  
8 following year. Both findings suggest that the LIS limits  
9 the incentives for benchmark plans to bid competitively.

10           The LIS also reduces competition in another way  
11 because plan sponsors can inflate the benchmarks after a  
12 merger or acquisition. Sponsors can normally offer just  
13 one basic PDP, but there is a two-year exception for  
14 sponsors involved in a merger or acquisition.

15           During this transition period, a sponsor could  
16 have two basic plans, and it can bid strategically to  
17 inflate the benchmarks without losing any LIS enrollees.  
18 The sponsor can do this by charging a high premium for Plan  
19 1 while making Plan 2 a zero-premium plan. Plan 1 will not  
20 qualify as a benchmark plan, but its high premium puts  
21 upward pressure on the benchmark.

22           Sponsors that only have one basic plan would

1 normally avoid this approach because their auto-enrollees  
2 would be reassigned to other plans. But in this case, the  
3 auto-enrollees in Plan 1 will simply be reassigned to Plan  
4 2, because CMS reassigns beneficiaries to another zero-  
5 premium plan offered by the same parent organization before  
6 reassigning them to plans offered by other companies. We  
7 found suggestive evidence, described in more detail in your  
8 mailing materials, that several plan sponsors have used  
9 this strategy following recent acquisitions.

10           Now I am going to switch gears and outline two  
11 potential policy changes that would improve competition  
12 among benchmark plans. The first change would be to give  
13 benchmark plans stronger incentives to bid lower. Right  
14 now, every benchmark plan in a region typically receives  
15 the same number of auto-enrollees, so plans do not have an  
16 incentive to reduce their premiums any further.  
17 Policymakers could instead reward plans that bid lower by  
18 giving them more auto-enrollees, which might also require  
19 the development of a new way of calculating the benchmarks.  
20 In the paper, we outlined one potential approach where CMS  
21 would specify the number of benchmark plans in a region and  
22 the share of auto-enrollments that each plan would receive.

1           Another way to promote competition would be to  
2 give LIS beneficiaries who are choosers a cash award when  
3 they enroll in a lower-premium benchmark plan. However,  
4 this approach may not be very effective because the  
5 potential size of the award is unclear and because the  
6 share of Part D enrollees who voluntarily switch plans is  
7 relatively low. As a result, we think that changes to the  
8 auto-enrollment process are more likely to increase  
9 competition.

10           One tradeoff to keep in mind here is that efforts  
11 to improve competition could also increase the number of  
12 LIS beneficiaries who need to switch plans to avoid paying  
13 a premium.

14           Policymakers could also improve competition by  
15 eliminating the ability of plan sponsors to inflate the  
16 benchmarks after a merger or acquisition. We think this  
17 could be done in one of three ways.

18           The first way would be to stop reassigning LIS  
19 beneficiaries to another zero-premium plan offered by the  
20 same parent organization. This would prevent sponsors from  
21 raising the premium for one plan and relying on the  
22 reassignment process to shift its auto-enrollees to the

1 other plan.

2           The second way would be to require sponsors to  
3 submit the same bid for all basic plans, which would  
4 prevent sponsors from raising one plan's premium while  
5 keeping the other plan's premium below the benchmark.

6           The third way would be to eliminate the  
7 transition period that allows sponsors to offer multiple  
8 plans for two years after a merger or acquisition.  
9 However, we would need to discuss this option with CMS and  
10 plan representatives to better assess its feasibility.

11           That brings us to the discussion portion of the  
12 session. First, we would like to know if the Commission is  
13 interested in doing additional work on this issue in a  
14 future meeting cycle. Second, to the extent that you are  
15 interested, we'd like to get your feedback on the policy  
16 options that we outlined, especially the idea of giving  
17 lower-bidding plans a larger share of auto-enrollments.

18           That concludes my presentation. I will now turn  
19 it back to Mike.

20           MS. KELLEY: Mike, we can't hear you. But I think  
21 Mike wants to --

22           DR. CHERNEW: Now can you hear me? Yeah. Dana

1 was about to say that she thinks I would like to go to the  
2 Round 1 queue, and she is right. I would like to go  
3 straight to the Round 1 queue. Dana?

4 MS. KELLEY: Okay, Marge, you are first.

5 MS. MARJORIE GINSBURG: Okay. Great. Thank you.  
6 Wonderful report, and it's, I think, very exciting to get  
7 into the details of this issue.

8 A couple of questions. On page 1 of the report,  
9 at the end of the first paragraph, I was unsure about  
10 whether this is the correct word. It says "which results  
11 in higher benchmarks and increases Part D spending."  
12 Should the word be "benchmarks" or "premiums"? I know this  
13 is kind of in the weeds a bit, but I wondered if you've got  
14 that in front of you and somebody can -- Eric, whether you  
15 can comment on that?

16 MR. ROLLINS: Sure. In this case, to some  
17 extent, they are one in the same, the benchmark being the  
18 average premium in a region. So to the extent that we  
19 think that the current system has incentives for plans to  
20 set their premiums higher than they might be under a  
21 different set of incentives, the benchmarks are also  
22 higher, and overall Part D spending is higher.

1 Does that answer your question?

2 MS. MARJORIE GINSBURG: Yeah, I think it does.

3 I went back and I looked at the Northern  
4 California benchmark plans with standalone PDPs, and there  
5 are several standalones that would have qualified as  
6 benchmarks but are not on our benchmark list that we use in  
7 Northern California. Do you have any thoughts about why a  
8 company would decide not to be a benchmark if, in fact,  
9 they qualify, in terms of their premium amount?

10 MR. ROLLINS: I don't have the information in  
11 front of me that you have, so I'm going to speculate just a  
12 little bit. There are plans that have premiums that are  
13 lower than the benchmark but they aren't benchmark plans  
14 because they offer enhanced coverage.

15 MS. MARJORIE GINSBURG: But they offered both. I  
16 mean, many PDPs offer a variety of plans in their  
17 standalone list, sometimes as many as four different plan  
18 levels. So I was just curious whether there was any  
19 thought about why somebody would choose not to be a  
20 benchmark plan if they qualified.

21 MR. ROLLINS: I would have to probably follow up  
22 with you on that. To the extent that you're offering a

1 basic PDP and your premium comes in below the benchmark,  
2 you are a benchmark plan. It's not an option for the plan,  
3 at that point. The de minimis piece that I was talking  
4 about, where plans just narrowly miss the benchmark, that  
5 is optional. Plans can do it or not do it, although as I  
6 was saying, most of them do agree to participate. But if  
7 you're offering basic coverage and your premium is below  
8 the benchmark, you are a benchmark plan, whether or not you  
9 want to be.

10 MS. MARJORIE GINSBURG: Okay. And how often do  
11 plans voluntarily leave benchmark status? Do we have any  
12 indication of plans that intentionally did not bid at the  
13 benchmark range?

14 MR. ROLLINS: I don't have firm numbers, but, you  
15 know, there are plan sponsors, and we discussed this a  
16 little bit in the mailing materials. Some companies don't  
17 seem to be terribly interested in offering a zero-premium  
18 plan. So, for example, Anthem and Mutual of Omaha are two  
19 plan sponsors that come to mind, that they offer a large  
20 number of basic PDPs, but by and large they're not  
21 benchmark plans in many, or even any regions.

22 Exactly as to what their motivations are, you



1 know, I don't know immediately off the top of my head. But  
2 the companies do vary, to some extent, in their view of the  
3 LIS segment of the market and whether or not they think  
4 it's desirable.

5 MS. MARJORIE GINSBURG: Okay. And my last  
6 question, do we have any statistics on how often  
7 beneficiaries are reassigned to new benchmarks?

8 MR. ROLLINS: I don't have those at hand. Given  
9 the data we have, that is something we could look into and  
10 I can ultimately get back to you with some numbers. I  
11 think at one point former Commissioner Jack Hoadley put out  
12 a paper on the reassignment process, that looked at the  
13 very early experience, like 2006 to 2010, and I think he  
14 might have had some statistics on how many people were  
15 getting sort of periodically reassigned, which is what I  
16 think your question is. But I don't have any figures at  
17 hand.

18 MS. MARJORIE GINSBURG: Good. Thank you.

19 MS. KELLEY: Bruce, I have you for Round 1.

20 MR. PYENSON: Yes. Thank you. Eric, this is a  
21 wonderful paper. Thank you.

22 I have a question about Slide 10, or a couple of

1 questions about Slide 10. I really appreciate how you  
2 lined up the premiums here, or, in effect, the difference  
3 between the plan premium and the benchmark. And I  
4 understand this is -- I believe this is number of plans as  
5 opposed to enrollment. But it's striking how many of the  
6 enhanced plans are below the benchmark. And I guess it's  
7 easy to make a plan enhanced by offering some extra  
8 benefits or changes in some of the cost sharing.

9 Do you have insight into what the split is  
10 between -- well, are any of these PD plans, as in MA-PD, or  
11 is this all standalone PDPs?

12 MR. ROLLINS: This figure shows just standalone  
13 PDPs.

14 MR. PYENSON: Oh, okay. I wonder if you know why  
15 it is that enhanced PDPs, the basic bid amount before the  
16 enhanced amount, is not included in the calculation of  
17 benchmarks? What was the rationale for that? Was that the  
18 expectation that they would all be to the right?

19 MR. ROLLINS: So the basic portion of the premium  
20 is included in the calculation of the benchmark. That's  
21 true for all PDPs and MA-PDs.

22 MR. PYENSON: Okay. So it's not just the basic

1 plans but it's only the basic plans that would be eligible.

2 MR. ROLLINS: Correct.

3 MR. PYENSON: Okay. Thank you.

4 MS. KELLEY: Pat?

5 MS. WANG: Thanks. Eric, thank you. As usual, I  
6 learn so much when I read your work.

7 So I'm a little bit confused about how the  
8 benchmark premium is set. The paper refers to calculation  
9 using a weighted average of PDP and MA-PD premiums in a  
10 region. So, you know, PDPs are slightly more than half of  
11 LIS enrollment and MA-PDs are, whatever, 45-ish percent of  
12 LIS enrollment. And the reason I'm asking about this is  
13 that the benchmark is kind of the target, that if you're an  
14 MA plan you're bidding against, and there's a little  
15 mystery as to, you know, how those get derived.

16 Do you know whether or not -- Bruce kind of asked  
17 the question about this table -- do you have information on  
18 the bidding behavior of MA-PDs for this premium as compared  
19 to PDPs? And I guess that the part of the question that  
20 I'm confused about is when an MA-PD plan bids, and they are  
21 bidding on Part D, it's kind of circular because they're  
22 bidding against the benchmark and they may be spending Part

1 C rebate dollars to spend down to a zero-premium level.

2 So can you just say more about how this works?

3 Like what premium is being used here to determine the  
4 benchmark premium, and do you have any insight into how MA-  
5 PDs bid, compared to PDPs?

6 MR. ROLLINS: So in terms of how the benchmark is  
7 calculated, like you said, they use both PDP and MA-PD  
8 premiums. To the extent that you have a plan that offers  
9 enhanced coverage or something that's richer than the  
10 standard Part D benefit, CMS is only going to use the  
11 portion of your premium that reflects the basic coverage.  
12 So that's one element.

13 The second element is that for the MA-PDs, like  
14 you noted, there's a process, which I agree is somewhat  
15 convoluted, of how, you know, they can use some of their  
16 Part C rebates to buy down some of their premium. What's  
17 used in the calculation is sort of the plans' Part D  
18 premium for basic coverage before that rebate allocation  
19 process plays out. The concern was that -- and initially  
20 that was not the case. The first several years of Part D  
21 they included MA-PD premiums after they had been reduced by  
22 the rebates, and the concern was that it made the

1 benchmarks too low and that there was one other factor that  
2 was making the benchmark sort of segment of the PD market  
3 unstable.

4           In terms of how MA-PDs bid compared to PDPs, I  
5 don't have figures off the top of my head, but that's  
6 certainly something we could follow up on.

7           MS. WANG: Okay. Thank you. Interesting. Thank  
8 you.

9           MS. KELLEY: Amol?

10          DR. NAVATHE: Hi, Eric. Great chapter. Thank  
11 you for the write-up. I have kind of what may be a really  
12 nitty-gritty question, which is on the bottom of page 5,  
13 about the auto-enrollment, you note that the agency decided  
14 -- CMS has decided to use auto-enrollment for all LIS  
15 beneficiaries who do not choose a plan, not just those who  
16 qualify for full Medicaid benefits, and I was curious what  
17 the margin there was by expanding that group that's being  
18 auto-enrolled. Is that a huge expansion or is it actually  
19 a small number?

20          MR. ROLLINS: So I can answer -- I'm going to  
21 answer your question kind of like halfway, unfortunately.  
22 Roughly speaking, you've got 13 million or so people who

1 are LIS beneficiaries. In really rough terms, you've got 7  
2 million who have full Medicaid benefits, 3 million who've  
3 got partial Medicaid benefits, and another 3 million who  
4 just get the LIS. They don't have any Medicaid coverage.  
5 Now, those figures are really rough, so I think that  
6 answers part of your question. What I don't have off the  
7 top of my head is what share of those people are picking  
8 plans on their own. The share of each of those segments  
9 who are getting auto-enrolled could differ, and I don't  
10 have those figures in front of me. So that's why I say I  
11 can only answer your question kind of halfway.

12 DR. NAVATHE: Okay. That's helpful. Thank you.

13 MS. KELLEY: Jaewon?

14 DR. RYU: Yeah, thank you, Eric. I enjoyed the  
15 chapter as well. With some of the potential adjustments  
16 that you're proposing or that are being contemplated in the  
17 chapter, any sense of order of magnitude on how much we  
18 think the benchmark could move downwards and how much  
19 savings there could be programmatically?

20 MR. ROLLINS: I think it's really hard to say.  
21 As we noted in the paper, as you can see from the slide  
22 that we have up here, a lot of the basic plans right now

1 are bunched into a very narrow sort of stretch. And so how  
2 much they could bid lower if given the incentive to do so  
3 is a little unclear. You know, like you can see, there are  
4 a number of enhanced plans that have -- you know, they  
5 might be \$10, \$20 below the benchmark. So it's hard to  
6 give a firm answer. I think this is meant to suggest  
7 there's kind of an issue here. We might want to rethink  
8 the incentives.

9 I think another factor -- and I think we're  
10 pretty up front about this in the paper -- is, you know, we  
11 can say it would be a good idea to give plans more auto-  
12 enrollees if they bid lower, but we don't know exactly how  
13 strong that relationship would be between sort of the size  
14 of the carrot, if you will, the reward, and sort of how  
15 much of a change in plan behavior we can expect to see.

16 MS. KELLEY: Bruce, did you have one last Round 1  
17 question?

18 MR. ROLLINS: Bruce, I can't hear you.

19 MR. PYENSON: Ah, thank you. Eric, just on what  
20 contributes to the benchmark, I think the contribution of  
21 each plan's basic bid is weighted by the LIS enrollment of  
22 the plan.

1 MR. ROLLINS: That's correct.

2 MR. PYENSON: So, in effect, on this slide  
3 there's probably very little contribution from the plans in  
4 green because the vast majority of LIS are in the benchmark  
5 plans. And so --

6 MR. ROLLINS: Yes, I would agree with that.

7 MR. PYENSON: And so maybe I'd rephrase my  
8 question about the weighting based on LIS enrollment. I  
9 don't know if there was any history to that, but it seems  
10 an interesting decision to have chosen that kind of  
11 weighting.

12 MR. ROLLINS: So, initially, that was not the  
13 methodology they used. When they first started Part D, the  
14 premiums for the PDPs and MA-PDs were weighted based on  
15 their overall enrollment, not the LIS enrollment. And CMS  
16 switched its methodology, I think -- I'm looking at my  
17 notes -- starting in 2009. At the time there was concern  
18 that the non-LIS beneficiaries were, compared to the LIS  
19 segment, enrolling in lower-premium plans, and so including  
20 them in the calculation sort of put downward pressure on  
21 the benchmarks. Again, that was the rationale at the time.  
22 It was over a decade ago. That relationship may not -- you



1 know, that rationale may not be as true today. That would  
2 be something we would need to look into a little more. But  
3 that was the history on the issue.

4 MR. PYENSON: Thank you.

5 MS. KELLEY: Mike, we can't hear you.

6 DR. CHERNEW: Okay. I keep inadvertently muting  
7 myself.

8 So we're going to transition to Round 2, and  
9 fortunately, Bruce, you can continue since you are a Round  
10 2 person or reactor. And then we'll go to Marge. Marge,  
11 you will be next in line after Bruce, and then we'll work  
12 our way through the Round 2 queue. So, Bruce? And now,  
13 Bruce, we can't hear you.

14 MR. PYENSON: Thank you. I want to express my  
15 support for the work on this issue and fixing the benchmark  
16 process. I think it is very -- the work that Eric has done  
17 is very suggestive that the benchmarks for LIS are higher  
18 than they could be, and that the incentives to get to lower  
19 benchmarks are not as strong as they should be.

20 What I would -- in thinking about that, the  
21 concentration of LIS members in just a few plans,  
22 especially the PDP plans, is very relevant to the

1 discussion we had last month about concentration in health  
2 care on the part of organizations, and it's certainly the  
3 case that these members are sought after by certain  
4 companies who will also go out of their way to avoid losing  
5 -- bidding too high and potentially losing their members.  
6 So I think there's a real opportunity here because the  
7 members are so attractive to certain plans, and after all,  
8 the marketing expenses and the competition for the LIS has  
9 been greatly reduced by the nature of the organizations and  
10 the nature of the bidding process.

11           What I would like to see is a bit more work on  
12 how it is that some significant RD plans can offer enhanced  
13 benefits at significantly below the LIS benchmark, and that  
14 has to do with choice of formularies and other phenomena.  
15 But I think because the benchmarks are, after all, risk-  
16 adjusted, the differences suggest an underlying difference  
17 in business operations and incentives.

18           So I'm very supportive of this work. I think the  
19 direction and the proposals are good, and I'm eager to see  
20 this go to completion.

21           Thank you.

22           MS. KELLEY: Marge?

1 MS. MARJORIE GINSBURG: Thanks. Again, thanks  
2 for a wonderful report. My interest in this is fairly  
3 specific I think most of you know I'm actually a living  
4 and breathing SHIP counselor, and I deal with LIS clients  
5 frequently, particularly ones that I may help enroll in LIS  
6 because they're not on Medicaid. It's an extremely  
7 satisfying process to help people find drug plans that  
8 they're actually going to be able to afford given their  
9 high level of medications that they're taking.

10 I find this an exciting endeavor because it seems  
11 like there's so few ways we might actually use the concept  
12 of market competition to bring costs down. What an idea.  
13 It's been very hard to do in other domains, but I think  
14 this one definitely has potential, and I think the way it's  
15 been described in the report is spot on.

16 The issue about the concern about whether that  
17 would mean a reduction in the number of benchmark plans  
18 available, one of the other things that we do with clients  
19 -- all SHIP counselors do this -- is to use Plan Finder to  
20 make sure that the plan they're signing up for, in fact, is  
21 going to offer the medications that they have. And I think  
22 all of you know everybody's formularies are and can be

1 different. So just because they're an LIS client doesn't  
2 necessarily mean that, you know, one of the benchmarks is,  
3 in fact, going to offer the pharmaceutical coverage that  
4 they particularly need, which is why it's -- that whole  
5 concept of using Plan Finder is so important in helping  
6 people sign up and then helping people switch if, in fact,  
7 there's a better benchmark that's going to offer more  
8 comprehensive coverage.

9           So one of the concerns in the report was, Will  
10 this result in fewer benchmark plans being available? I  
11 think it said in the report -- and I know it's true for  
12 Northern California -- I think we have seven or eight  
13 benchmark plans. That's been pretty stable for the years  
14 that I've been doing counseling. But what happens if this  
15 drops to three or four plans? Does that then mean there's  
16 going to be a bigger struggle for people finding a good  
17 match with the drugs that they're on? Or, as it said in  
18 the report, that people, in fact, are going to need to be  
19 reassigned to new plans because they're going to lose the  
20 plan that they have grown to know and love?

21           I think these are still questions that need to be  
22 looked at, and I think somebody asked the question earlier

1 about how much money can we really save. I mean, if we do  
2 this, if we model this in a way that looks reasonable, what  
3 are we talking about how this is going to benefit the  
4 taxpayer? I don't think this is going to benefit the LIS  
5 beneficiary, and I don't support bribing LIS beneficiaries  
6 to pick lower plans. I just don't think that's a great  
7 idea. But I'd be very interested in knowing what do we  
8 expect this to -- how this might financially benefit the  
9 taxpayer.

10 So those are the outstanding questions. Very  
11 exciting work. I'm all for it. Thank you.

12 MS. KELLEY: Paul?

13 DR. CHERNEW: Thanks, Marge.

14 DR. PAUL GINSBURG: Thanks. Yeah, this is great  
15 work, and we definitely should be working on these issues.  
16 I had a thought as to whether we should think a little  
17 bigger. What I mean by that is that when Part D was  
18 designed, you know, the guiding force was to make this a  
19 competitive approach, competition among plans, and I think  
20 we went for a single market of both non-LIS and LIS  
21 probably to make sure that the LIS plans were good enough,  
22 because they were trying to appeal to the non-LIS

1 population.

2           What I'm thinking is that our attempt to do this  
3 with one unified market has really not worked out. And  
4 along with the options that Eric suggested, which I think  
5 have a lot of potential, we probably should consider  
6 actually breaking the two markets apart and using different  
7 approaches to competition. So for the non-LIS population,  
8 it'll be mainly driven by beneficiaries making trade-offs  
9 between a higher premium and broader choice of drugs or  
10 whatever. But for the LIS population, where we don't  
11 involve them today in making these trade-offs because of  
12 their very limited ability to pay, maybe we should just,  
13 you know, pursue it separately. There are other approaches  
14 to create a competitive market that are not driven by  
15 consumers but are still driven by bidding. And that's just  
16 something to think about as we go forward.

17           MS. KELLEY: Brian?

18           DR. DeBUSK: Thank you. I really enjoyed the  
19 work, Eric. I was reading through the paper. You know,  
20 this is really a classic exercise in game theory. It was  
21 really remarkable. And what really told the story for me  
22 was the clustering, the distribution, the frequency

1 distribution that you did showing how all the plans cluster  
2 right there are the benchmark. You clearly offered a  
3 dominant design, and plans are clearly taking advantage of  
4 that dominant design.

5 I liked a couple of -- several of the items in  
6 the paper, several of the ideas for how to basically  
7 disrupt that design. The ones I really wanted to focus on  
8 were the disproportionately auto-enrolling based on where  
9 the bid fell within the range. I really liked the idea of  
10 the lowest bidder getting -- I think you used 40 percent in  
11 the paper, but basically disproportionately allocating  
12 those auto-enrollments because, you know, Bruce has taught  
13 me one thing over the last four years, and that is that  
14 auto-enrollments are very, very valuable to these plans.  
15 He's taught me many things.

16 So I think the 40 percent auto-enrollment -- or  
17 stratifying the auto-enrollment I think is a great idea. I  
18 also think the idea put forth in the paper about not  
19 reassigning the beneficiaries to the parent company -- you  
20 know, I think the risk of all these beneficiaries slipping  
21 through a plan's fingers has a lot of risk there. So I  
22 think removing that option where, if they don't reach

1 benchmark status, their enrollees are redistributed, I  
2 think that would be a significant incentive to continue  
3 bidding competitively.

4           The final thing that I wanted to add actually  
5 wasn't in the paper, but it really complements these other  
6 two strategies. This de minimis option where if they're  
7 within 2 percent of the benchmark, you know, the plan  
8 basically just gets a do-over. That inherently creates an  
9 incentive to bid just a hair high. And one of the things  
10 I'd like us to consider in the paper is if a plan misses  
11 benchmark status, perhaps we don't just let them concede  
12 that 1 percent or that 2 percent and revert back down to  
13 the benchmark. Perhaps they actually do that with a modest  
14 penalty, so where they can buy back into the program, buy  
15 back in with maybe a 1 or 2 percent benchmark -- or premium  
16 that's below the benchmark. So basically you create a  
17 disincentive to try to win just a little -- to bid just a  
18 little high.

19           But, again, I think this is classic game theory,  
20 and I think the options that were put forth in the paper  
21 are very insightful, and I think they could incent  
22 competition among these plans.



1 Thank you.

2 MS. KELLEY: We have Pat next.

3 MS. WANG: Thank you.

4 So great work, Eric. On this Slide 15, I think  
5 the third bullet -- eliminate the ability of plan sponsors  
6 to inflate benchmarks -- this remains me of contract  
7 consolidation. It's like the one piece of sort of merger  
8 and acquisition and things that plans can engage in to  
9 benefit themselves kind of got missed. So I would be very  
10 in favor of this third bullet. I think it's  
11 straightforward.

12 The other issues, I just want to go backwards to  
13 the question that I raised in Round 1. So roughly half, a  
14 little bit less than half of LIS beneficiaries are enrolled  
15 in Medicare Advantage prescription drug plans, and so this  
16 discussion has really focused on the freestanding Part D  
17 plans, members in Medicare fee-for-service for medical  
18 services. Freestanding Part D plans, they're bidding  
19 behavior and a desire to use competition and other means to  
20 drive the bids down.

21 But as Eric explained earlier, this phenomenon  
22 and the experience on the freestanding Part D plan very

1 much affects what happens on the Medicare Advantage Part D  
2 side, and my concern and the reason I asked about MA-PD  
3 bidding behavior is I think that there may be different  
4 incentives that drive how a PDP bids versus how an MA-PD  
5 bids.

6           When you look at the consolidation of PDP LIS  
7 lives in six national plans, I can surmise -- and I don't  
8 think it's a stretch -- that there is an art form of  
9 formulary placement to maximize benefits and rebates to  
10 drive a certain level of premium.

11           On the MA-PD side, I can tell you at least my  
12 observation. There's a different set of incentives in how  
13 the basic plan, basic benefits might get structured, which  
14 has to do with Stars, medication adherence, avoiding  
15 medical costs that are avoidable and unnecessary, outcomes  
16 base. I think it's a different -- I think it might be a  
17 different -- I think it's definitely a different set of  
18 considerations. It's care management around the Part D and  
19 the medical benefit together.

20           So my concern about sort of focusing this way  
21 just on the freestanding PDP plans, which is great, needs  
22 to have some awareness of how it affects the MA-PD side. I

1 don't know the trend of MA-PD plans and how they are  
2 bidding the Part D basic benefit and whether there is a  
3 trend or not of them having to spend down Part C rebate  
4 dollars to match the benchmark that is being driven by the  
5 freestanding plans, for example.

6           So I would have a hesitation and sort of a time-  
7 out of rushing forward with being more aggressive on  
8 driving down the PDP premium by, for example, offering  
9 greater auto-enrollment. That's not an incentive that  
10 means anything to an MA-PD because what happens on the PDP  
11 world is dragging the MA-PD with it, and I just would want  
12 to know what that current relationship is and how more  
13 aggressive actions on the freestanding PDP side could  
14 ripple over.

15           Thanks.

16           MS. KELLEY: Bruce, did you want to get in on  
17 this point?

18           MR. PYENSON: Yes. Thank you.

19           I totally agree with Pat, and I think as the work  
20 develops, it would make sense to separate MA-PD from PDP  
21 for the reasons that Pat said.

22           I'd be interested in Paul's view of that since I

1 think he had an opinion about separating, separately  
2 viewing LIS from non-LIS but also separately viewing MA-PD  
3 from PDP.

4 DR. PAUL GINSBURG: I think it's a great idea and  
5 getting ready to say it.

6 MS. KELLEY: Dana?

7 DR. SAFRAN: Thank you.

8 And I apologize because I missed the first part  
9 of the discussion, but I just wanted to say that as I think  
10 I heard -- maybe it was Brian saying when I came back on.  
11 The clustering right around the benchmark is just really  
12 quite remarkable and suggests gaming that's going on.

13 So I have two things to comment on. One is I  
14 really liked the suggestion in the chapter about the  
15 possibility of a bidding process that would create the  
16 incentives that seem to be lacking right now to bid lower  
17 benchmark -- bid lower amounts to potentially lower the  
18 benchmark.

19 The other comment I had is just a small editorial  
20 one, and that is, I found myself struggling in the chapter  
21 because I hadn't seen an explanation early on about how the  
22 benchmarks get set. So I just kept trying to infer from

1 what I was reading about how the process goes. I think,  
2 unless I missed something, that it would be helpful to  
3 incorporate something a little bit earlier in the chapter  
4 about how the benchmark process works today.

5 But otherwise, it's great work, and I'm glad  
6 we're pursuing it. I think it's an important piece of  
7 work.

8 MS. KELLEY: David?

9 DR. GRABOWSKI: Great. Thanks.

10 Eric, great work. Really, really, like others,  
11 glad that we're pursuing this.

12 In terms of the options, I'll be brief here. I'm  
13 a fan to giving lower bidding plans a larger share of the  
14 auto-enrollments, so Bullet 1. I also like Bullet 3 in  
15 terms of eliminating the ability of plan sponsors to  
16 inflate the benchmarks after a merger or acquisition. It  
17 just seems really fraught with lots of potential for gaming  
18 to allow plans to inflate the benchmarks after these  
19 mergers. So I really like Policies 1 and 3.

20 I'm not as much a fan of Policy 2 and don't think  
21 we should pursue the cash awards, that I think we could go  
22 at that through giving the plans a larger share of the

1 auto-enrollments.

2           The only other comment I was going to make was  
3 just in response to Brian's suggestion, which I thought was  
4 awesome about the de minimis plans. Eric, you do the  
5 comparison with the game show, The Price is Right. If you  
6 go over on that show, you don't get a do-over. As Brian  
7 suggests, we're really giving a do-over here. So I like  
8 this idea quite a bit of having the plans that do want to  
9 buy back in to pay a penalty. I think that's a really  
10 elegant idea. So I want to just endorse that.

11           But thanks. Once again, I'm glad we're going  
12 down this path. Thanks.

13           MS. KELLEY: Larry, I think you are the last  
14 Round 2.

15           DR. CASALINO: Yeah. So I put my hand up just  
16 before David spoke, but basically, David said everything I  
17 was about to say. I completely agree with each point.

18           David, I think you said -- or if you didn't say  
19 it, I'll say it. I agree with Marge. I think the second  
20 bulleted recommendation, pay a cash reward, I would hope  
21 that we wouldn't have to do that if the first and third  
22 bullets of the elimination of de minimis helped.

1           Then I guess just the other thing I'd add, if it  
2 really looks like it doesn't make sense to analyze the  
3 freestanding plans and the Medicare Advantage plans  
4 together, quite obviously, we should do them separately,  
5 then, if we can.

6           MS. MARJORIE GINSBURG: May I make one more  
7 comment? Yes? No?

8           MS. KELLEY: Yes.

9           MS. MARJORIE GINSBURG: Okay. Nobody is kicking  
10 me out.

11           About the choice of a drug plan when you're in  
12 original Medicare versus MA plans -- and again, this is my  
13 experience -- people either come to us because they're in  
14 original Medicare, they get on LIS, and now they want to  
15 make sure they get a drug plan that's going to best serve  
16 them.

17           If people are already in an MA plan and now get  
18 on LIS, then there's the opportunity to make sure they're  
19 getting the best benefit from the drug plan that's  
20 associated with that MA plan.

21           But now they're faced with a dilemma. Are they  
22 going to change MA plans in order to get a better drug

1 plan? And I'm very enthusiastic about us moving forward  
2 and looking at these two, but I think they really use  
3 different. And the decision process for beneficiaries is  
4 very different. I'm not sure how that works out, and we  
5 definitely should pursue it.

6 But I just wanted to make sure we don't try to  
7 combine this issue into one pot because I don't think they  
8 fit into one pot.

9 Thank you.

10 MS. KELLEY: Mike, that's all we have.

11 DR. CHERNEW: Great. That's all we have for now.  
12 I'll keep watching the chat.

13 So a few things. The first is that I think we --  
14 it's not surprising to me that the clusters around the  
15 benchmark, that is very common. You see that, for example,  
16 also in employer MA plans. I'm not sure I would call that  
17 "gaming" as much as responding to incentives, and this  
18 entire discussion is about how to set the incentives to get  
19 what we want to have happen. It's been a very rich  
20 discussion.

21 I hear basically three main goals. The first one  
22 is, in some sense, we don't want to drive the benchmark too



1 low because we don't want to have a disruptive  
2 reassignment, but we would like to shift people towards  
3 perhaps the lower bidding plan.

4           And I guess the core question -- and this will be  
5 something we'll discuss over the next several months -- is  
6 what we want to do with any associated savings. I have to  
7 say I don't have a strong opinion, but I am not amenable to  
8 sharing some of those savings with the beneficiaries per se  
9 if it can be done in an administratively simple way.

10           The broader point, I think, I'd like to make is  
11 that it is clear both there's enthusiasm and that we are at  
12 the beginning of the mountain. There's a lot to do here.  
13 Some of these things like separating out MA and MA-PD and  
14 PD plans, separating the LIS from the non-LIS market, I  
15 think, is going to require a lot of attention.

16           There's ways, for example, in which the  
17 connection of them helps provide some discipline for  
18 aspects of quality. That doesn't mean I think they should  
19 stay connected. It just means it's going to require some  
20 attention. So we are at the beginning, beginning of this  
21 process.

22           So I guess that is really all I have to say here.

1           Dana, I think you sent me a message about public  
2 comments. I think my comment about public comments is it's  
3 hard to work that out to the GoToMeeting, but we do look  
4 forward to hearing from members of the public. And there's  
5 a range of ways to do that. You can reach out to the staff  
6 in a whole variety of ways.

7           Hopefully, when we are in person, you will be  
8 able to make truly public comments to us, but we do pay  
9 attention to all of the comments that otherwise come in.

10           So, Jim, would you like to talk a little bit  
11 about the public comments?

12           DR. MATHEWS: So we do have an email set up on  
13 our website whereby you can submit comments on this  
14 meeting's agenda, and we do give those full consideration.

15           DR. CHERNEW: Absolutely.

16           So I think it's been a pretty robust  
17 conversation. I am going to pause for a minute to see if  
18 anybody else wants -- any other Commissioners want to jump  
19 in. Otherwise, I'm going to thank you all for a very  
20 productive and thoughtful day, and at 5:30, we will begin  
21 our virtual happy hour. I think that was the timing of it.

22           MS. KELLEY: 5:15, Mike.

1 DR. CHERNEW: Oh, 5:15. 5:15, we're going to  
2 begin our virtual happy hour. So let's all try and get  
3 appropriately happy by then.

4 All right. When I see the wave from Bruce and  
5 Pat, I know that's the wave.

6 All right. We will start again tomorrow morning.  
7 I believe it's 9:30, and again, thank you all for a great  
8 day. Thanks for everybody who attended, and please do send  
9 us comments through the website or contacting the staff.  
10 Thank you very much.

11 [Whereupon, at 4:31 p.m., the meeting was  
12 recessed, to reconvene at 9:30 a.m. on Tuesday, November  
13 10, 2020.]

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MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

Via Go-To-Webinar

Tuesday, November 10, 2020  
9:30 a.m.

COMMISSIONERS PRESENT:

MICHAEL CHERNEW, PhD, Chair  
PAUL GINSBURG, PhD, Vice Chair  
LAWRENCE P. CASALINO, MD, PhD  
BRIAN DeBUSK, PhD  
KAREN B. DeSALVO, MD, MPH, Msc  
MARJORIE E. GINSBURG, BSN, MPH  
DAVID GRABOWSKI, PhD  
JONATHAN B. JAFFERY, MD, MS, MMM  
AMOL S. NAVATHE, MD, PhD  
JONATHAN PERLIN, MD, PhD, MSHA  
BRUCE PYENSON, FSA, MAAA  
BETTY RAMBUR, PhD, RN, FAAN  
WAYNE J. RILEY, MD  
JAEWON RYU, MD, JD  
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- Andy Johnson.....	53
Adjourn.....	119

P R O C E E D I N G S

[9:30 a.m.]

1  
2  
3 DR. CHERNEW: Good morning, everybody, and  
4 welcome to our Friday morning MedPAC session. We're  
5 thrilled to have you. I won't take much time with broad  
6 introductions. We are starting this morning with the topic  
7 of separately payable drugs, and I'm going to turn it over  
8 to Dan.

9 Dan, you are up.

10 DR. ZABINSKI: All right. Thank you, Mike. Good  
11 morning, everybody. To start, I'd like to thank Kim Neuman  
12 and Nancy Ray for the input and guidance that they have  
13 provided on this topic.

14 Today we're going to talk about how drugs are  
15 paid in the hospital outpatient prospective payment system,  
16 or OPPTS, and discuss how that system could be improved.  
17 Our hope is that the policy changes that we're about to  
18 cover will have implications for how we think about  
19 separately paid items across Original Medicare.

20 I'd like to remind the audience that they can  
21 download the PDF versions of these slides using the handout  
22 section in the control panel on the right-hand side of the

1 screen.

2 Overall, the OPSS is a nuanced and complicated  
3 system, and the OPSS system of drug payment is no  
4 exception. Therefore, I think it will be helpful to  
5 provide an overview of what we'll be discussing.

6 We'll start by talking about the unit of payment  
7 in the OPSS, and we'll follow that with an explanation of  
8 how drugs are paid.

9 In the OPSS, most drugs are packaged into the  
10 payment of the related service, but some are paid  
11 separately, and we'll talk about the policies for  
12 separately paid drugs and the problems that we see with  
13 those policies. Then we'll talk about how the approach for  
14 separately payable drugs in the OPSS could be improved.

15 Even though the focus of this presentation is  
16 drugs, we think it will be helpful to first talk about  
17 payment bundles in the OPSS.

18 In the OPSS, most payments are for a primary  
19 service where primary services are the reason for a visit  
20 such as an MRI or a surgical procedure.

21 The OPSS uses bundled payments in which the cost  
22 of ancillary items are packaged with the primary service

1 into a single payment unit.

2           For example, suppose you're not feeling well and  
3 your chest feels tight and congested. So you go to an  
4 outpatient clinic, and the doctor orders a chest X-ray to  
5 check for pneumonia. In this case, the visit is the reason  
6 you're there, so it's the primary service and it's paid  
7 separately, while the chest X-ray is an ancillary, and its  
8 cost is packaged into the payment rate of the clinic visit.

9           Now, it's really important to understand that  
10 when an item is packaged, that does not mean there is no  
11 reimbursement to the provider for that item. Instead, the  
12 cost of the item is reflected in the payment rate of the  
13 related service with which the ancillary is used.

14           The payment bundles in the OPPS contrast with a  
15 fee schedule, in which everything has its own separate  
16 payment, including ancillary items.

17           The benefit of using payment bundles rather than  
18 a fee schedule is that bundles provide powerful incentives  
19 for providers to seek out the lowest-cost, most efficient  
20 way to furnish the primary service.

21           Now we'll turn our discussion to drug payment in  
22 the OPPS.



1           Many drugs in the OPPS are ancillary and are not  
2 costly in relation to the applicable primary service. The  
3 OPPS generally packages the costs of these ancillary drugs  
4 into the payment rate of the related service.

5           Under the OPPS, drugs are packaged if they do not  
6 meet certain cost thresholds or they are what CMS has  
7 defined as "policy packaged," which are drugs that function  
8 as supplies to a service.

9           Packaging ancillary drugs is generally beneficial  
10 because it provides strong incentives for providers to be  
11 efficient because the combination of inputs that a provider  
12 uses to treat a patient determines whether the provider  
13 experiences a financial gain or loss.

14           In addition, great care should be taken when  
15 deciding to pay separately for drugs rather than packaging  
16 them, because if we pay separately for a drug that is not  
17 clinically better than competing drugs that are packaged,  
18 Medicare would make a double payment -- one payment for the  
19 separately paid drug and one for the drugs that are  
20 packaged.

21           In contrast to packaged drugs, the OPPS does pays  
22 separately for many drugs, which means a drug gets a

1 payment that is separate from the payments for the services  
2 provided during the same visit.

3 Over time, the prominence of separately payable  
4 drugs has increased in the OPSS, with program spending  
5 increasing from \$5.1 billion in 2011 to \$14.8 billion in  
6 2019.

7 Like most features of the OPSS, the policies for  
8 separately payable drugs were developed on an ad hoc basis.  
9 Specifically, the OPSS has two policies for separately  
10 payable drugs: pass-through drugs and separately payable  
11 nonpass-through drugs.

12 The reason that the pass-through policy exists is  
13 that during the development of the OPSS there was  
14 consideration to package all drugs. However, there were  
15 also concerns that for new drugs the needed cost and use  
16 data would not be available to include them in the payment  
17 rates of their related services.

18 So in response, the Congress created the pass-  
19 through policy, and payments for pass-through drugs began  
20 when the OPSS was launched in August 2000. This policy  
21 provides separate payments for new drugs, which mitigates  
22 providers' financial risk. Also, some stakeholders argue

1 that these payments maintain incentives for drug innovation  
2 by manufacturers.

3 In contrast, the separately payable nonpass-  
4 through policy began in 2004. The intent is to provide  
5 adequate payment for relatively costly drugs that are  
6 already established on the market. It excludes drugs that  
7 are ancillary, so the focus ends up being drugs that are  
8 the reason for a visit.

9 These two policies for separately payable drugs  
10 have different criteria for eligibility in the OPPS, and to  
11 some degree they serve different purposes.

12 For a drug to be eligible for pass-through  
13 payments it must be new to the market and have a cost that  
14 exceeds three thresholds that are related to the payment  
15 rate of the applicable primary service.

16 Having pass-through status has a definite time  
17 limit as drugs can be pass-through for two to three years.  
18 After their pass-through status expires, a drug either  
19 becomes separately paid under separately payable nonpass-  
20 through policy or it's packaged.

21 For a drug to be eligible for the separately  
22 payable nonpass-through policy, it must be a drug that is

1 established on the market rather than a new drug, and it  
2 must have a cost per day that exceeds a threshold, which is  
3 set at \$130 for 2020, but CMS updates that threshold for  
4 drug price inflation each year.

5 It also cannot be a "policy packaged" drug, which  
6 are drugs, again, that function as supplies to a service  
7 and do not have pass-through status.

8 Now, there is no specified time limit for  
9 separately payable nonpass-through drugs. They can hold  
10 this status as long as their cost per day exceeds the \$130  
11 cost threshold. Any drug that does not meet the criteria  
12 for either the pass-through drugs or separately payable  
13 nonpass-through drugs is packaged in the OPPTS.

14 A concern we have is that the criteria that drugs  
15 have to meet to be eligible for either the pass-through or  
16 the separately payable nonpass-through policy can allow  
17 drugs to have separately payable status even though they  
18 could be packaged without putting providers under excessive  
19 risk.

20 What we want to do is balance the benefit of  
21 packaging, which is that it promotes efficiency, while  
22 recognizing that some drugs should be paid separately.

1           In our June 2020 report, we had a chapter that  
2 identified features of an effective system for identifying  
3 drugs that should be separately paid, and there are two  
4 features of particular note.

5           One is that there is a strong rationale to pay  
6 separately for drugs that are the reason for a visit  
7 because these drugs are not ancillary to a service.

8           Second, there is a strong rationale for requiring  
9 that drugs that are ancillary to a service show clinical  
10 superiority over other ancillary drugs to have separately  
11 payable status for a limited time period.

12           Our immediate goal for the OPPS is to apply these  
13 two features to the separately payable nonpass-through and  
14 pass-through policies.

15           As we consider how to apply these two features to  
16 the separately payable nonpass-through and pass-through  
17 policies, it is helpful to recognize that OPPS drugs fall  
18 into two broad categories.

19           One category are drugs that are a reason for a  
20 visit. These drugs are not ancillary. They are high-cost;  
21 they typically treat a condition and are usually  
22 administered by infusion. Usually, the only service on the

1 claim is drug administration.

2 The other category are ancillary drugs. These  
3 drugs are not the reason for a visit and are adjunct to a  
4 service.

5 If we consider these two broad categories  
6 alongside the two desirable features presented on the  
7 previous slide, we reach two conclusions.

8 One is that the OPPS should pay separately for  
9 drugs that are the reason for a visit.

10 For drugs that are ancillary, the OPPS should try  
11 to package them as much as possible, keeping in mind that  
12 we should pay separately if packaging a drug exposes  
13 providers to excessive financial risk.

14 At this time, we believe the best policy is to  
15 keep both the separately payable nonpass-through and the  
16 pass-through policies, but we should modify them so that  
17 they are consistent with the two desired features discussed  
18 earlier.

19 For the pass-through policy, we should keep these  
20 current features: One is that a drug must be new to the  
21 market; and, second, the drug cost must be high in relation  
22 to the payment rate of the applicable service. Then pass-

1 through status would be limited to two to three years.

2 Changes that we believe should be made to the  
3 pass-through policy include:

4 Exclude drugs that are the reason for a visit.  
5 We say this because both the pass-through and the  
6 separately payable nonpass-through policy include drugs  
7 that are the reason for a visit. Pass-through drugs that  
8 are the reason for a visit would qualify for the separately  
9 payable nonpass-through policy in the absence of pass-  
10 through payments. Therefore, to simplify the OPPS system,  
11 we should restrict the pass-through policy to ancillary  
12 drugs, and this change would substantially reduce the  
13 number of pass-through drugs.

14 We should also require a drug to show clinical  
15 superiority over drugs included in the bundle of the  
16 applicable service. Without a clinical superiority  
17 requirement, a new drug could be granted pass-through  
18 status even though it has no clinical benefit over packaged  
19 drugs that have similar therapeutic uses. Under this  
20 scenario, Medicare makes a double payment when a hospital  
21 uses the pass-through drug -- one payment for the pass-  
22 through drug and one for the packaged drug that it is

1 replacing in the applicable service.

2           We want to be clear that clinical superiority  
3 requirements are used in several Medicare fee-for-service  
4 payment systems such as new drugs and devices in the new  
5 technology add-on payment, or NTAP, policy in the inpatient  
6 PPS.

7           Because the NTAP policy includes new drugs, we  
8 believe the clinical superiority requirements in the NTAP  
9 policy could be applicable to a clinical superiority  
10 requirement in the OPPS pass-through drug policy.

11           Relative to the pass-through policy, the  
12 separately payable nonpass-through policy is less  
13 complicated. Current features of the separately payable  
14 nonpass-through policy that should be continued are: It  
15 should focus on established drugs -- first of all, it  
16 should focus on established drugs, and also we should  
17 continue to use the cost per day threshold for eligibility,  
18 which is currently \$130 per day, but we're open to changing  
19 that threshold. Also the focus should be on drugs that are  
20 not ancillary.

21           Changes that should be made to the separately  
22 payable nonpass-through policy include: explicitly



1 requiring a drug to be the reason for a visit, and expand  
2 it to include new drugs that are the reason for a visit.  
3 Currently, these drugs would be paid separately under the  
4 pass-through policy for two to three years.

5 On this slide, we summarize how the proposed  
6 changes to the pass-through and separately payable nonpass-  
7 through policies would affect the system of drug payment in  
8 the OPPS.

9 To obtain pass-through status, a drug would have  
10 to be new to the market, ancillary to a service, costly in  
11 relation to the applicable service, and clinically superior  
12 to competing drugs. A drug can hold pass-through status  
13 for two to three years.

14 To obtain separately payable nonpass-through  
15 status, a drug would have to be the reason for a visit, and  
16 cost per day must exceed some threshold, currently \$130,  
17 but we are open to changing that.

18 Finally, packaged drugs are those that do not  
19 have pass-through status and are either a supply to a  
20 service or have cost per day less than the separately  
21 payable nonpass-through policy.

22 Now, the impact of our proposed policy changes

1 include that there be fewer pass-through drugs because the  
2 policy would be limited to drugs that are ancillary and  
3 also drugs would have to show clinical superiority to  
4 qualify.

5 Pass-through drugs that are the reason for a  
6 visit would be moved to the separately payable nonpass-  
7 through policy. And on net, you would have fewer  
8 separately paid drugs and more packaged drugs.

9 So our next steps for this work are to first  
10 respond to the Commissioners' comments and directions  
11 provided today.

12 If interest from Commissioners is sufficient, we  
13 will develop recommendations that would be presented in  
14 spring of 2021 that reflect the changes to the policies for  
15 separately payable drugs in the OPPS that we discussed  
16 today.

17 Finally, we have introduced the idea of adding a  
18 clinical superiority requirement to the OPPS drug payment  
19 policies, and we would like to hear Commissioners' thoughts  
20 on a broader application of clinical superiority  
21 requirements throughout Original Medicare.

22 That concludes the presentation. I'll turn

1 things back to Mike.

2 DR. CHERNEW: Dan, thank you. I think there are  
3 two Round 1 questions. I want to ask a Round 1 question  
4 first, though. Can you go back to Slide 13? Then we'll go  
5 to Bruce and to Larry.

6 So what I'm interested in understanding, in this  
7 process where are ancillary drugs that are high-cost but  
8 established -- or where are high-cost established ancillary  
9 drugs?

10 DR. ZABINSKI: They are packaged, and that's the  
11 current status right now under the OPPS.

12 DR. CHERNEW: Okay. Got it. And now we'll go on  
13 to Bruce and then Larry. Bruce?

14 MR. PYENSON: Thank you. Thank you very much for  
15 a terrific presentation, and I think this is the relevant  
16 slide for my question, Dan. The cost per day greater than  
17 a threshold issue, I understand that's at \$130 today. And  
18 you've used the term "excessive risk for a provider." And  
19 I wonder if you could share some of your thinking on how do  
20 you determine what excessive risk is for a provider. It  
21 strikes me that's a very different amount for a small  
22 facility than for, you know, a facility with millions of

1 dollars of revenue. And how do you -- what sort of  
2 benchmarks have you thought about for coming to a  
3 threshold?

4 DR. ZABINSKI: Well, I mean, as you say, there's  
5 a lot to consider. The idea would be to compare, say, how  
6 much the drug costs in relation to the service and also how  
7 often it's used with the service. The less it's used with  
8 a service, the higher -- there's a tendency to have more  
9 risk unless it's packaged into the relevant payment rate  
10 for, you know, the related service.

11 I don't think there's any, you know, definite  
12 cutoff. I sort of think about it, you know, on average a  
13 provider would lose, say, 10 percent of the payment rate in  
14 relation -- for the related service. That starts to get  
15 into the range of excessive risk, I guess. You know, I'm  
16 basing that in part on what CMS does with the cost relative  
17 to the related service for pass-through drugs. There's a  
18 number of cost criteria, and one is that the difference  
19 between the cost of the pass-through drug versus the drugs  
20 that are in the payment rate of the related service, that  
21 has to be at least 10 percent, and that's where I draw that  
22 from. It's sort of to be somewhat consistent with what

1 already exists.

2 MR. PYENSON: And I'm wondering if someplace in  
3 the Medicare reimbursement program there's a notion of,  
4 say, two standard deviations or something like that, or  
5 outliers. We've certainly seen things like that, I think,  
6 for some of the accountable care organizations. It just  
7 seems to me the excessive -- what we're often  
8 characterizing as excessive risk maybe means something  
9 else.

10 DR. ZABINSKI: And one thing I think to keep in  
11 mind in all this, I've mentioned during the presentation  
12 that the system is pretty complicated, and while you want  
13 to do this appropriately and effectively, you also don't  
14 want to make it cumbersome and excessively complicated for  
15 anybody to understand. So you sort of have to balance  
16 things, I guess.

17 MR. PYENSON: Thank you.

18 MS. KELLEY: Larry?

19 DR. CASALINO: Thanks, Dan. Nice work.

20 My question is for the passthrough drugs. Let's  
21 suppose a clinically superior drug comes along. What  
22 happens? Do the bundles then go away completely? It's

1 sometimes the case that a drug may appear to be clinically  
2 superior on balance, but that there's different effect and  
3 side-effect profiles that might lead a physician with  
4 certain patients to still want to use the previous drug  
5 that was bundled. And would there still be the option to  
6 do that, or when the clinically superior drugs comes along,  
7 are there no more bundles anymore for that service and  
8 there's not really a way to use one of the previous drugs  
9 if you wanted to make it --

10 DR. ZABINSKI: No, you definitely would be able  
11 to continue to use the old drug. The cost of the old drug  
12 would continue to be reflected in the payment rate of the  
13 service.

14 The way passthrough payments work is this. Say  
15 you had some service and you got a drug package into it,  
16 and that packing that drug adjusts the payment of that  
17 service by \$100. And then you got a new drug comes along  
18 that's clinically superior, and say it costs \$120. The  
19 passthrough payment is that cost, that \$120 minus the cost  
20 of the drugs that are already reflected in the payment rate  
21 of the related service. So the passthrough payment itself  
22 is actually \$20.

1 DR. CASALINO: I see. So if you want to use the  
2 old drug, you just get the regular bundle of \$100, say.

3 DR. ZABINSKI: Right. Exactly.

4 DR. CASALINO: If you want to use the clinically  
5 superior drug, you still get that same bundle plus \$20.

6 DR. ZABINSKI: Right. And then once the -- yeah.  
7 Once the passthrough payment expires, you can package that  
8 new clinically superior drug into the payment rate of the  
9 related service.

10 DR. CASALINO: I see. So --

11 DR. CHERNEW: Yeah.

12 DR. CASALINO: Michael, just briefly and then a  
13 question, quickly.

14 So let's say the new drug, the two or three years  
15 are up, and now it gets packaged into the bundle. So now  
16 you've got \$120, let's say, in there for the drug instead  
17 of \$100. Wouldn't there be an incentive there to still use  
18 the old drugs and get the \$120 and just put that \$20 in  
19 your pocket?

20 DR. ZABINSKI: Yeah. What's going to happen is  
21 you're going to end up somewhere between \$100 and \$120,  
22 depending upon how often each drug is used with the

1 service. If it's 50 percent of the time, then you're going  
2 to end up halfway in between at \$110. And, yeah, so then  
3 you'd have an incentive to use the lower-cost drug still  
4 because then you get a \$10 savings, and that's the idea of  
5 package payments. You want the provider to think about not  
6 only what's best for my patient while keeping the costs  
7 down.

8 DR. CASALINO: This might not be a big deal. I'm  
9 talking about now just the packaging after the two or three  
10 years. This might not be a big deal if the cost difference  
11 is \$10 or something like that, but if it were a really  
12 expensive drug and gets bundled in, then you'd have a  
13 strong incentive. Then the bundle becomes quite a bit more  
14 lucrative if you used a previous drug. Now, not many  
15 physicians would do that if the other drug is really  
16 superior in a particular situation.

17 DR. ZABINSKI: Right.

18 DR. CASALINO: It's an area to at least think  
19 about, I think.

20 DR. CHERNEW: Yeah. Larry?

21 DR. CASALINO: Yeah.

22 DR. CHERNEW: I'm sorry. Can I jump in?



1 DR. CASALINO: Please.

2 DR. CHERNEW: This is exactly the line of  
3 questioning and discussions, I think, we need to go on. I  
4 think you have essentially put your thumb on the crux of  
5 the issue in some ways.

6 The bundle, of course, reflects the average  
7 utilization, and there's an incentive to use the cheaper  
8 drug. And that's the way bundling works for everything.  
9 You always have an incentive to save money in the bundle,  
10 and this is just applying that to drugs. And the more  
11 people use the lower-priced drug, any individual person,  
12 the lower the overall price of the bundle, and the more  
13 they use the more expensive drug, the higher the price of  
14 the overall bundle. And you try and hope that the  
15 incentives are working so that they're only using the  
16 higher-priced drug when it's clinically indicated, and you  
17 hope that your quality metrics and physician  
18 professionalism maintains the use of that drug, but that's  
19 the sort of structure there.

20 The part that I think is also interesting is if  
21 you have the drug paid separately, then I think the  
22 physician gets the payment for the bundle, which reflects

1 the price of the old drug, and there's a separately payable  
2 drug payment for the new drug. So, in some sense, you're  
3 paying a bundled price that's reflecting the use of the old  
4 drug and the separately payable price as well.

5           Eventually, I assume what would happen, Dan, is  
6 if everybody switched to the new drug, the price of the  
7 bundle would actually drop over time because there's no  
8 longer any use of the old drug in the bundle. Is that  
9 basically right?

10           DR. ZABINSKI: I mean, well -- oh, I see what  
11 you're saying. Yeah. For a limited time, yeah. That  
12 would happen, and eventually, when the passthrough status  
13 of that new better drug gets used -- you know, as the  
14 passthrough status expires, then that new drug eventually  
15 becomes an old drug. And then it gets packaged.

16           DR. CHERNEW: Yeah. But for a while during the  
17 passthrough in some sense, there's some aspect of, quote,  
18 "double payment" because the bundle reflects the old drug  
19 and you're using the new drug. I think, again --

20           DR. ZABINSKI: Right, right.

21           DR. CASALINO: But, Mike, if I understood  
22 correctly, if I understood Dan correctly, it wouldn't be

1 extra or double payment in that situation because you're  
2 not getting the entire price of the new drug. You're just  
3 getting the extra price beyond what you get in the bundle  
4 already. It would be kind of a double payment if you got  
5 the full price plus the bundle.

6 DR. CHERNEW: I understand.

7 So back to Dan's example, if it's \$100 and \$120,  
8 the separately payable payment is the \$20, not the \$120.

9 DR. ZABINSKI: Right. But that points to why you  
10 want to have a clinical superiority. You don't want to pay  
11 that extra 20 bucks for something that's not giving you  
12 anything beneficial.

13 DR. CHERNEW: Right. I understand. That may be  
14 a whole Round 2 set of discussions, but that was useful,  
15 Larry.

16 Dana, while I've been rambling on, have -- oh,  
17 Brian, I see, has a Round 1 question. Are there other  
18 Round 1 questions first in the queue, Dana?

19 MS. KELLEY: Yes, we have quite a bit of list  
20 here.

21 DR. CHERNEW: Okay. So then, Dana, I'm going to  
22 let you go through the list.

1 MS. KELLEY: All right. Dana, you're next.

2 DR. SAFRAN: Thank you.

3 I have two questions. I think the first one is  
4 very simple. The second one might be a little more  
5 complex.

6 So the first question is in the paper, it refers  
7 to December 1996 as the time frame for defining what is new  
8 to market, and that just really caught my attention. I  
9 don't understand why new to market doesn't have some, you  
10 know, last X years definition to it.

11 And my second question is that you share with us  
12 the really significance rise in cost in spending for these  
13 separately payable drugs in less than a decade, from \$5  
14 billion to \$14 billion. Can you say a little bit more  
15 about whether this is due primarily to increase in the  
16 volume or use of separately payable drugs versus the  
17 increase in price? I guess there's a third category that's  
18 kind of a subset of volume, which is there is more of them,  
19 and so that contributes to more volume.

20 And related to that, what do you expect the  
21 impact of these proposed changes to be on that rate of  
22 growth, the tripling in spending then?

1 DR. ZABINSKI: Okay. Let's see. Yeah. The 1996  
2 new to market, I'm just pulling that off of the way CMS is  
3 defined what "new to the market" is, but when you think  
4 about -- see, when something gets passthrough status, it  
5 gets it and it just -- and you can't get that status again.  
6 So, as you go through time -- I hope I'm explaining this  
7 well. As you go through time, it's sort of like a new drug  
8 is one that has not had passthrough status before,  
9 essentially. So if a drug has had passthrough status, it  
10 can't be it can get it again.

11 So the 1996 is just a baseline when the whole  
12 program started in 2000, and CMS never updated it. But  
13 there's sort of a practical thing about this. As a drug's  
14 passthrough status expires, it can't have it again. So all  
15 the drugs that are going to be passed through are new  
16 drugs.

17 Did that answer the question?

18 DR. SAFRAN: As well as we probably can. Let's  
19 move on. Yeah. Thanks, Dan.

20 DR. ZABINSKI: On the spending, it's more -- the  
21 increase is more due to prices than volume. Volume has had  
22 an effect, but it's more basically new high-cost drugs. In

1 particular, the spending is really driven by new  
2 chemotherapy treatments or cancer treatment drugs. It's  
3 like in excess of 80 percent of the additional spending is  
4 on cancer treatment drugs, and it's mostly a price thing  
5 rather than a volume.

6           Then the expected impact of these changes we're  
7 discussing on spending, that's not going to be much. The  
8 big thing here is we're trying to introduce getting  
9 clinical superiority requirement for new drugs, and that's  
10 going to have some effect on spending but not a lot.

11           I think the bigger impact on spending can be  
12 through changing the way you pay for the drugs. Kim Neuman  
13 and Nancy Ray have been talking about with consolidated  
14 billing and reference pricing and other things over the  
15 last few years, and I think that our goal is to try to get  
16 those implemented through original Medicare eventually, but  
17 that's the better way to attack the spending issue.

18           DR. MATHEWS: Dan, let me jump in here, if I  
19 could, for just a second.

20           DR. ZABINSKI: Please do.

21           DR. MATHEWS: What Dan is trying to say is that  
22 when you look at the set of drugs that currently have

1 passthrough status that would become packaged if they were  
2 not clinically superior to an existing product in the  
3 bundle, that that is probably a relatively small set of  
4 drugs at the moment, and the savings from those specific  
5 drugs may or may not rise to a level of significance.  
6 Obviously, we would have to work with CBO should the  
7 Commission move towards a recommendation here to get a  
8 score.

9           But the larger issue here is to try and impose  
10 some drag on the price of future new products or even  
11 existing products that have passthrough status, whereby the  
12 dominant criteria now that Medicare uses to determine what  
13 is passthrough is, is it new, and is it expensive? And if  
14 the drug meets those criteria -- and I know there are  
15 others; I am oversimplifying here -- it will get  
16 passthrough status and be paid whatever it's paid.

17           What we are suggesting here through this policy  
18 is that with the implementation of a substantial clinical  
19 improvement criteria, that there would be fewer drugs in  
20 the future that can obtain passthrough status simply by  
21 being new and expensive. And that's the key feature of the  
22 proposal that we are talking about here with respect to

1 passthrough.

2           So it might not be a lot of money right now at  
3 this point in time, but ideally, there would be substantial  
4 benefits to the program in the future.

5           DR. SAFRAN: Yeah. Thank you, Jim. That sort of  
6 strikes again at the heart of my question or the second  
7 part of my question.

8           So, Dan, thanks for answering all that, and, Jim,  
9 thanks for the additional clarification. That's very  
10 helpful.

11           MS. KELLEY: Betty?

12           DR. RAMBUR: Thank you. Thank you very much for  
13 an interesting report.

14           I think this is a Round 1 question, and I  
15 apologize if this is obvious to everybody. But it's not  
16 obvious to me.

17           Regarding the clinical superiority requirement,  
18 it seems very logical, and I now understand better about  
19 the potential impact. But I'm muddled on the process for  
20 determining superiority and any regulatory or reporting  
21 burdens that are encompassed in that.

22           DR. ZABINSKI: Jim, do you want to handle that,



1 or should I take that?

2 DR. MATHEWS: Either way. If you want to make a  
3 run at it, I'm happy to let you do that. Alternatively, I  
4 could proceed, and you could correct everything that I get  
5 wrong. Why don't we do that, and you can add clean-up.

6 So, obviously, clinical superiority is a concept  
7 that's got a lot of variation in it, you know, condition,  
8 patient response, and we, if we were to proceed towards a  
9 recommendation here, would not necessarily be the arbiters  
10 of what constituted clinical superiority. But one could  
11 envision a scenario not unlike the NTAP process for the  
12 inpatient perspective payment system or other instances in  
13 Medicare where clinical superiority is used, where there is  
14 an application process, the manufacturer submits evidence  
15 on clinical superiority. It may not be for all patients,  
16 but for some subset of patients, there may be improved  
17 efficacy, fewer side effects, that kind of thing. And the  
18 Secretary could make a determination whether the evidence  
19 submitted in any way, shape, or form, met the criteria for  
20 substantial clinical improvement.

21 How did I do, Dan?

22 DR. ZABINSKI: Great. Better than I could.

1 Let's put it that way.

2 DR. RAMBUR: Thank you.

3 It seems to me thinking about clinician's  
4 perceptions of what's superior, et cetera, that that will  
5 take some attention and nuance to be precise and effective.

6 MS. KELLEY: Karen?

7 DR. DeSALVO: Thanks, Dana, and thank you, Dan.

8 The questions come up in the conversation. Jim,  
9 you mentioned it about if this is a strategy that will help  
10 us address launch price, and if there are other problems  
11 that we're trying to solve with these kinds of changes, do  
12 we think that it will keep prices flat for longer by having  
13 a pathway for them to be bundled? Just an affirmation that  
14 this is the strategy mostly about launch price, or are  
15 there other problems that we think we can solve if we move  
16 in this direction?

17 DR. ZABINSKI: Do you want to --

18 DR. MATHEWS: Since I got myself into this mess,  
19 I'll continue here.

20 So, arguably, there could be some effect on  
21 launch price. If there is now a requirement that something  
22 has to be superior in order to qualify for separate

1 payment, the fact that something is expensive in and of  
2 itself is no longer going to meet that requirement, and  
3 therefore, there may be less incentive to price things high  
4 at launch.

5           However, this would not completely eliminate  
6 those incentives because if something was innovative, more  
7 effective than an existing product, the Sovaldi being a  
8 primary example here, it could, indeed, be an extremely  
9 expensive product and on the basis of clinical superiority  
10 could qualify here. So this will not completely mitigate  
11 those incentives to price high, but it will at least impose  
12 a bar over which the manufacturer has to exceed in order to  
13 qualify for separate payment.

14           DR. CHERNEW: Jim, let me just say -- I'm sorry.  
15 I want to say one other thing. The right way to think  
16 through this discussion now is not that we are taking a big  
17 examination of the broad issues related to launch prices  
18 and drugs, although that is something that is quite  
19 interesting and may well be coming down the line. The way  
20 to think through this is to try and improve a relatively  
21 specific part of the way in which we pay for drugs.

22           That said, I agree with Jim. In some cases, it

1 will have that effect.

2 I think the fundamental problem, that incentives  
3 to set reasonable launch prices aren't strong enough yet,  
4 but we're not going to solve that problem with this alone.

5 DR. DeSALVO: Just a quick follow-up, what do we  
6 think is -- I'm not still clear about what problem this  
7 will solve, principally. It's not clear to me.

8 DR. MATHEWS: So a couple of things. One, in the  
9 materials, in the presentation, we point out the very rapid  
10 growth in spending for separately payable drugs under the  
11 OPSS, either through passthrough or separately payable non-  
12 passthrough. Ideally, this policy would impose some drag  
13 on that spending growth going forward.

14 The second thing that this would do is -- you  
15 know, currently, Medicare would be obligated to pay for  
16 something expensive and new and then continue to pay for  
17 that expensive thing once it rotated off of passthrough  
18 status to separately payable non-passthrough, and what this  
19 is signaling in a very small part of the Medicare program,  
20 you know, separately payable drugs for the OPSS, is that  
21 the fact that something is new and expensive is no longer  
22 going to suffice for it to receive separate and

1 preferential treatment that contributes to spending growth,  
2 that if something is going to be given that special payment  
3 treatment, it has got to be an advance in clinical  
4 superiority relative to the existing product.

5           So I'm not expressing myself articulately here,  
6 but in my mind, that is the most significant element of the  
7 policy that we are discussing.

8           DR. CHERNEW: Yeah. We're going a long time on  
9 Round 1, and I want to get to Round 2. Everyone, please, I  
10 know there's a list. Be cognizant of that in your  
11 comments.

12           The simple answer, Karen, is this a nibble at  
13 that problem, and that's what it tries to solve. And we  
14 can have a broader discussion about that.

15           Who's next, Dana?

16           MS. KELLEY: Marge.

17           MS. MARJORIE GINSBURG: My comment may, in fact,  
18 be more Round 2-ish than Round 1. I know it's unusual in  
19 the writeups we do that we include concrete examples of  
20 what we're talking about. To me, this is one of those  
21 topics where it would really help -- and I know it's hard,  
22 because if you give an example of what the status was in

1 2010, that's going to change dramatically from what it  
2 should be in 2012. But I think this is complex enough that  
3 it would help all readers to have specific examples of what  
4 we're doing now and what we want to change, in terms of  
5 actual clinical examples and using actual drugs.

6 That's all. Thank you.

7 DR. CHERNEW: Okay. Dana. I think we should  
8 move on. If that's not a question I think we should move  
9 on. Maybe there was. I'm just worried about time. I  
10 don't mean to cut off your answer, Dan, but we have  
11 probably four or five more Round 1's and then we still have  
12 Round 2.

13 MS. KELLEY: Okay. Paul is next.

14 DR. CHERNEW: I'm sorry. Was there a question,  
15 Marge, that you needed Dan to answer? I took that more as  
16 a general comment that examples would be good.

17 DR. ZABINSKI: It's something we can definitely  
18 do. I'm thinking immediately about each year there seems  
19 to be a new skin substitute that comes out and gets a  
20 separate payment. And there's a question of why. Without  
21 having to show any clinical superiority they automatically  
22 get a separate payment. And it's something we could talk

1 about.

2 DR. CHERNEW: We'll work on that. That's a good  
3 point for the chapter. Who was next, Dana?

4 MS. KELLEY: Paul.

5 DR. PAUL GINSBURG: Yeah. Thanks, Dana. A  
6 question is if under a separately payable non-passthrough  
7 drugs presumably we have situations where there are  
8 alternative separately payable drugs, say. For example,  
9 let's say there's a biosimilar that comes out for a drug  
10 that's infused. So I take it our separately payable system  
11 just pays each one an amount based on its whatever, and we  
12 have no incentives at all for physicians to choose the  
13 less-expensive alternative.

14 DR. ZABINSKI: That's correct.

15 DR. PAUL GINSBURG: Yeah, and that's all I had.

16 MS. KELLEY: Okay. Brian.

17 DR. DeBUSK: Dan, one quick question. Let's say  
18 you had a \$1,000 APC and \$100 of that APC was contrast  
19 media. Let's say this is an imaging APC. If a passthrough  
20 status contrast media came along, say for \$150, and I chose  
21 to use it, I would still receive the \$1,000 for the imaging  
22 APC, but then I would be separately paid for the \$150

1 additional contrast media. There is a true double payment  
2 there. Correct?

3 DR. ZABINSKI: No. What you end up, you get a  
4 \$50 payment for the new contrast material. That is the  
5 difference between the old one and the new one.

6 DR. DeBUSK: Okay. So even if I -- you only pay  
7 on the differential now, so the actual amount that I would  
8 be paid would be the APC. So let's say I have a second APC  
9 that only has a -- it's a similar imaging procedure but  
10 it's a different APC, and it only uses \$50, or it only has  
11 \$50 packaged into it. Would I then receive a \$100 payment  
12 if I used the same drug in that procedure?

13 DR. ZABINSKI: Yeah. I mean, I've thought about  
14 that myself and I actually investigated. It's really  
15 unusual to happen, if it ever happened at all. I never  
16 found a case where that happens.

17 DR. DeBUSK: Okay.

18 DR. ZABINSKI: And, you know, in all likelihood  
19 those two services, because they're similar, they would end  
20 up in the same APC.

21 DR. DeBUSK: Okay. I was just curious because in  
22 the June report, page 171, we do distinctly talk about the



1 situation would result in double payments by Medicare, a  
2 payment for the cost of the packaged drug and a distinct  
3 payment for the separately payable drugs. So there's  
4 really an overlapping payment, not a double thing.

5 DR. ZABINSKI: Well, to some extent. I mean, you  
6 think about if instead you had that new drug is packaged,  
7 its rate is going to be reflected in the payment rate of  
8 the service, and the addition to the payment rate is not  
9 going to be the full amount of that new drug. So there is  
10 some degree of double payment.

11 DR. DeBUSK: Okay. Thank you.

12 DR. ZABINSKI: -- amount of the drug itself, but  
13 there is a double payment.

14 DR. DeBUSK: Thank you.

15 MS. KELLEY: Bruce, did you have another  
16 question?

17 MR. PYENSON: Yeah, a very quick question. The  
18 test of clinical superiority, are you envisioning that  
19 happening before the decision is made for separately  
20 payable, or is that something like an evidence development  
21 test period?

22 DR. ZABINSKI: Personal preference is to require

1 it before the separate payment gets granted. That's just  
2 personal preference. But how that all works in practice,  
3 that's going to be a decision by CMS and Congress. It's  
4 basically outside our purview, I think. But Jim, you might  
5 want to add to that? Okay.

6 MS. KELLEY: Okay, Mike. Should we move to Round  
7 2?

8 DR. CHERNEW: I had a list of people left on  
9 Round 1. Maybe I was confusing my Round 1 and Round 2.  
10 But if we're done with the Round 1 then absolutely, and I  
11 think Brian was the first speaker in Round 2.

12 MS. WANG: I'm sorry. I actually had a Round 1,  
13 Dana.

14 DR. CHERNEW: Yeah.

15 MS. WANG: I don't know if you saw me in there.

16 MS. KELLEY: I didn't. I'm sorry.

17 MS. WANG: Just really quick. May I? I'm sorry.

18 DR. CHERNEW: Absolutely, and I think Jonathan --  
19 yes, Pat. Jonathan, were you Round 1 or Round 2?

20 DR. JAFFERY: Actually, my question got answered  
21 already.

22 DR. CHERNEW: Oh. Gold star, Jonathan. Pat,

1 you're up.

2 MS. WANG: Okay. This is really quick and it's  
3 foundational. I'm confused, Dan, about the relationship  
4 between, let's say, chemo agents that are administered  
5 under OPPS and subject to payment, and the same chemo drug  
6 that is paid for as ASP plus 6. Could you just clarify, is  
7 the ASP+6 only for a private physician office, because  
8 we're talking the same drugs here, right?

9 DR. ZABINSKI: Well, let's see. It gets really  
10 dicey, the chemo agents. The standard payment is ASP plus 6  
11 in the OPPS for it, unless it's paying through the 340B  
12 program then it's ASP minus 22.5.

13 MS. WANG: Okay. So I'm in a hospital clinic,  
14 I'm a physician administering a chemo agent. Is the ASP  
15 plus 6 in addition to the OPPS payment? I'm confused about  
16 the relationship.

17 DR. ZABINSKI: Well, no. What happens there is  
18 basically you have a drug administration service and then  
19 there's no drug cost reflected in that. And then you have  
20 the chemo agent. And the hospital gets paid ASP plus 6.

21 MS. WANG: Is the ASP plus 6 in addition to the  
22 separately payable amount?

1 DR. ZABINSKI: No. That is the separately  
2 payable amount.

3 MS. WANG: I see. Okay. Thank you.

4 DR. ZABINSKI: I mean, the hospital gets paid for  
5 the drug administration and the drug.

6 MS. WANG: At ASP plus 6. Okay, thank you. And  
7 so would the implications of a clinical superiority  
8 evaluation extend into the non-hospital world, into a  
9 physician office or cancer center, freestanding oncology  
10 center, in the way that -- if there's a determination made  
11 about clinical superiority of new drugs, do you see that as  
12 having any spillover effect to the non-hospital world?

13 DR. ZABINSKI: Well, it depends on -- you get  
14 into a lot of, you know, nitty-gritty details here.  
15 Specifically, we're thinking this would be applied only to  
16 the hospital, but in terms of decisions about what drugs to  
17 use, perhaps the hospital can have some influence on what  
18 their physicians choose to use. So I guess my answer is  
19 not directly but perhaps indirectly.

20 MS. WANG: Okay. Thank you very much. Thank  
21 you, Dan.

22 DR. CHERNEW: So I know Jim wants to jump in. I

1 want to say something first. When we say "clinically  
2 superior," do we mean clinically superior to what is in the  
3 existing bundle, or clinical superior to other potentially  
4 separately payable drugs? So if there's a biologic that  
5 has separately payable status and a biosimilar were to come  
6 out that was the same as the biologic, but clinical  
7 superior to what was before, there would be a separately  
8 payable status and there would be no connection between the  
9 prices of the biologic and the biosimilar. Is that  
10 basically right, Dan? And when we say "clinically  
11 superior" we mean relative to not the first biologic that's  
12 at the table but relative to something else?

13 DR. ZABINSKI: Yes. If I'm following you, yes,  
14 that's correct.

15 DR. CHERNEW: Okay. We'll ponder that later, but  
16 Jim, you wanted to say something before Round 2, and then I  
17 promise we'll get to Brian.

18 DR. MATHEWS: Yeah. So just to put a marker down  
19 with respect to the question Brian asked about the specific  
20 payment amount, whether the separately payable product gets  
21 the full separate amount, in which case it is a true  
22 duplicate payment, or whether it only gets a differential,

1 in which case it is a partial duplicate payment, I just  
2 want to pause there for a second, and we will loop back  
3 with you with a definitive answer. I want to make sure we  
4 get this right. So just to put a marker down that this  
5 response may be refined as soon as we can.

6 DR. CHERNEW: Okay. Now, the highlight of the  
7 session, Brian.

8 DR. DeBUSK: Ooh, that's pressure. Hey, Jim,  
9 first of all, thank you for doing that, because I had  
10 looked at the 2020 report it's pages 171, and then in TDAPA  
11 policy there's a similar issue that's discussed on page  
12 189.

13 Anyway, first of all, thank you. This is a  
14 fascinating topic for me. Dan, great work and I really  
15 enjoyed your chapter. You know, there's a number of ways,  
16 as I was reading this chapter, to look at it, because we  
17 could look at this very, very narrowly as just an issue  
18 with transitional drug payments in APCs that already have  
19 those drugs packaged into them. But we can also look at it  
20 at a higher level. And as I mentioned earlier, for  
21 example, in the ESRD payment system the TDAPA has the same  
22 problem. I mean, TDAPA, you literally could be either

1 double paying or incrementally paying for the same drug,  
2 whether it's separately payable, even if there's something  
3 in that existing functional category used.

4           So this isn't, to me, just an OPPS issue. We  
5 have some similar challenges in the DRG system in  
6 inpatient. I would argue that even the direct practice  
7 expense component of the physician fee schedule has some of  
8 these elements.

9           So I think that this is a broad issue that spans  
10 several other payment systems, and I also think that it  
11 spans drugs and devices. So I'm hoping, first of all, I  
12 hope we dig into this more deeply, but I also hope that we  
13 do this more broadly, because I think this really leads us  
14 into the issue of how does Medicare feather new technology  
15 into really any payment system. So there are some very  
16 broad implications here, and I hope that we pursue those.

17           Now, getting back to the specifics of the  
18 chapter, I really think that, Dan, you and the staff have  
19 done a great job of trying to simplify a system that's been  
20 made needlessly complex. The separately paid, non-  
21 passthrough drugs, I mean, there really isn't a benefit to  
22 having a transition period there. If the drug, or the

1 device, for that matter, is the sole purpose or the  
2 principal component of the procedure, then I don't see the  
3 benefit of giving it this temporary passthrough status. I  
4 would just simply treat it as a separately payable drug and  
5 use their existing price mechanisms. As the drug is  
6 initially launched we would base reimbursement off of the  
7 WAC. Then, as we collect ASP data, we would transfer over  
8 to ASP-based reimbursement. All those mechanisms are in  
9 place, so that strikes me as a very clean solution.

10           Drugs that are packaged, existing drugs that are  
11 already packaged, also struck me as a very clean solution.  
12 I think packaging is the future, for all the reasons that  
13 have been outlined, not just in this chapter but also  
14 outlined in Chapter 6 and Chapter 7 of the June 2020  
15 report. And, incidentally, I thought it was interesting  
16 that Chapters 6 and 7 really described the same issue, this  
17 issue of double payment or how to deal with new technology,  
18 back to back. So Jim and the staff, I think you have been  
19 leading us in this direction for some time now. Thank you.  
20 I think it's a great direction.

21           So let's talk a moment about what happens when a  
22 new drug is introduced into a bundle that already has a



1 portion of payment set aside for that drug category. First  
2 of all, I strongly support the substantial clinical  
3 improvement criteria. I think that is just great policy on  
4 a number of fronts. I do think it creates this issue,  
5 which is discussed in the paper -- I believe actually it's  
6 discussed in the June 2020 report -- about how would you  
7 address drugs that are clinically beneficial in different  
8 ways, because obviously the clinical benefits isn't a  
9 single dimension.

10 I think that that leads us into this issue -- and  
11 Jim, thank you again for researching this further -- how  
12 those differential payments would be established, because I  
13 would argue that we really want to only pay based on the  
14 strict differential between what's already factored into  
15 the bundle and what the proposed price of the new drug is.  
16 I think managing that gap would be very important, because  
17 if that gap becomes too large, for example, in TDAPA, you  
18 create an incentive to always use the new drug simply  
19 because you have some degree of overlapping payment,  
20 whether it's modest or whether it's great.

21 And then as you also mentioned in the discussion,  
22 once that incentive to use the new drug, the artificial

1 incentive, is in place, that usage starts showing up in  
2 cost reports, it starts getting repriced into the bundles.  
3 So what you have is an inflationary mechanism into the APC  
4 or the DRG or the ESRD bundle itself, or the dialysis  
5 bundle, I should say.

6           So I think this is really important to make sure  
7 that we do implement clinical superiority criteria and that  
8 we carefully manage those differentials. But I also think  
9 it's important that we look at this in a very broad  
10 spectrum. So I'm hoping that this permeates a lot of the  
11 work that we do, not just limiting it to the APCs and drugs  
12 used in APCs.

13           Thank you.

14           MS. KELLEY: Bruce?

15           MR. PYENSON: Thank you, Dan. I think this is a  
16 terrific chapter, and at the risk of expanding the scope  
17 further, I think it would be worthwhile to consider whether  
18 the proposal creates differential reimbursement with  
19 respect to physician office, since much of the topic at  
20 hand is chemotherapy. So I'd ask that that be part of the  
21 exploration.

22           In addition, I think there's an opportunity here

1 to have evidence development for some types of drugs with a  
2 conditional period. That's not going to apply to  
3 everything but I suspect there could be a transition period  
4 where a drug that gets covered while evidence is being  
5 developed and part of that process could also be a reduced  
6 reimbursement during that transition period, that might be  
7 considered part of the investment by the manufacturer in  
8 bringing a drug to market.

9           So I think there's opportunity here to think  
10 broadly, but the implications for physician office-based  
11 chemotherapy is something I think is worth paying attention  
12 to. Thank you.

13           MS. KELLEY: I think Dana Safran is next.

14           DR. SAFRAN: Thank you. Very supportive of the  
15 direction here, and I think my comments really just apply  
16 to the issue around clinical superiority. And so I think  
17 that, number one, the response that Jim gave to my earlier  
18 question really did affirm for me the importance of doing  
19 this because it does suggest the potential to begin to  
20 rationalize the kinds of prices that are being attached to  
21 new drugs that are coming to market.

22           One of the questions that I have -- I know it's

1 not an answerable one, so I'm just putting it in this part  
2 of our conversation -- is we're going to have to grapple  
3 with the question of how much clinical superiority counts  
4 as clinical superiority, and how is that related to how  
5 much of an increase -- you know, what the marginal pricing  
6 can be relative to the existing therapies?

7 I think I also to me -- and I think someone was  
8 just making this point; maybe it was Bruce. The amount of  
9 data that we'll have on clinical superiority at the time  
10 the drug is introduced will probably benefit from  
11 additional data being collected over the subsequent time  
12 period. So to me that suggests that at the same time that  
13 in the chapter we point to the need to collect information  
14 to know about the cost for when the drug gets incorporated  
15 into the bundle, we should also be ongoingly collecting the  
16 data that we need to ongoingly assess clinical superiority.  
17 And I recognize that that begins to open the door to  
18 something broader for clinical superiority assessment, and  
19 I don't think that that's a bad thing for the Medicare  
20 program.

21 So those are my comments. Thank you.

22 MS. KELLEY: Mike, I think you're next.

1 DR. CHERNEW: I am next. I'm going to say a few  
2 things, and then we can continue or move on to the next  
3 session. But let me make some broad points.

4 With regard to the structure of the chapter, I  
5 think we hear loud and clear that some specific examples  
6 matter in a range of ways, and there's some nuanced  
7 clarification about things like clinically superior to  
8 what, clinically superior to things in a bundle, clinically  
9 superior to other separately payable drugs, how is the  
10 thing working with particular cancer drugs and those  
11 different biologics, for example. All of that I think is a  
12 reasonable thing to work through in the chapter, and, Dan,  
13 you did an outstanding job with a very complicated topic,  
14 and we will try to be as concrete as possible in the  
15 examples moving forward.

16 I think the big conceptual issue is we're trying  
17 to balance some various things. One thing, of course, is  
18 we want to promote an incentive to keep spending down by  
19 avoiding drugs entering the system that are very high  
20 priced but not better, and I'm going to pause for a second,  
21 but I think, Dan, if I were to say that was the sort of  
22 elevator speech or the motivation for this, how close would

1 I be to right?

2 DR. ZABINSKI: Really close. I will say you're  
3 spot-on.

4 DR. CHERNEW: I'm going to stick with "really  
5 close." That being said, there's a very complicated  
6 process. There's the ASP plus 6 process and a whole slew  
7 of other things going on. So let me just say a few broad  
8 things. One of them is it's very important that I think  
9 Dan and the staff and many of you, certainly I recognize  
10 and feel strongly we need to preserve the incentive to  
11 innovate. It is important for a whole variety of reasons.  
12 So the goal is not to prevent innovation, and I think the  
13 proposal was constructed to do that. That's where you see  
14 things like clinical superiority.

15 The rub for me in part is, depending on how this  
16 is structured, we also want to promote competition amongst  
17 similar things. So, for example, if there's three  
18 biologics -- a biologic and three biosimilars, we don't  
19 want them all in their own separately separable payable  
20 categories with their own prices. I think the core mistake  
21 sometimes is we treat the cost of the drug as if it's  
22 actually a cost as opposed to it just being a price. And

1 when we set the price -- when we set the threshold for  
2 moving into a different category at a high price, there's  
3 incentive, I think, for organizations to potentially try  
4 and get into that separately payable category.

5           So there's a lot, I think, to be done to try and  
6 balance the incentives for innovation that are crucial, the  
7 incentives for efficient use, the incentives or efficient  
8 pricing. The challenge that I think I'll talk with the  
9 staff about -- and you can comment now or send messages  
10 later as it all sinks in -- is do we have this narrow type  
11 of recommendation that I think is an improvement in trying  
12 to solve a problem which we may or may not have convinced  
13 you of? Or do we wait to wrap this into a broader attempt  
14 to address a much, much, much bigger point? And, Brian,  
15 your comments I think were spot-on. This is not unique in  
16 a whole number of ways. In fact, I view this as a foray  
17 into all that's complex about a fee-for-service system, but  
18 we move into different alternative payment models and  
19 bundled systems and episodes. We have questions about how  
20 the episode payment is going to reflect new services.  
21 Amol, I imagine you spent a lot of time thinking about how  
22 that happens. This is just a subset of that kind of

1 question.

2           So let me pause for a second if anyone wants to  
3 say anything else. Otherwise, we'll move on to the next  
4 session, which is ESRD and Medicare Advantage. But let me  
5 just see if anyone has reactions to those big-picture  
6 things or thoughts now. And if you don't have them now but  
7 you have them later, please reach out.

8           [Pause.]

9           DR. CHERNEW: As the slide changed, Andy's making  
10 his point. So, Jim, I take from your silence you're fine  
11 with that as well. My comments were meant in some sense as  
12 my summary of at least what I am thinking now. Again, I  
13 will look forward to hearing from you, but I guess in the  
14 interim we'll move on to Andy and Medicare Advantage. This  
15 is maybe going once, going twice, going three times. And  
16 we are now on to Medicare Advantage and ESRD. Andy, you're  
17 up.

18           DR. JOHNSON: Thanks, Mike.

19           Good morning. This presentation addresses access  
20 to Medicare Advantage plans for beneficiaries with end-  
21 stage renal disease, or ESRD. I would like to thank Nancy  
22 Ray, Carlos Zarabozo, Luis Serna, and Eric Rollins for



1 their help on this topic.

2           The audience can download a PDF version of these  
3 slides in the handout section of the control panel on the  
4 right side of the screen.

5           The 21st Century Cures Act lifted existing  
6 limitations on MA enrollment for Medicare beneficiaries  
7 with ESRD, allowing those beneficiaries to enroll directly  
8 in an MA plan starting in 2021. Some observers expect that  
9 MA plans' coverage of cost sharing and the required cap on  
10 out-of-pocket expenses will attract a growing share of ESRD  
11 enrollees in the coming years. In today's presentation, I  
12 will review information about Medicare spending and  
13 coverage options for beneficiaries with ESRD.

14           Then we will move on to MA payments. I will  
15 start by reviewing how MA plans are paid for enrollees with  
16 ESRD and will share results of our analysis comparing MA  
17 payments with plans' medical costs for enrollees with ESRD.

18           We consider two payment issues: first, I will  
19 present information about the prices MA plans pay for  
20 dialysis; and, second, we discuss whether the statewide  
21 basis for Medicare payments may overpay or underpay some  
22 plans.

1           Finally, we turn to access to MA plans and  
2 consider whether plans' coverage of cost sharing or plans'  
3 networks for dialysis facilities could deter beneficiaries  
4 with ESRD from enrolling in an MA plan.

5           Treatment for ESRD requires dialysis to remove  
6 waste from the blood or a kidney transplant. Dialysis is  
7 usually provided three times per week. Patients with ESRD  
8 require many health care services, in addition to dialysis,  
9 and average Medicare spending for beneficiaries with ESRD  
10 is more than eight times the average spending for  
11 beneficiaries without ESRD.

12           This means that beneficiaries with ESRD are  
13 liable for substantial out-of-pocket costs, averaging about  
14 \$13,000 per year. Many beneficiaries with ESRD have  
15 supplemental coverage from Medicaid, Medigap, or an  
16 employer-sponsored plan to help with cost sharing; however,  
17 these options are not available to all beneficiaries.

18           Prior to 2021, beneficiaries with ESRD were  
19 prohibited from joining most MA plans; however, they could  
20 remain in a plan, if they were already enrolled, or they  
21 could join a special needs plan. Even with these  
22 limitations, about 131,000 beneficiaries with ESRD were

1 enrolled in MA in 2019. That's about 25 percent of all  
2 Medicare beneficiaries with ESRD.

3           Beginning with coverage for 2021, the 21st  
4 Century Cures Act allows beneficiaries with ESRD to enroll  
5 directly in an MA plan. Because of this change, CMS  
6 expects an additional 83,000 beneficiaries will enroll in  
7 an MA plan over the next six years.

8           The agency expects additional MA enrollment  
9 because of the extra benefits that plans offer, including  
10 lower than fee-for-service cost sharing for most services;  
11 in particular, the cap on out-of-pocket spending is \$7,550  
12 for 2021 and is much less than the average out-of-pocket  
13 spending for beneficiaries with ESRD.

14           Medicare requires MA plans to offer the same  
15 benefit package to all plan enrollees.

16           In 2004, the Commission recommended that Congress  
17 allow all beneficiaries with ESRD to enroll in private  
18 plans, noting an improved risk adjustment system and a  
19 study finding equal or better quality of for most ESRD plan  
20 enrollees.

21           The Commission strongly supports beneficiaries'  
22 ability to choose among Medicare coverage options. Some

1 beneficiaries with ESRD may benefit from the substantial  
2 extra benefits that plans offer and the care coordination  
3 and cost-control tools that plans employ.

4           In recent years, we have tracked growth in an  
5 increasingly robust MA program, including growth in  
6 enrollment, increased plan offerings, and a historically  
7 high level of extra benefits. These indicators of a  
8 vibrant MA program set the context for considering the  
9 potential for expanded ESRD enrollment over the next few  
10 years.

11           Now let's review how MA plans are paid for  
12 enrollees with ESRD. Medicare payment is equal to an ESRD  
13 state rate multiplied by a risk score. The ESRD state rate  
14 is equal to the average fee-for-service Medicare spending  
15 for beneficiaries with ESRD in each state.

16           The risk score increases or decreases payment for  
17 enrollees based on their expected Medicare expenditures.  
18 The ESRD risk adjustment model is based on fee-for-service  
19 beneficiaries with ESRD and is separate from the other risk  
20 adjustment models.

21           Although plans do not submit a bid for enrollees  
22 with ESRD, CMS collects information about each plan's costs

1 and revenues for those beneficiaries through the bid  
2 payment tool. We used bid payment tool data to compare  
3 revenues with costs for enrollees with ESRD in each MA  
4 contract.

5           Now, on Slide 7, our analysis found that, on  
6 average, revenues were greater than medical costs for ESRD  
7 enrollees. This chart depicts the distribution of medical  
8 cost-to-revenue ratios across MA contracts.

9           Looking only at ESRD enrollment, a contract with  
10 costs that are equal to revenues has a ratio of 1.0. Each  
11 green bar shows the share of MA contracts within the cost-  
12 to-revenue range noted on the bottom, and the corresponding  
13 white bars show the share of MA enrollees with ESRD  
14 enrolled in those contracts.

15           The sum of the three white bars on the left  
16 indicate that 56 percent of MA enrollees with ESRD are in  
17 an MA contract with equal or smaller medical costs than  
18 revenues. However, the chart indicates a wide range of  
19 financial performance for enrollees with ESRD.

20           In a separate analysis of plans that exclusively  
21 enroll beneficiaries with ESRD, we found that those plans  
22 are generally profitable.

1           Although we find payments in the aggregate are  
2 adequate to cover medical costs for enrollees with ESRD,  
3 plan advocates have claimed that payments are not adequate  
4 for two reasons.

5           First, MA plans pay more for dialysis treatments  
6 because plans are not able to negotiate rates as low as  
7 fee-for-service Medicare. And, second, within-state  
8 spending variation and differences in the distribution of  
9 MA and fee-for-service enrollment across each state lead to  
10 MA payments that may be too low. We consider each of these  
11 issues over the next two slides.

12           To address the first issue, we evaluated dialysis  
13 prices using MA encounter data for 2018. You may recall  
14 that we previously found encounter data were not suitable  
15 for analyzing MA service use because missing and incomplete  
16 data introduce downward bias on utilization estimates.

17           Unlike analysis of service use, the distribution  
18 of dialysis prices is not necessarily biased by missing  
19 data. We assessed the extent of missing dialysis data and  
20 found that encounter data included about 80 percent of the  
21 dialysis treatments we would expect to observe, and we  
22 concluded that the encounter data were a reasonable basis

1 for this analysis.

2 Slide 9 summarizes our results. We found that MA  
3 contracts paid an average of about 14 percent more per  
4 dialysis treatment than fee-for-service Medicare rates in  
5 2018, accounting for differences in age and wage index.

6 Dialysis prices in MA are a function of  
7 negotiations between plans and providers, and one reason  
8 for a high average price may be that consolidation in the  
9 outpatient dialysis industry hampers plans' ability to  
10 negotiate lower prices. Two dialysis companies operate 74  
11 percent of outpatient dialysis facilities.

12 However, we find a wide range of dialysis prices  
13 per treatment with some MA contracts paying an average  
14 price below fee-for-service Medicare rates, covering 18  
15 percent of MA dialysis treatments. And some contracts  
16 covering about 5 percent of MA dialysis treatments paid an  
17 average of 40 percent or more above Medicare fee-for-  
18 service rates.

19 Given the expectation for increasing ESRD  
20 enrollment in MA, the balance of negotiating leverage  
21 between MA plans and dialysis providers may shift. We will  
22 continue to monitor MA dialysis prices and consider whether

1 high prices lead to diminished access to MA plans for  
2 beneficiaries with ESRD.

3           The second payment issue is whether state-based  
4 ESRD payment leads to underpayment or overpayment for MA  
5 plans. The ESRD state rates are based on local fee-for-  
6 service spending for beneficiaries with ESRD.

7           Two studies of this issue found that some  
8 metropolitan areas had ESRD spending that differed from the  
9 state average and, therefore, differed from Medicare  
10 payments. The two studies found maximum differences in the  
11 range of 10 to 15 percent above or below the state average  
12 spending.

13           Payment accuracy requires balancing two factors.  
14 First, payment areas should be small enough to minimize  
15 spending variation within each area. And, second, payment  
16 areas need to include enough fee-for-service beneficiaries  
17 to maintain stable spending estimates over time.

18           We do not know whether there are sufficient data  
19 to use a smaller geographic unit as the basis for ESRD  
20 rates, but if the Commission is interested, we could  
21 explore an alternative basis for ESRD payments, such as  
22 MedPAC areas.



1           Now we turn to access to MA plans for  
2 beneficiaries with ESRD.

3           Although the 21st Century Cures Act eliminated  
4 enrollment barriers, some MA plans with financial losses  
5 for ESRD enrollees may seek to deter ESRD beneficiaries  
6 from enrolling in their plan.

7           We evaluated two strategies within the bounds of  
8 Medicare rules that could be used to deter ESRD enrollment.

9           One strategy is to allow high out-of-pocket  
10 spending for ESRD enrollees, diminishing beneficiaries'  
11 ability to reduce their cost-sharing liability by enrolling  
12 in an MA plan.

13           The second strategy is for plans to establish  
14 dialysis facility networks that do not provide adequate  
15 dialysis facility options.

16           First, we consider the level of cost sharing that  
17 MA plans impose for dialysis services. Plan cost sharing  
18 can vary by service category, and dialysis services have  
19 their own category. By law, plans can impose a maximum of  
20 20 percent coinsurance for dialysis, equivalent to the  
21 dialysis cost sharing in fee-for-service Medicare.

22           We reviewed plan benefit package data and found

1 that 81 percent of plans imposed the maximum dialysis cost  
2 sharing, covering about 74 percent of enrollees with ESRD  
3 in 2020. These percentages have increased only slightly  
4 since the passage of the Cures Act, suggesting that high  
5 dialysis cost sharing has always been common for MA plans.

6           Considering cost sharing for all services, plans  
7 are required to offer a limit on the total out-of-pocket  
8 spending. The 2021 out-of-pocket cap limits spending to  
9 about 60 percent of the total out-of-pocket liability for  
10 the average beneficiary with ESRD.

11           That means the widespread use of high dialysis  
12 cost sharing may not deter enrollment in MA plans because  
13 the cap on out-of-pocket spending is in place. However, if  
14 the cap were to be increased for ESRD enrollees, it would  
15 be detrimental to MA plan access. We will continue to  
16 monitor any changes to the out-of-pocket spending cap.

17           Next we turn to network adequacy. Two standards  
18 enforce the network adequacy requirement for most provider  
19 types.

20           The first standard establishes a minimum number  
21 of facilities or physicians per capita in a county.  
22 Second, a set of time and distance standards ensure that a

1 plan's network is consistent with the prevailing pattern of  
2 health care delivery in a community. Different standards  
3 are established for each facility type and physician  
4 specialty.

5           In recent rulemaking, CMS permanently replaced  
6 the time and distance standard with a plan's attestation  
7 that their network of dialysis facilities is adequate. CMS  
8 noted comments from stakeholders that dialysis providers  
9 may leverage network adequacy requirements in order to  
10 negotiate prices well above Medicare fee-for-service rates.

11           Please note that the last sub-bullet on Slide 13  
12 is different from your mailing materials.

13           In the rulemaking, CMS stated that it will  
14 replace network adequacy evaluation with attestation for a  
15 specialty or facility type in circumstances where it may  
16 not be necessary to evaluate the number and accessibility  
17 of each of the provider types in a particular year. CMS  
18 apparently applied this provision to outpatient dialysis  
19 facilities for 2021, and so plans will not be evaluated on  
20 the minimum number of facilities per county standard but  
21 will attest to both standards for dialysis facilities.  
22 Neither of these changes apply to any other provider type.

1           In a comment letter, the Commission strongly  
2 opposed this change out of concern it could diminish access  
3 to MA plans for beneficiaries with ESRD.

4           If a dialysis facility is removed from a plan's  
5 network, patients may choose to continue receiving care  
6 from the facility rather than remain enrolled in the plan.  
7 The plan is also not likely to attract new enrollment from  
8 patients at the removed facility.

9           A plan's attestation does not provide any  
10 specific information about dialysis treatment options in a  
11 plan. When considering coverage options, beneficiaries are  
12 only certain about in-network dialysis facility options.  
13 Therefore, under the new rules, removing a dialysis  
14 facility from a plan's network could be an effective  
15 strategy for deterring ESRD enrollment.

16           If there is Commission interest, we can revisit  
17 this issue in a future meeting and consider whether further  
18 action is needed to maintain access to MA plans for  
19 beneficiaries with ESRD.

20           In this presentation, we covered a wide array of  
21 topics addressing MA enrollment for beneficiaries with  
22 ESRD, and we are looking forward to your discussion. In

1 particular, we would appreciate your feedback about  
2 pursuing future work in two policy areas. First, we could  
3 explore revising the ESRD state rates by using an  
4 alternative geographic unit, such as MedPAC areas. We  
5 would evaluate whether the available data would allow for  
6 smaller ESRD payment area and whether payment accuracy  
7 would be improved by doing so. Second, we could pursue  
8 changes to network adequacy requirements for outpatient  
9 dialysis facilities, such as reinstating the time and  
10 distance standards.

11 Thanks, and now I'll turn it back to Mike.

12 DR. CHERNEW: Great. That was terrific.

13 We have a few Round 1 questions. So I'll let us  
14 go through the list. I think the first person on the list  
15 was Jonathan. Am I right, Dana?

16 MS. KELLEY: That's correct.

17 DR. JAFFERY: Thanks.

18 Andy, great presentation. Thank you so much.

19 So my question is about the topic and the concept  
20 about the statewide variation and thinking about are we  
21 overpaying or underpaying plans. Do you have thoughts  
22 about some of the primary drivers of the variation? I

1 think in the reading, it mentioned about 30 percent of  
2 payments are for the dialysis payments themselves, which  
3 seem a little more fixed, but obviously, we see variation,  
4 a lot of variation in all sorts of things in Medicare and  
5 health care in general.

6 So do you have any thoughts about what's driving  
7 that in particular?

8 DR. JOHNSON: We haven't gotten into any of the  
9 specific variation within the ESRD state rates. I think  
10 for now I would only point to the geographic variation  
11 you're aware of, that all medical spending varies quite a  
12 bit by geographic area, and ESRD beneficiaries have a lot  
13 of spending. So the differences would be noticeable for  
14 this group in particular.

15 DR. JAFFERY: Okay. Thank you.

16 MS. KELLEY: Marge?

17 MS. MARJORIE GINSBURG: So maybe I missed this,  
18 but I'm curious. Were the MA plans supportive of the idea  
19 of allowing ESRD patients to be enrolled, or do they accept  
20 this kicking and screaming?

21 I have a hard time believing that MA plans can't  
22 make this work out to their advantage, but I am curious

1 whether the change in the rules about allowing ESRD  
2 patients to come to them directly was with their enthusiasm  
3 or resistance. Do we have any idea?

4 DR. JOHNSON: At least some share of plans do not  
5 seem to be supportive and have been pushing a lot of  
6 changes to the payment policy and suggesting that the  
7 payments are inadequate.

8 As to your other point, though, we did look at  
9 the types of plans that exclusively enroll ESRD  
10 beneficiaries, and they tend to make the finances work so  
11 that it does provide evidence that it's possible in at  
12 least some areas for some of the plans.

13 MS. KELLEY: Larry?

14 DR. CASALINO: Yeah. Andy, this may be a naïve  
15 question, but my understanding is that for most services in  
16 general, Medicare adjusts payments geographically on a  
17 national basis based on things like is the rent higher or  
18 their cost of space higher in City A than City B or County  
19 A or County B, are labor expenses higher or lower, and so  
20 on. So why are we talking about within state variation and  
21 prices at all? Why not just adjust geographically for  
22 costs on a national basis the way Medicare does for other

1 things?

2 DR. JOHNSON: I think the limitation has been the  
3 number of fee-for-service beneficiaries that are available  
4 to serve as the basis for a benchmark, and so far, CMS has  
5 used just states as the basis for that benchmark. So there  
6 is the same payment rate, the same base payment rate for an  
7 entire state, no matter where a plan is participating.  
8 Plans can have service areas that are county-by-county  
9 basis. So they might serve one metropolitan area and not  
10 the whole state, and another plan might serve a totally  
11 different metropolitan area. And if those areas have  
12 spending that is different from the state average, then the  
13 MA payment rates might be overpaying or underpaying  
14 relative to what the local rates are. But I think  
15 limitation is about the available ESRD enrollees and fee-  
16 for-service Medicare that serve as the basis for those  
17 rates.

18 DR. CASALINO: I see. So compared to the unit,  
19 which I think is the county that Medicare accounts for cost  
20 for other services, there wouldn't be enough ESRD patients  
21 in some counties to make that kind of calculation?

22 DR. JOHNSON: That's right.



1 DR. CASALINO: But why not just use -- why worry  
2 about ESRD patients as a specific group at all in this  
3 regard? Rents are rents. Labor costs are labor costs.  
4 Those are true whether it's ESRD beneficiaries or from  
5 other beneficiaries. I don't understand the special -- I  
6 still don't understand using different geographic areas  
7 than for the rest of Medicare.

8 DR. JOHNSON: So, currently, the entire payment  
9 system for ESRD enrollees is separate from the non-ESRD  
10 enrollee payment system, and so what I think you're asking  
11 is why isn't there just one payment system for everybody.  
12 And I'm not sure what the answer is, if that's your  
13 question.

14 DR. CASALINO: Yeah. And I won't editorialize,  
15 and I don't really know very much about this. But I think  
16 it's worth thinking about.

17 MS. KELLEY: Paul, did you have something on this  
18 point?

19 DR. PAUL GINSBURG: Yeah. It's a follow-up to  
20 Larry.

21 Larry, the big difference between MA rates and  
22 the rates that we pay hospitals or physicians is that MA

1 rates are capitated. So, in a sense, it's an entirely  
2 different thing, and we've always tied them to fee-for-  
3 service experience on a per-beneficiary basis. And that's  
4 why, historically, we've used the cap fee. You know,  
5 MedPAC has better ideas to do that in MedPAC areas, but I  
6 think that's why you're seeing statewide, presumably  
7 statewide payment back because the program started very  
8 small. Since it was only people, beneficiaries that were  
9 enrolled in MA that developed ESRD while they were  
10 enrolled, the number was small. There probably wasn't  
11 enough data in fee-for-service ESRD to use for that.

12 DR. CHERNEW: Yeah. I think what Paul is saying  
13 is that for hospitals, you're trying to adjust a price, and  
14 so you're looking at wage indices. In MA, you're trying to  
15 adjust for a spending, which is a price time to use. So  
16 the geographic variation in use gets captured in MA rate  
17 more so than just -- the differences in, for example, MA  
18 benchmarks normally across geographic areas isn't just the  
19 wage index. It reflects differences in utilization between  
20 different places, and that's the parallel to what's  
21 happening in ESRD.

22 I think, Paul, I can see you a little bit in a

1 small little square. If you nod, I think I'm just  
2 repeating what you said.

3 So I think that's why they're doing it  
4 differently because the use component is different.

5 DR. CASALINO: Mike, I don't want to prolong  
6 this, but I'll just point out that that basically rewards  
7 overuse or overutilization.

8 DR. CHERNEW: Yeah. Yes.

9 DR. CASALINO: Just for ACO rates and so on and  
10 so forth. But I don't think we should forget that.

11 So, basically, if you're in a state right now  
12 that has high utilization for any ESRD beneficiaries,  
13 they're going to pay more than if you're in a state where  
14 care is perhaps given better and more efficiently.

15 DR. CHERNEW: Absolutely. Which is the same --  
16 the geographic panelists at IOM or National Academy of  
17 Sciences did this for Minneapolis and Miami, this exact  
18 same as you happen. If you're in a place with high home  
19 care use, the MA rate is much higher, for example.

20 DR. CASALINO: Right.

21 DR. CHERNEW: So we should move on. I think  
22 there's a few more Round 1's. I'm not sure I have it

1 exactly. I think we have --

2 MS. KELLEY: David is next.

3 DR. CHERNEW: Perfect.

4 DR. GRABOWSKI: Great. Thanks, Dana, and thanks,  
5 Andy, for a great chapter and great presentation.

6 I wanted to ask you just about -- I think this is  
7 really focused on Slide 9, just on that result that's in  
8 the headline there about -- oh, thank you -- MA contracts  
9 paid 14 percent more per dialysis treatment on average than  
10 fee-for-service. Andy, is that for the entire country?  
11 But this doesn't reflect where folks go for dialysis. This  
12 is within, within provider? Like how did you -- did you  
13 make sure to adjust for that? I just want to say more  
14 about what you did to get that number.

15 DR. JOHNSON: So we adjusted for differences in  
16 age and wage index. So it does take into account the wage  
17 index that would apply to the fee-for-service payment  
18 rates, but we first aggregated to the contract level and  
19 found an average for each contract and then overall  
20 average.

21 DR. GRABOWSKI: At that area level? Is that the  
22 calculation you made? It's not per sort of where folks are

1 actually receiving treatments? This is sort of at an area  
2 level and then aggregated up to the U.S.? Am I think about  
3 that correctly?

4 DR. JOHNSON: For the wage index adjustment in  
5 fee-for-service, ESRD, PPS, I think it's about 53 percent  
6 of the rate is adjusted by the wage index, and so we did  
7 the same thing but to back out the wage index from each of  
8 the MA payment areas so that we normalized -- or  
9 standardized the prices across the entire country and then  
10 compared the fee-for-service to MA averages.

11 DR. GRABOWSKI: Okay. Thanks.

12 MS. KELLEY: Pat?

13 MS. WANG: Thanks.

14 Andy, this is just a point of clarification. In  
15 the paper, on page 7, you talked about the ESRD subsidy,  
16 and for plans with ESRD payments that do not cover ESRD  
17 costs, this allows plans to draw down rebate funding to  
18 make up for the gap by reducing supplemental benefits. Is  
19 this specific to reducing supplemental benefits for ESRD  
20 patients or just for the entire Medicare membership  
21 enrolled by that plan?

22 DR. JOHNSON: It would be for the whole

1 membership of the plan.

2 MS. WANG: Okay. So a consequence of inaccurate  
3 payment or a gap in payment is that all members of the plan  
4 use supplemental benefits?

5 DR. JOHNSON: They could if the plan used this  
6 ESRD subsidy. It's optional for the plan, but they could  
7 use the rebate funding for the whole enrollment to  
8 reconcile any differences in their population.

9 MS. WANG: In the analysis that you did to match  
10 revenue to cost for the sample that you could simulate, I  
11 just -- and, again, this is on page 8 of the paper. You  
12 talked about average medical cost of 67/52 PMPM. Average  
13 plan revenue, 67/69. So the ratio was 0.997. Is that  
14 revenue the total premium received by the plan? I mean,  
15 where would admin or -- it includes, like, running the  
16 plan, doing care management. Is that included in this  
17 total revenue PMPM or not?

18 DR. JOHNSON: The revenue should be all of the  
19 money that the plan received from Medicare. On the cost  
20 side, it only includes the medical costs because --

21 MS. WANG: Okay.

22 DR. JOHNSON: So admin is not included in that,

1 and any --

2 MS. WANG: Okay.

3 DR. JOHNSON: -- profit, that would not be  
4 included like it is for normal.

5 MS. WANG: Okay. So a medical loss ratio of .997  
6 means the plan is losing a ton of money. I just want to  
7 point that out because there's nothing about the cost of  
8 running the plan or doing care management in particular for  
9 a very high-need population. Okay.

10 The other thing I just was curious about -- I  
11 think you did an admirable job of trying to sort of piece  
12 together the information you had to do this cost-to-revenue  
13 analysis. It seems like about 25 percent of ESRD, people  
14 with ESRD are currently enrolled in MA. Under the current  
15 rules, where if you develop ESRD while you're an MA member,  
16 you stay in the plan.

17 Is there any reason to think that the profile of  
18 spending for members that have been in a managed  
19 environment might be different from members who might be  
20 coming in straight from fee-for-service and have unmanaged  
21 total health care costs? I just wondered. I mean, you had  
22 to use the information that you had, but I just wondered

1 whether you felt like this was a representative sample of  
2 ESRD spending in Medicare Advantage.

3 DR. JOHNSON: I think what you're asking is  
4 whether or not the spending profile would be similar among  
5 the fee-for-service patients, and I guess there are reasons  
6 why it could be different. I'm not sure that we've tried  
7 to quantify those.

8 MS. WANG: Okay. Final question. On the issue  
9 that was just being discussed before about the statewide  
10 average fee-for-service cost, has there been any effort to  
11 look? I realize that the number of enrollees is small,  
12 beneficiaries is small, but has there been any effort to  
13 look at variation in cost within a state, rural area versus  
14 major metropolitan area, or, you know, just even the  
15 grossest subcategories within state variation and spending?

16 DR. JOHNSON: So the two studies that I mentioned  
17 have done it for the fee-for-service population, and that's  
18 something that we could get into and try and do a more  
19 comprehensive national assessment. I'm not sure that any  
20 study has looked at the MA costs for a specific region.

21 MS. WANG: Okay. Thank you.

22 MS. KELLEY: Bruce?



1 MR. PYENSON: Thank you.

2 Andy, this is superb work. In my experience,  
3 ESRD is just about the most complicated area in Medicare  
4 Part A and B, and I'm sure Brian is going to ask you to  
5 integrate that with Part D, in which case this will be way  
6 off the charts on complexity, so terrific work.

7 I wanted to ask about -- I think it's Slide 13.  
8 I think it was 16 percent higher reimbursement, and I want  
9 to -- maybe it was not Slide 13, but Slide -- well, but my  
10 compliments on your use of the encounter data to finding a  
11 way to use that creatively and get useful information.

12 In my experience, many MA plans do not pay  
13 dialysis organizations using the Medicare bundle, just like  
14 some organizations don't pay hospitals using DRGs, and so  
15 this is kind of a geeky question. In particular, many MA  
16 organizations pay for ESAs and fused iron separately or  
17 perhaps other things.

18 In your use of the encounter data, were you able  
19 to spot that sort of thing? One of the reasons I'm asking  
20 is in looking at claims data from MA, I've seen much higher  
21 than 14 percent differential. So I'm curious, your  
22 thoughts about that, different kind of separately payable

1 but sort of a fee-for-service rather than bundle.

2 DR. JOHNSON: On the overall results, there  
3 certainly were some contracts that had an average price  
4 that they paid that was much higher. There wasn't as many,  
5 but the prices went several times more than the fee-for-  
6 service rate for some contracts.

7 The way we tried to capture the payments that  
8 plans made to the dialysis provider was using the type of  
9 bill code. So it wasn't specific to the ESRD bundle,  
10 included any of the payments that went through, and I think  
11 you're right that different plans used different methods of  
12 reporting -- or rather, the providers used different  
13 methods of reporting to the plan, what the costs were and  
14 what the claim was for. Sometimes it could have been for  
15 the ESRD bundle. Sometimes it could have been for dialysis  
16 and drugs separately, but as long as the payment was going  
17 to the facility, it was included. We used each beneficiary  
18 month as a unit to say that if a plan paid the facility any  
19 amount of money for this beneficiary in the month, that  
20 went into the calculation of payments per treatment.

21 MR. PYENSON: So the code you were using was a  
22 bill code, was a bill type, or --

1 DR. JOHNSON: It is the -- I know them as 72X  
2 codes, but I'll have to look up what the variable name is,  
3 type of billing and type of service.

4 MR. PYENSON: Since the encounter data is used  
5 for risk adjustment, are the drug claims, like for ESAs and  
6 IV iron, are those used for -- typically chaptered and used  
7 for risk adjustment?

8 DR. JOHNSON: I think they are. So you're  
9 asking, in the fee-for-service population, with ESRD, which  
10 was used as the basis for ESRD risk adjustment model, all  
11 of the spending for those beneficiaries would be captured.

12 MR. PYENSON: I'm thinking of the submission of  
13 encounter data for routine submission for MA plans for  
14 general risk adjustment.

15 DR. JOHNSON: So in the ERS D PPS and fee-for-  
16 service there is the case mix adjusters, the facility-level  
17 and patient-level adjustments, and you're wondering if  
18 plans tended to adjust their payments similarly to the fee-  
19 for-service? Is that --

20 MR. PYENSON: I'm wondering if routinely the  
21 plans would submit claims that just had a drug claim to  
22 capture diagnoses for a Part C drug claim.

1 DR. JOHNSON: I would have to go back and look.

2 MR. PYENSON: Okay. Thank you.

3 MS. KELLEY: Dana?

4 DR. SAFRAN: Thank you. Just two questions from  
5 me, and truly great work. One is related to the move to  
6 attestation. Can you help us understand a little bit more  
7 about the rationale and maybe justification for removing  
8 the time and distance standards and moving to attestation?  
9 And does it have any relationship to the increasing use of  
10 home dialysis? Is that part of what's behind it? It would  
11 be helpful to understand the rationale, and if it's not  
12 driven by home dialysis how does the increasing use of home  
13 dialysis factor into network adequacy considerations?  
14 That's my first question.

15 DR. JOHNSON: So the first part of the question,  
16 CMS didn't give a very specific rationale for eliminating  
17 the time and distance standards and replacing with an  
18 attestation, but they did note that several stakeholders  
19 found that dialysis organizations were using the network  
20 adequacy standards to leverage higher prices from the  
21 plans. So that does seem to be the main concern. And  
22 later CMS noted that the flexibility of replacing the time

1 and distance standards with attestation would allow plans  
2 to negotiate lower prices. That was what they said.

3           On the second part, for the minimum number of  
4 facilities per county, there wasn't an explanation given  
5 for that, and it was not noted that that would apply to  
6 dialysis facilities. And I should say I think this is the  
7 case that it applies to dialysis facilities. There is a  
8 rather non-transparent provision in the rulemaking that  
9 says we'll remove a specific facility type from the  
10 standards by excluding them from a specific spreadsheet,  
11 and on the spreadsheet dialysis facilities are not included  
12 in the standards.

13           For home dialysis, CMS did note that home  
14 dialysis is something that plans could use to help provide  
15 an adequate dialysis coverage. I think the concern is that  
16 home dialysis is not an appropriate treatment modality for  
17 all patients with ESRD, and so it certainly could help, and  
18 I think CMS wanted to push that, which makes sense. But it  
19 doesn't mean that home dialysis is a substitute for in-  
20 center dialysis for all patients, and I think I recently  
21 saw a figure -- I don't remember the exact number but the  
22 vast majority of patients who use home dialysis also use

1 in-center dialysis at some point over the lifetime of their  
2 treatment.

3 DR. SAFRAN: That's helpful. Thank you. The  
4 second question is the rationale related to how attestation  
5 could allow the plans to get better pricing, I have to say  
6 I don't understand.

7 But my second question is related to the  
8 significantly higher pricing that you show us that MA plans  
9 are paying relative to fee-for-service. Given that extreme  
10 consolidation in the dialysis market with two companies  
11 really accounting for three-quarters of the market, is it  
12 possible to consider having MA plans leverage the Medicare  
13 fee-for-service negotiated rates for dialysis? I recognize  
14 that would be unprecedented. At least I think it is for  
15 how MA plans get pricing for their networks. But I just  
16 wanted to ask the question.

17 DR. JOHNSON: I think there is one precedent for  
18 that in MA policy which is for regional plans contracting  
19 with in-patient hospitals, and regional plans do not have a  
20 service area on a county-by-county basis. They have much  
21 larger areas. I think there are whole states or multiple  
22 states at a time. I have to double-check that, but by

1 agreeing to provide, or have a service area that is that  
2 large, the plan is allowed to say that this hospital is  
3 essential for network adequacy and we made a good-faith  
4 effort to contract with that hospital, and in the case that  
5 the negotiations fail the plan can say they are out of  
6 network but they will accept Medicare fee-for-service rates  
7 for payments. That's the one area I'm aware of.

8 DR. SAFRAN: Thank you.

9 DR. CHERNEW: Dana, I want to come back to that  
10 topic in Round 2, so I'll say something between the rounds.  
11 I think we have a few more people left in the Round 1, so I  
12 think it's Jaewon next.

13 MS. KELLEY: Yes.

14 DR. RYU: Yeah, thanks. I have two questions as  
15 well. The first is on, I think it was Slide 9, getting to  
16 the 14 percent average higher rate. And I think in the  
17 materials it's Figure 2. That 14 percent average, it looks  
18 like there's quite a bit of spread or distribution  
19 surrounding that average. Any observations or patterns  
20 that you can make based on whether it's market type  
21 scenarios or types of plans that are paying on the higher  
22 end of that average versus plans that are paying on the

1 lower end of that average?

2 DR. JOHNSON: I didn't do any specific analyses.  
3 There did seem to be not an obvious pattern to that. I  
4 think some of the larger insurers tended to be not on the  
5 very far right end but were also not exactly on the low end  
6 of the distribution, and there were smaller insurers spread  
7 throughout. So it did not seem to be a clear pattern, at  
8 least based on size of enrollment, and I didn't try and  
9 assess the services areas of individual plans. That would  
10 have been a much more difficult analysis.

11 DR. MATHEWS: But Andy, this is something we  
12 could do if the Commission were interested in exploring  
13 different geographic units as the basis for payment. We  
14 could dig into this more than we have for the purpose of  
15 this presentation.

16 DR. JOHNSON: Yes, we could.

17 DR. RYU: And then the second question was around  
18 the areas within the state that have over/under payment  
19 relative to the state average ESRD payment. And I'm just  
20 curious. I know that Jonathan asked a similar question,  
21 and I think Pat may have touched on it as well. But a  
22 slightly different was have you seen any difference around



1 plan behavior based on whether you're in an overpayment  
2 segment or section of the state or whether you're in an  
3 underpayment section of the state, and availability of MA  
4 plans to ESRD beneficiaries in those two different  
5 scenarios. Is there a difference?

6 DR. JOHNSON: We haven't dug into the within-  
7 state variation but I'll take this as a nod for interest in  
8 pursuing that work. We will try to answer that question.  
9 I think the one area where it seems to stand out is with  
10 the ESRD chronic conditions special needs plans. Those  
11 plans are only available in a few states, and the majority  
12 of enrollment is in California, which has one of the higher  
13 state rates. But I will say California, there is also  
14 variation within California, and I'm not sure whether or  
15 not the plans are operating in the parts of the state where  
16 they would get higher than average payments or lower than  
17 average payments.

18 DR. RYU: Thank you.

19 MS. KELLEY: Jon Perlin?

20 DR. PERLIN: Andy, let me also thank you for a  
21 terrific chapter. You know, I think the basic tension here  
22 is network adequacy and appropriate payments. My questions

1 were very, very similar to Dana's, in terms of trying to  
2 think through whether simply leveraging the fee-for-service  
3 negotiated rate would mitigate against the challenge on the  
4 one end of too broad a geography state rate and too narrow  
5 a geography. But at least to really a nuance on that  
6 question which is that as we think about the smaller  
7 geographic unit do we have any concerns, on page 13  
8 referencing that, of sort of gaming to nominally meet the  
9 criteria but really not offering improved service, other  
10 than driving cost by being just outside of the particular  
11 lower pay geography and locating preferentially in terms of  
12 either a partial sort of plan for ESRD patients, and  
13 ultimately the impact on the location of the dialysis  
14 centers.

15 DR. JOHNSON: So I think that there are two  
16 issues that you mentioned initially, which was about MA  
17 plans being able to pay the fee-for-service rates to  
18 dialysis providers, which I think would help bring down  
19 some of the total medical costs. So on that medical cost-  
20 to-revenue ratio you see a lot of plans come down. But the  
21 ESRD state rates is the amount that Medicare pays to MA  
22 plan, and so there still could be a variation across the

1 state. More plans, I think, would fall into the category  
2 where the average state rate covered more of their costs,  
3 but there still would be some areas of the state where the  
4 geographic spending is higher at an ambient level and the  
5 state average might be too low.

6 DR. PERLIN: Okay. I appreciate that. I'm just  
7 wondering about the fungibility of geography if you go to  
8 smaller units, in terms of optimizing the rate. I'm trying  
9 to think, if one wanted to optimize, there may be very  
10 strange behaviors around the geographic boundaries.

11 DR. JOHNSON: I think that's a good thing to be  
12 concerned about, and if the rate was to be smaller than the  
13 state level, I mean, I think that would be an improvement  
14 on that dimension overall, where there might be issues  
15 right now where the parts of the state with higher spending  
16 are less well covered for ESRD, MA plans of those areas is  
17 less, especially for the ESRD C-SNPs. There would be an  
18 incentive to enroll more ESRD enrollees in the parts of the  
19 state where the average spending is lower than the out-of-  
20 state average.

21 DR. CHERNEW: I think that was the end of Round  
22 1, and so I'm going to jump in. Dana, was I right about

1 that?

2 MS. KELLEY: That's correct.

3 DR. CHERNEW: So we're going to go to Round 2 in  
4 a second, first to Jonathan and then to Amol, but let me  
5 make a general point about this. Some of this came up in  
6 the Round 1 questions about policy options, but you'll see  
7 what I'm hoping to get out of this Round 2.

8 My personal view is that a lot of these axis  
9 issues arise because the plans are finding it impossible to  
10 serve dialysis patients, and a lot of the reason why that's  
11 true is because they're paying higher than fee-for-service  
12 prices. And I think the core problem is that because  
13 there's simply not enough competition in the dialysis  
14 market because of the consolidation of the dialysis market,  
15 which makes it different than a lot of other places, which  
16 means the pricing part is very different.

17 My general view, and this is what I'd like to  
18 hear, is we need to solve those problems together. If we  
19 spend a lot of time promoting access, in other words,  
20 forcing plans to serve people in markets that just aren't  
21 profitable, without allowing them to narrow their networks,  
22 to do something else, which is hard to do, I think it's

1 going to be very hard to move forward.

2           So my personal view is while there is a lot to  
3 discuss, we're going to need to figure out how to do  
4 something, that I think Dana and Jon were talking about,  
5 which is not easy, with how to address the market power  
6 issues that are occurring in the dialysis market, which are  
7 making it complicated to run a good MA ESRD program. And  
8 I'm worried about trying to solve just one piece of this,  
9 because I think it's going to really have to come together  
10 more holistically.

11           So we're going to move on. I think, Jonathan,  
12 you're next. But what I'm looking for out of this is to  
13 understand if we should take snippets of problems to try  
14 and solve or try and address what I think is the root cause  
15 and then how to go from there.

16           Jonathan?

17           DR. JAFFERY: Yeah, thanks, Mike, for that intro,  
18 and again, Andy, thanks for the presentation and the  
19 excellent report. And I think, Andy, you mentioned at some  
20 point near the end of your presentation that this  
21 presentation explored a wide array of topics, I think that  
22 you said, which I think has been clear in our discussion.

1 And, you know, as I think through this and as I've listened  
2 to the questions and comments the other Commissioners have  
3 made, I think my thinking is very similar to what a lot of  
4 people have said. I'm going to see if I can tie those  
5 together and actually if it sort of aligns with what Mike  
6 was just saying about it's hard to kind of tackle each of  
7 these sort of separately. They really have some interplay.

8           And I think it's important to reflect on this  
9 population of patients and the whole ESRD payment system as  
10 being somewhat unique, as Bruce was talking about, the  
11 complexity of it. But it's a pretty unique set of patients  
12 in terms of what their needs are. I think we have a lot of  
13 examples of subsets of patients that get this kind of  
14 intensive treatment multiple times a week, for indefinite  
15 periods of time.

16           And the other pieces that are unique, I think  
17 within that it uses up a significant chunk of Medicare  
18 spending. Andy, you can correct me, but I think it's about  
19 7 percent, and it's been at that rate, more or less, for as  
20 long as I can remember, so for probably decades.

21           And then the other very unique thing is what Mike  
22 and Dana and others have mentioned, is that there is

1 nowhere else where we have something this level of market  
2 consolidation, so we have a really different dynamic than  
3 anything else.

4           So as I think about that there are two or three  
5 things that had come up in my thinking. And so, first of  
6 all, in terms of patient access, most of the questions  
7 didn't talk a lot about the travel, the time and distance  
8 requirements, but I think that's pretty key. As you  
9 pointed out, while there are -- and Dana had commented  
10 about this too -- there are probably good reasons for us to  
11 try and encourage more home dialysis use than we have in  
12 this country. We're not going to be in a situation where  
13 it's appropriate for everybody. It just isn't.

14           And so we have a lot of beneficiaries who,  
15 especially in rural areas, may be traveling far distances,  
16 over difficult terrain, during periods of the year where  
17 there's a lot of inclement weather, and to get to a  
18 lifesaving treatment three times a week is just not really  
19 very easy, if you've got to travel far. So I think it's  
20 really important that we go back to our previous comments,  
21 as a Commission, to really support those things.

22           And that said, this gets into this interplay, if

1 health plans are forced to utilize, or to be able to have a  
2 broader network, and there are such intense market  
3 consolidation, then they may be at a disadvantage in terms  
4 of prices. So I do think that this is a situation that  
5 might be unprecedented but one that we should really  
6 explore, this idea of utilizing fee-for-service payments  
7 for this population.

8 I think the other thing that had come up in some  
9 of the comments or, rather, the Round 1 questions has to do  
10 with the variation. And so while we do have sort of an  
11 immediate concern and issue around the fact that at the  
12 state level it creates some distortion so that some plans  
13 may be getting overpaid and some getting underpaid, I think  
14 what I'm hearing and what I was concerned about coming is,  
15 you know, what exactly are the justifications broadly for  
16 this degree of variation? So there are wage index issues,  
17 and there's risk adjustment, and that certainly makes  
18 sense. But as we see across Medicare and health care  
19 spending broadly, a lot of this is utilization patterns  
20 that may not be justified. And if only about 30 percent of  
21 payments are for the treatments themselves, there's a lot  
22 of variation that we may want to think about how we move



1 towards more of a national benchmark. And this has a broad  
2 applicability for things we've talked about in MA plans  
3 overall and in ACOs. It is hard to understand why long  
4 term our targets for all these models should vary so widely  
5 and go beyond some of the labor costs and things that exist  
6 at the local and regional level.

7           So just to sum up, I think that in the short  
8 term, I certainly favor reinstating the time and distance  
9 requirements because I think that's a big issue for  
10 beneficiary access. And at the same time, even if we're  
11 thinking about longer term how to get at more of a national  
12 benchmark, there's opportunities to think about a smaller  
13 unit. The state-based payment may not be -- clearly has  
14 some issues.

15           I think in conjunction with that, exploring a cap  
16 on payments or using the fee-for-service payments as the  
17 model for payments here makes sense. And I do think longer  
18 term I'd love to explore some of the basis for the wide  
19 geographic variation in spending, and perhaps the ESRD  
20 population gives us an opportunity to explore that in a  
21 relatively contained number of beneficiaries where we have  
22 high spending, lots of utilization, and actually a fair bit

1 of clinical data that's collected already because of the  
2 ESRD requirements.

3           So it's definitely a complex topic, and, again, I  
4 think these topics do interact, intersect, and it's going  
5 to be hard for us to tackle them independently. But  
6 together hopefully we can come up with something pretty  
7 cohesive. So thank you for the opportunity to comment.

8           MS. KELLEY: Amol.

9           DR. NAVATHE: Great. Thank you. Andy, fantastic  
10 job with the paper and publication. Really good.

11           I'm thrilled that we're taking something like  
12 this on. I think this is sort of an exemplar of MedPAC  
13 looking forward and anticipating issues as they're  
14 potentially arising, which I think is really great.

15           There's clearly a lot of dynamic effects here  
16 that I think potentially are going to complicate things and  
17 may change some of the association and some of the  
18 relationships that we're observing. And so I think that  
19 piece is worth noting. I think it is noted in the paper.  
20 I think it's worth noting while we're speaking as far as  
21 any recommendations or further work that we do here.

22           First let me register my support for the

1 recommendations or the approach and discussion points that  
2 you've outlined here. I think I have a couple of  
3 additional points that are worth diving into perhaps.

4           So first is kind of getting a fact right, if you  
5 will. So I appreciate the innovative way that you have  
6 viewed encounter data to infer the prices on the dialysis  
7 side. I think it would be worth figuring out if there's a  
8 way to dig more deeply into that because what we're finding  
9 there is a linchpin for basically almost everything else,  
10 and I outlined up front that it's kind of hard to separate  
11 payment from network adequacy from these other issues, cost  
12 sharing, et cetera, et cetera. So that's really important.

13           The reason I say that is because I think there is  
14 some evidence, even some of our own work has shown that, in  
15 general, the adherence, if you will, to dialysis sessions,  
16 or the number of dialysis sessions per beneficiary are  
17 higher in Medicare Advantage, certainly in SNPs but also  
18 Medicare Advantage more broadly. And so if that is, in  
19 fact, true, then some of the assumptions that I believe  
20 that were used to get that 14 percent number may actually  
21 have some variance around them, which would actually drive  
22 toward smaller price effects, I believe, than we're noting.

1 So that may be hard to solve, but I think it's worth just  
2 throwing out there, given that it's so fundamentally  
3 important to all of our inferences. If there's anything  
4 that we can do to dig more deeply into that piece, I think  
5 that would be important.

6           The third piece I think is largely building upon  
7 a lot of what -- the questions I think we're hinting at in  
8 Round 1, and Jonathan also indicated, you know, in the  
9 figure where we look at the variation of the cost-revenue  
10 ratio, obviously a lot of variation. I think it would be  
11 really important to understand more deeply what that  
12 variation looks like, how much of that variation is within  
13 state, within market even, versus across market. Are there  
14 other MA contracts in the same area which have a lot of  
15 variation? And I think taking that one step further, which  
16 is what are the characteristics of those markets, what are  
17 the characteristics of those contracts that we can observe  
18 them in terms of enrollment of number of ESRD  
19 beneficiaries, in terms of, you know, rural versus urban.  
20 I think there's a lot of pieces here that are important,  
21 and since we're supporting -- registering our support for  
22 pursuing this work, I think additional data work there I

1 think would really help us understand better what some of  
2 the dynamics are and, therefore, you know, wrap our hands  
3 around this, if you will.

4 I think it's going to show us that rural areas  
5 are a particularly challenging piece here, at least any  
6 markets that include rural areas. That's one of the  
7 reasons that I think out of the box I'd support, as  
8 Jonathan does, the sort of network adequacy requirements  
9 reinstating the time and distance standards.

10 There's going to be clearly a trade-off here  
11 between trying to precision payment, if you will, versus  
12 sample size issues, and I think exploring that area or  
13 other geographic units is worth doing. I think even in  
14 light of Jon Perlin's concern around some of the potential  
15 gaming that could happen around those units, I think still  
16 there's probably a lot of benefit trying to see if we can  
17 get some of those payment elements more precise, if you  
18 will.

19 One broad point here is I think -- and this is  
20 perhaps touching a little bit on what Larry was talking  
21 about earlier on around, you know, having a different way  
22 that we pay here. I think the ESRD population is pretty

1 different than other populations and largely, you know,  
2 vulnerable to a lot of challenges, both clinical,  
3 socioeconomic, and otherwise. So I think having an  
4 approach here that is heavily focused on protecting the  
5 ESRD beneficiary is paramount, in my opinion. And so I  
6 support the Commission sort of kicking it in that  
7 direction, and whatever we can do, I think the analysis  
8 that you've done, for example, on the impact on cost  
9 sharing itself is also really important. It's very likely  
10 that the ESRD beneficiaries would hit the cost-sharing  
11 limit, you know, for the next month right away, and I think  
12 addressing those issues is also an important piece, I  
13 think, of stitching together payment elements that Mike  
14 commented on, but I think pulling all this together.

15           One thing that does strike me that I highlighted  
16 earlier on is that some of these dynamics could change  
17 actually considerably. So if we have an influx, an  
18 impressive influx of ESRD patients into MA that previously  
19 were not there, that could change some of the market power  
20 negotiating dynamics. And I think it's worth making sure  
21 we're on top of that. And so one thing I wondered here is,  
22 in addition to the sort of straw man potential

1 recommendations that we're putting here, could we also make  
2 a more concerted effort to push for greater monitoring  
3 around specific aspects? This is likely to be a moving  
4 target, and I think if we can push, you know, through  
5 whatever way, even if it's indirectly through Medicare,  
6 CMS, to more aggressively monitor this around specific  
7 dimensions that we are outlining in the paper, I think that  
8 could also do a lot of good.

9           So thank you so much. I think it's a really  
10 important population, really an exemplar example of an  
11 issue of looking forward here and anticipating what might  
12 be coming, and thanks for listening.

13           MS. KELLEY: Paul?

14           DR. PAUL GINSBURG: Thanks. You know, I think we  
15 had two lead comments that I thought were very valuable. I  
16 just wanted to bring up our way of -- you know, a context  
17 of this that ESRD patients in MA started very small because  
18 they had to be in the plans, and this has grown over time,  
19 and we'll have a major expansion. I think this changes a  
20 lot of things.

21           You know, as far as payment rates, we've said  
22 that it's the market power that leads to higher payment

1 rates in MA ESRD for dialysis, although Amol had really  
2 good comments about understanding this better. But I was  
3 thinking that we have lots of hospitals who serve Medicare  
4 patients who are very dominant in their markets. They may  
5 be the sole hospital. They may be a must-have hospital,  
6 like in Boston, you know, most employer-based coverage has  
7 to include the Partners hospitals in their networks;  
8 otherwise, it's just not attractive. And this would be  
9 relevant to MA enrollees as well. But you don't see these  
10 hospitals charging large premiums to MA plans for enrollees  
11 that use those hospitals. So there's something in -- I  
12 think the principle that the payment rates that fee-for-  
13 service Medicare has achieved, you know, should translate  
14 to the providers that MA plans use, and I don't think  
15 there's any exception to that, except for the dialysis  
16 treatments.

17 Another thought is that as far as the statewide,  
18 I think I misspoke before saying that it was a small number  
19 of ESRD enrollees. I think the problem and perhaps the  
20 reason why CMS went to state rates initially was that there  
21 just may not have been enough ESRD beneficiaries in fee-  
22 for-service to actually get accurate numbers at the county



1 level, which is our system. And I think by using a MedPAC  
2 area, there may very well be sufficient sample size -- or I  
3 should say population size to get accurate estimates. And  
4 I think that it's really in the interest of the program to  
5 line up MA ESRD as much as possible with the rest of MA  
6 practices in Medicare.

7 I'll just stop there.

8 MS. KELLEY: Brian, did you still want to  
9 comment?

10 DR. DeBUSK: Yes, thank you, Dana. I just want  
11 to mention again really meaningful work, great chapter,  
12 well written. I wanted to comment on the issue of MedPAC  
13 units.

14 First of all, I think they should be used here in  
15 the ESRD payment calculations instead of state-level data.  
16 But I also wanted to advocate for using MedPAC units  
17 broadly throughout MA, because I think -- and this is my  
18 inner Jon Christianson speaking, but as MA penetration  
19 rates get higher and higher in counties, the fee-for-  
20 service data in highly penetrated MA counties is going to  
21 become more and more fragile. So I think this idea of  
22 moving the MA ESRD payments and MA in general toward MedPAC

1 units is a huge step in the right direction.

2 I also do favor looking at network adequacy and  
3 looking at some of the cost-sharing provisions just to make  
4 sure that the MA plans aren't dissuading MA enrollment.  
5 But the one thing I would ask is I hope as we do this, we  
6 make sure we're not overconstraining these programs,  
7 because in such a highly consolidated market, forcing  
8 network adequacy requirements, forcing new cost-sharing  
9 provisions or more restrictive cost-sharing provisions, I'm  
10 just afraid we might be overconstraining this problem. And  
11 as we do it, hopefully we could explore -- and I don't know  
12 if there's a precedent for this. I don't know if there's  
13 any type of statutory authority for this. But I wonder if  
14 dialysis providers that provide a certain mix -- provide  
15 services to a certain mix of Medicare patients or some  
16 other constraint, if they could be required to accept rates  
17 that are closer to Medicare rates for these MA patients.

18 You know, Bruce and I have talked about this  
19 before about MA being able to access Medicare rates for  
20 out-of-network patients, but I don't know what's out there,  
21 if there's as pathway to getting these dialysis facilities  
22 to accepting Medicare rates or something closer to Medicare

1 rates for MA.

2 That was it. Thank you.

3 MS. KELLEY: Pat.

4 MS. WANG: Thanks. I echo everybody's praise for  
5 your work, Andy. This is a really important paper, and  
6 it's a really important topic for us to be taking up at the  
7 dawn of greater enrollment in MA of ESRD patients.

8 So as a basic principle, many of the dilemmas  
9 that have been described and the relaxation of time and  
10 distance requirements are all sort of circling around this  
11 issue of, you know, the costs are too high, the payments  
12 are too low, and so people are responding in different ways  
13 to try to give plans more flexibility or what have you.  
14 I'm glad we're talking about this because the answer to  
15 this issue is for payments to be accurate. It's just a  
16 fundamental principle. Payments have to be appropriate for  
17 the members served, and I think some of these issues start  
18 to fall away.

19 On the issue of statewide costs, I endorse what  
20 others have said. I think it's very important to see  
21 whether or not that can be broken down into smaller units.  
22 It's not just the dialysis costs. It's all of the other

1 input prices of physician services, hospital services,  
2 ambulatory care. I mean, there's just a lot of variation,  
3 I think, in the input price in addition to differences in  
4 utilization that should be explored, and I just think the  
5 cost variation across a gigantic state with potentially  
6 tens of millions of people in it, or even smaller, just  
7 really needs to be broken down to a smaller level.

8           On the issue of the dialysis centers, I think  
9 it's a very important conversation, and the requirement  
10 that ESRD beneficiaries have access two to three times a  
11 week to life-saving treatment is, in my mind, very similar  
12 to requiring access to inpatient services for which we have  
13 default rates. Brian referred to it as "out of network."  
14 But the existence of a default rate in the absence of a  
15 negotiated rate, the default rate being Medicare fee-for-  
16 service, brings people to the table, and I think between  
17 that and the example that Andy gave of regional PPOs, there  
18 might be justification in this case to employ that  
19 principle. It's just consolidation coupled with the  
20 essentiality of access to these services really might  
21 justify that sort of approach.

22           I just want to thank you for the work, Andy, and

1 I think that there's a lot more to be done. Thanks.

2 MS. KELLEY: Larry.

3 DR. CASALINO: Yeah, I have a comment that leads  
4 to a question. The comment is on the time and distance,  
5 time and distance standards. This is different for  
6 dialysis patients than many other beneficiaries, I think.  
7 It's not just a matter of convenience. I don't know how  
8 many Commissioners and staff know somebody who was on  
9 dialysis. My mother was on it for ten years. And  
10 particularly in elderly beneficiaries, dialysis sessions  
11 are not a trivial thing. There's massive fluid and  
12 electrolyte shifts, and at the end of the session, you  
13 often don't feel very well at all, really for the whole  
14 day, and certainly not in the hours immediately after the  
15 session. Having to drive some extra distance, especially  
16 if the weather is bad, is potentially life-threatening for  
17 the beneficiary and for anybody else who happens to be on  
18 the road or near the road. So it's not just a question of  
19 convenience. It's really a question of life and death in a  
20 way. So I recognize the problems with reinstating the time  
21 and distance standards, but I think I would favor that.

22 But my question is this -- a large part of the

1 conversation that we're having we wouldn't be having and  
2 Medicare wouldn't have to worry about if there wasn't such  
3 consolidation among dialysis providers. And so my question  
4 is a general one for Jim, for Mike, for whoever. If MedPAC  
5 identifies a problem or problems caused by consolidation,  
6 one approach is to kind of twist ourselves in knots trying  
7 to deal with that and accepting the consolidation as an  
8 accepted fact. From a broad policy point of view, which I  
9 realize exceeds MedPAC's powers, your solution should be to  
10 not have so much consolidation.

11           So if MedPAC identifies consolidation as a  
12 problem, what, if anything, can MedPAC do or who can MedPAC  
13 talk to, what can MedPAC publish? Obviously, this is a job  
14 for the antitrust agencies, but this problem is not unique  
15 to dialysis, but it's particularly acute in dialysis. What  
16 can MedPAC do, if anything, when deleterious effects of  
17 consolidation are noted?

18           Jim, I'd love to hear your comments on it.

19           DR. MATHEWS: Well, I was hoping Mike would jump  
20 in here.

21           DR. CHERNEW: Well, I was hoping you would.

22 Actually, I was muted when I tried to say something, and

1 then I realized that the better part of discretion is to  
2 keep yourself on mute.

3           So I think that's a really good point, Larry, and  
4 I think this is true in a lot of areas. The honest answer  
5 is I don't think we have a ton of direct levers beyond our  
6 general contacts with people in the world and shedding  
7 light on the issue. We can deal much more easily with how  
8 Medicare pays when the market powers affecting Medicare per  
9 se, and this seems to be one area where that's true. I see  
10 many fewer levers for dealing with broader antitrust  
11 issues. Frankly, we're not the only agency that has that  
12 problem. Once there's a lot of consolidation having  
13 happened, even the agencies you mentioned have a hard time  
14 figuring out what to do to unravel them.

15           And this is a much bigger issue that we can shed  
16 light on, particularly how it affects the Medicare program  
17 and the Medicare beneficiaries, but I don't see an easy  
18 answer. It's certainly something that we will discuss, and  
19 having the discussion here about the role of price, and  
20 Paul's point about well, why is it here and not in  
21 hospitals, is a useful continuation of our discussion,  
22 which we will have.

1           That's why you should have gone first, Jim.

2           MS. KELLEY:   Shall I move on?

3           DR. CASALINO:   Jim, are you going to respond?

4           DR. MATHEWS:   No.   I have nothing more to add.

5           DR. CASALINO:   Then just very briefly, one  
6 function I think MedPAC can serve is to try to be an early  
7 warning system about consolidation, because Mike's right, I  
8 think.  Once there is a lot of consolidation even the  
9 antitrust agencies can't do very much about it, generally  
10 speaking.

11           So I think, as a general principle, if MedPAC  
12 identifies areas in which consolidation looks like it's  
13 becoming a problem, it would be interesting to know.  
14 Surely we can put that in a report, but are there other  
15 actions MedPAC can take -- letters to Congress, letters to  
16 the antitrust agencies.  And then once there is established  
17 consolidation, again, perhaps that could be called out more  
18 clearly in reports, and then again there's the letter to  
19 Congress, or I don't know if it's beyond the balance for  
20 MedPAC to write letters to antitrust agencies.

21           But let's face it.  Consolidation is one of the  
22 responses of the health care system, and to treat it as an



1 accepted fact, especially when it isn't already a fact, as  
2 it is now in dialysis, and then just try to work around it  
3 in ways that are unnecessarily convoluted because of the  
4 consolidation, I think is maybe not the best way to go.

5 DR. MATHEWS: So I guess maybe I will add a  
6 comment or two here. First and foremost, you know, in the  
7 conduct of all of our work, when we -- and by "we" I mean I  
8 -- try to be cognizant of our statutory mandates. You  
9 know, we are asked to weigh in on issues specific to Title  
10 XVIII of the Social Security Act, and as part of our  
11 mandate we are required to make examinations of how the  
12 Medicare program interacts with the outside world.

13 So it's not a question that we can only narrowly  
14 focus on Medicare, and we need to be cognizant of the  
15 impacts of external forces, such as consolidation, on the  
16 program. But, you know, our statutory charge is the  
17 Medicare program, and I am not sure we necessarily have the  
18 leeway to start writing letters to the FTC or other  
19 entities with antitrust obligations and authorities.

20 I agree with Mike that in instances where we do  
21 see trends in consolidation, and particularly instances  
22 where those trends are at least influenced by Medicare

1 payment policies, we do report them out and we develop  
2 payment policies to address them. Over the years we have  
3 observed successive waves of hospital acquisition of  
4 physician practices -- cardiology, orthopedics, now  
5 oncology -- and in the course of observing those trends we  
6 have identified site-neutral payment policies as a solution  
7 that makes it less lucrative for the parties involved to  
8 engage in those transactions.

9           And obviously we can continue to do those kinds  
10 of policy responses, but I think we need to be very, very  
11 cautious about being the entity that serves, you used the  
12 phrase earlier, "early warning system" for Congress, for  
13 policymakers in general, about these broader market forces  
14 of which Medicare is influenced by and subject to, but not  
15 necessarily the driver.

16           DR. CASALINO: Just one quick response here and  
17 then I'll shut up. I agree that when we see Medicare  
18 policies that seem to be promoting consolidation that we  
19 want to call that out, and we have, right?. But it does  
20 seem to me it's symmetrical. If we see consolidation that  
21 affects Medicare, probably we should at least call that out  
22 pretty explicitly. And I'll stop there.

1 DR. CHERNEW: So just to give everybody a check  
2 as we hit noon, I don't get the full list. I have three  
3 people on the list. We have 15 minutes. Dana, your turn  
4 to call the next person.

5 MS. KELLEY: We have four people on the list.  
6 Bruce is next.

7 MR. PYENSON: Oh, thank you. I agree with the  
8 comments that the other Commissioners have made. I would  
9 just want to reiterate my support for looking at changing  
10 the network rules so that dialysis centers could be  
11 considered out of network and MA plans could take advantage  
12 of the fee-for-service rates there. I suspect that our  
13 analysis of the encounter data is perhaps dramatically  
14 understating the higher amount that Medicare Advantage pays  
15 the DOs.

16 I would identify the Medicare cost reports of the  
17 dialysis organization as another potentially valuable  
18 source for insight.

19 I do want to comment on the benefit design issue.  
20 My impression is that a large portion of patients, Medicare  
21 beneficiaries receiving chronic dialysis, are dual  
22 eligibles, and the benefit design issues for them are

1 perhaps different.

2 I would also like to suggest that, anecdotally,  
3 dialysis organizations very frequently waive member cost  
4 sharing. So although I think the discriminatory benefit  
5 design concern is real, it perhaps take a different  
6 dimension for patients receiving dialysis than, say,  
7 patients on chemotherapy who might be subject to high co-  
8 insurance for Part C drugs.

9 But overall I think moving ahead on looking at,  
10 as Mike characterized it, the supply problem, would be very  
11 fruitful, and I think it might even be a model for dealing  
12 with other kinds of concentration in other areas.

13 So, Andy, terrific work. You've got lots of  
14 followers here. Thank you.

15 MS. KELLEY: Jon Perlin.

16 DR. PERLIN: Yeah, let me add to the accolades  
17 for a really thoughtful piece of work, and also begin with  
18 very clear support for the recommendations.

19 I would just note that my Round 1 question about  
20 how policy could incentive strange geographic behaviors, in  
21 an attempt to resolve issues with network adequacy,  
22 particularly time and distance, it was really aimed at

1 concerns that you could actually yield a different set of  
2 strange network adequacy challenges, and Larry Casalino  
3 spoke eloquently, to the clinical fragility of these  
4 patients. Particularly, if you think about going to a  
5 dialysis center, the point that the patient is going to the  
6 dialysis center, they are already feeling ill because  
7 they're carrying toxins, and when they leave the dialysis  
8 center they're feeling poorly because they've just had  
9 these massive fluid shifts. So distance is just critical.

10           With that in mind, I think we do need to use the  
11 smaller geographic areas so we can assure the network  
12 adequacy. I think this issue of consolidation may actually  
13 be understated. On page 1 of the reading materials, there  
14 is the comment that 74 percent of the outpatient dialysis  
15 centers are operated by two companies. That does not  
16 include the percent where the payment doesn't go directly  
17 to those centers but, in fact, to nominally some other  
18 entity that, in fact, is contracting with one of the two  
19 companies that are the substantially vertically integrated  
20 dialysis providers.

21           So this is an issue that we're tapping into. Out  
22 of network or other mechanisms for fee-for-service may be

1 the most practical approach.

2           And third, I just wanted to make a point that,  
3 you know, one of the good things that occurred in the last  
4 year, folks like Jonathan Jaffery may know the details  
5 better than I might, was the Executive order that really  
6 facilitated living donor transplant and mechanisms to  
7 increase transplantation. You know, being able to get a  
8 transplant, when possible, is freedom from all of the  
9 liabilities that we're trying to address here, in terms of  
10 assuring adequacy of dialysis. Don't get me wrong -- there  
11 will be a group of patients who won't qualify, don't  
12 qualify, don't want, can't take transplantation.

13           But I would encourage us, in not this section but  
14 in our broader policy, to think about how our policies fall  
15 together such that there is incentivization toward the most  
16 liberating form of renal replacement, which is  
17 transplantation.

18           So, in summary, I support this approach, would be  
19 on the lookout for unintended consequences based on the  
20 sections. If we can overcome that through fee-for-service  
21 or rate access, that would be temporizing and really  
22 finally encourage a broader policy perspective. Thanks.

1 MS. KELLEY: Jaewon.

2 DR. CHERNEW: Thanks, Jon. We have -- yeah, we  
3 have Jaewon and then I think Dana, you're going to finish  
4 the session, because we're just about at the time. Jaewon.

5 DR. RYU: Yeah. So as far as the alternative  
6 geographic unit I agree with many of the comments that have  
7 been said.

8 I think the network adequacy and the time and  
9 distance reinstating, I completely, or I should say Larry  
10 and Jon Perlin's comments totally resonate with me as far  
11 as the clinical importance to the beneficiary for the time  
12 and distance. But I do hesitate here, and it has to do  
13 with -- and I think you referenced it in the chapter -- the  
14 balance of negotiating leverage between the plans and the  
15 dialysis providers. I think Jon Perlin used a great term,  
16 "temporizing" measures to kind of mitigate or offset  
17 considerations along those lines, whether it's, you know,  
18 Dana's suggestion or on the fee-for-service rates. I think  
19 in the absence of some other solution like that I do get  
20 concerned, because I think what we could have as an  
21 unintended consequence, because there isn't the right  
22 balance in that negotiating leverage, I think you could

1 have consolidation in the dialysis centers space lead to  
2 consolidation in the MA plan space.

3           Because the nature of who's going to be able to  
4 contract with the dialysis carriers at a sustainable level,  
5 I think that's something we just need to think through.  
6 And again, that's in the absence of some other solution  
7 like, you know, what Dana has proposed, and others. But if  
8 we don't have something like that, I think that's more  
9 concerning.

10           MS. KELLEY: Dana?

11           DR. CHERNEW: Thanks, Jaewon.

12           DR. SAFRAN: Yeah, thanks, and I'll be very, very  
13 brief. You know, Jaewon's comments just before me are  
14 interesting and I think thought-provoking. I would still  
15 weigh in with support for reinstating the time and distance  
16 standards. You know, I just am very concerned about  
17 attestation is the mechanism for ensuring network adequacy.

18           And, you know, my question earlier indicated, and  
19 as some of my colleagues have pointed to, I would really  
20 think that we should pursue this option of MA plans being  
21 able to leverage the Medicare fee-for-service negotiated  
22 rates, given both the consolidation and the small numbers



1 issue that they face.

2 So those are my comments. Thank you.

3 DR. CHERNEW: Great. Deep breath. This is the  
4 going once, going twice comment.

5 Okay. So we've had a lot of discussion this  
6 morning about two really important issues. In fact, I  
7 think as these meetings go, we were early on in a lot of  
8 these chapters, which means there's a lot of different  
9 directions for us to go back and grapple with, which we  
10 will do.

11 My summary for this particular session is, we  
12 really do need to think holistically about how the access  
13 and the payment models work and overall the role of MA for  
14 ESRD, given these market dysfunctions, and we will do that.  
15 I do think it's important to make sure that beneficiaries  
16 have access to the care that they need, but we have to  
17 figure out how to do that in an efficient way. I probably  
18 should have said the exact same thing for the separately  
19 payable drugs discussion.

20 But I will leave this with just a thank you to  
21 the staff for outstanding work again. Thank you to all of  
22 my fellow Commissioners who, as always, provide insightful

1 comments that we will have to really take to heart. And I  
2 do want to say to the public there are many ways to reach  
3 out and give your comments to us. You can do it through  
4 the website. You can reach out by email, I think, to the  
5 staff. We very much do want to hear feedback from those of  
6 you that have been listening to this discussion. And these  
7 are the beginning of the chapters where we are going, and  
8 so we will continue, I think, on both of these paths for  
9 separately payable drugs and MA and ESRD, so you will  
10 certainly hear more from us.

11 So with that I will say thank you again to my  
12 Commissioners. Have a wonderful Tuesday. See, that's a  
13 joke because I said it was Friday at the beginning of this  
14 meeting. It isn't, by the way. But have a wonderful  
15 Tuesday afternoon, and we will all be in touch. Thank you.

16 Jim, any closing comments?

17 DR. MATHEWS: Nope. Do it again in December.

18 DR. CHERNEW: Stay safe.

19 [Whereupon, at 12:13 p.m., the meeting was  
20 adjourned.]

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