MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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P R O C E E D I N G S

[10:47 a.m.]

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

MS. TABOR: Hi, this is Ledia.

DR. CHERNEW: Ledia.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

services.

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

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

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

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

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

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

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

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

I'll now turn it over to Ariel.

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

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

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

telehealth over comparable in-person services.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

issues and lead to higher spending.

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

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

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

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

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

DR. CHERNEW: Great. Thank you.

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

MS. KELLEY: Yes, that's correct.

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

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

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

bad for the Medicare program and for beneficiaries.

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

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

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

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

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

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

Dana, do we have others in Round 1?

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

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

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

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

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

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

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

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

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

but I'll keep thinking about that.

MR. PYENSON: Thank you.

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

DR. SAFRAN: Yes. Thank you.

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

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

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

also weigh in on this.

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

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

DR. SAFRAN: Thanks.

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

MS. WANG: Hi. Thank you.

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

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

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

Thank you.

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

MS. KELLEY: Karen?

DR. DeSALVO: Thank you, Dana.

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

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

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

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

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

MS. TABOR: I'd say that --

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

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

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

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

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

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

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

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

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

MS. THOMPSON: Thank you.

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

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

DR. CHERNEW: I have seen.

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

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

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

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

DR. CHERNEW: All right. Thank you.

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

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

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

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

Jon?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Larry?

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

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

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

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

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

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

hookup, for whatever reason, doesn't work.

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

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

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

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

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

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

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

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

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

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

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

because it does make a difference.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

you.

MS. KELLEY: David, you're next.

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

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

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

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

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

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

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

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

MS. KELLEY: Dana.

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

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

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

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

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

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

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

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

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

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

Thank you.

MS. KELLEY: Amol.

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

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

So then I thought, how does MedPAC do things?

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

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

reasons.

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

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

A couple other points along that. I think to the

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

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

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

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

Thanks.

MS. KELLEY: Jonathan Jaffery.

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

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

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

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

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

get -- expand coverage with evidence development.

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

Thank you.

MS. KELLEY: Marge?

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

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

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

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

MS. KELLEY: I have Bruce next.

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

Ledia, for a terrific chapter.

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

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

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

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

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

Thank you.

MS. KELLEY: Jaewon?

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

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

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

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

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

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

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

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

MS. KELLEY: Pat.

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

MS. KELLEY: And Betty also.

DR. CHERNEW: And Betty. Okay.

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

Pat, thanks for your comment.

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

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

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

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

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

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

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

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

I think the telephone really is an open door to a

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

That's all. Thank you.

MS. KELLEY: Wayne?

DR. RILEY: Yeah. Great discussion, Commissioners.

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

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

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

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

MS. KELLEY: And Betty.

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

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

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

So how do we package the payment to make that

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

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

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

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

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

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

DR. CHERNEW: Terrific. Thank you, everybody.

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

sense of where we're going.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. CHERNEW: Thanks, Brian.

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

Also, the audience can download a PDF version of

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We found that rural beneficiaries increasingly

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

With that I will turn it back over to Mike.

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

MS. KELLEY: That's correct.

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

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

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

DR. JAFFERY: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. KELLEY: Amol?

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

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

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

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

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

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

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

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

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

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

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

MR. O'DONNELL: Go ahead, Jeff.

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

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

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

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

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

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

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

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

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

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

MS. THOMPSON: Okay. Thank you very much.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Some of you brought this up in different kinds of

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

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

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

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

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

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

MS. KELLEY: Sue?

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

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

The beneficiaries that live in rural America are

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

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

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

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

the pre-hospitalization component of the continuum of care.

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

Thank you for the opportunity to make comments.

MS. KELLEY: Brian, I have you next.

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

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

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

Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

So thank you. I appreciate the opportunity to comment.

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

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

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

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

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

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

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

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

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

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

services and expanded its emergency department and its outpatient services.

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

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

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

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

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

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

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

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

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

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

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

Thank you very much.

MS. KELLEY: Jaewon.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

terrific, terrific job.

So see you all soon.

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

AFTERNOON SESSION

[2:16 p.m.]

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

Shinobu, you're up.

MS. SUZUKI: Good afternoon.

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

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

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

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

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

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

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

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

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

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

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

To counter plan incentives to avoid high-cost

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

factors?

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

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

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

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

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

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

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

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

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

As noted on the right, we used conservative

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

There are several policy implications for you to

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

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

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

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

us to pursue on this topic.

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

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

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

DR. CHERNEW: That's also true.

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

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

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

DR. CHERNEW: Yes.

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

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

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

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

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

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

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

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

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

DR. SAFRAN: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. WANG: Okay. Thank you.

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

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

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

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

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

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

DR. GRABOWSKI: So do the corridors then buffer

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

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

MS. KELLEY: Does that answer it, David?

DR. GRABOWSKI: Yeah. Sorry. Thanks.

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

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

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

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

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

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

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

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

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

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

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

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

MS. SUZUKI: $200.

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

MS. SUZUKI: Mm-hmm.

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

MS. SUZUKI: Yes.

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

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

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

of both rebate and coverage gap discount?

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

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

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

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

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

MR. PYENSON: Went over two minutes. Sorry.

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

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

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

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

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

DR. CASALINO: Thank you.

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

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

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

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

So I would like to say that along with doing the

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

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

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

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

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

Thank you.

MS. KELLEY: Brian?

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

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

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

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

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

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

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

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

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

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

distributed.

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

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

Thank you.

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

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

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

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

MS. KELLEY: Amol is next.

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

complex things into understandable ways.

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

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

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

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

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

Thanks.

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

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

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

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

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

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

Thank you.

MS. KELLEY: David, you're next.

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

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

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

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

Thanks.

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

MS. WANG: Thank you.

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

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

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

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

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

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

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

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

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

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

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

Thank you.

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

DR. CHERNEW: Yeah. Great.

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

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

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

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

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

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

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

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

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

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

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

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

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

Jim, do you have any comments on that?

DR. MATHEWS: Yeah.

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

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

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

Jim is shaking his head, I think, negative.

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

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

DR. CASALINO: Okay.

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

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

[Audio difficulties.]

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

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

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

wondering if that's on the table, Jim.

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

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

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

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

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

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

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

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

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

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

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

Go on, Paul.

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

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

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

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

DR. CHERNEW: Thank you, Betty.

I'm pausing just for a second.

[Pause.]

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

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

MR. ROLLINS: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

richer benefits.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

I would also like to highlight that the benchmark

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

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

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

projected spending growth.

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

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

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

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

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

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

in their bid.

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

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

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

Sponsors that only have one basic plan would

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

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

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

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

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

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

other plan.

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

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

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

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

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

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

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

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

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

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

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

Does that answer your question?

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

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

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

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

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

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

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

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

Exactly as to what their motivations are, you

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

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

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

MS. MARJORIE GINSBURG: Good. Thank you.

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

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

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

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

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

MR. ROLLINS: This figure shows just standalone PDPs.

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

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

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

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

MR. ROLLINS: Correct.

MR. PYENSON: Okay. Thank you.

MS. KELLEY: Pat?

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

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

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

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

So can you just say more about how this works? Like what premium is being used here to determine the benchmark premium, and do you have any insight into how MA-PDs bid, compared to PDPs?

MR. ROLLINS: So in terms of how the benchmark is calculated, like you said, they use both PDP and MA-PD premiums. To the extent that you have a plan that offers enhanced coverage or something that's richer than the standard Part D benefit, CMS is only going to use the portion of your premium that reflects the basic coverage. So that's one element.

The second element is that for the MA-PDs, like you noted, there's a process, which I agree is somewhat convoluted, of how, you know, they can use some of their Part C rebates to buy down some of their premium. What's used in the calculation is sort of the plans' Part D premium for basic coverage before that rebate allocation process plays out. The concern was that -- and initially that was not the case. The first several years of Part D they included MA-PD premiums after they had been reduced by the rebates, and the concern was that it made the

benchmarks too low and that there was one other factor that was making the benchmark sort of segment of the PD market unstable.

In terms of how MA-PDs bid compared to PDPs, I don't have figures off the top of my head, but that's certainly something we could follow up on.

MS. WANG: Okay. Thank you. Interesting. Thank you.

MS. KELLEY: Amol?

DR. NAVATHE: Hi, Eric. Great chapter. Thank you for the write-up. I have kind of what may be a really nitty-gritty question, which is on the bottom of page 5, about the auto-enrollment, you note that the agency decided -- CMS has decided to use auto-enrollment for all LIS beneficiaries who do not choose a plan, not just those who qualify for full Medicaid benefits, and I was curious what the margin there was by expanding that group that's being auto-enrolled. Is that a huge expansion or is it actually a small number?

MR. ROLLINS: So I can answer -- I'm going to answer your question kind of like halfway, unfortunately. Roughly speaking, you've got 13 million or so people who

are LIS beneficiaries. In really rough terms, you've got 7 million who have full Medicaid benefits, 3 million who've got partial Medicaid benefits, and another 3 million who just get the LIS. They don't have any Medicaid coverage. Now, those figures are really rough, so I think that answers part of your question. What I don't have off the top of my head is what share of those people are picking plans on their own. The share of each of those segments who are getting auto-enrolled could differ, and I don't have those figures in front of me. So that's why I say I can only answer your question kind of halfway.

DR. NAVATHE: Okay. That's helpful. Thank you.

MS. KELLEY: Jaewon?

DR. RYU: Yeah, thank you, Eric. I enjoyed the chapter as well. With some of the potential adjustments that you're proposing or that are being contemplated in the chapter, any sense of order of magnitude on how much we think the benchmark could move downwards and how much savings there could be programmatically?

MR. ROLLINS: I think it's really hard to say. As we noted in the paper, as you can see from the slide that we have up here, a lot of the basic plans right now

are bunched into a very narrow sort of stretch. And so how much they could bid lower if given the incentive to do so is a little unclear. You know, like you can see, there are a number of enhanced plans that have -- you know, they might be $10, $20 below the benchmark. So it's hard to give a firm answer. I think this is meant to suggest there's kind of an issue here. We might want to rethink the incentives.

I think another factor -- and I think we're pretty up front about this in the paper -- is, you know, we can say it would be a good idea to give plans more auto-enrollees if they bid lower, but we don't know exactly how strong that relationship would be between sort of the size of the carrot, if you will, the reward, and sort of how much of a change in plan behavior we can expect to see.

MS. KELLEY: Bruce, did you have one last Round 1 question?

MR. ROLLINS: Bruce, I can't hear you.

MR. PYENSON: Ah, thank you. Eric, just on what contributes to the benchmark, I think the contribution of each plan's basic bid is weighted by the LIS enrollment of the plan.

MR. ROLLINS: That's correct.

MR. PYENSON: So, in effect, on this slide there's probably very little contribution from the plans in green because the vast majority of LIS are in the benchmark plans. And so --

MR. ROLLINS: Yes, I would agree with that.

MR. PYENSON: And so maybe I'd rephrase my question about the weighting based on LIS enrollment. I don't know if there was any history to that, but it seems an interesting decision to have chosen that kind of weighting.

MR. ROLLINS: So, initially, that was not the methodology they used. When they first started Part D, the premiums for the PDPs and MA-PDs were weighted based on their overall enrollment, not the LIS enrollment. And CMS switched its methodology, I think -- I'm looking at my notes -- starting in 2009. At the time there was concern that the non-LIS beneficiaries were, compared to the LIS segment, enrolling in lower-premium plans, and so including them in the calculation sort of put downward pressure on the benchmarks. Again, that was the rationale at the time. It was over a decade ago. That relationship may not -- you

know, that rationale may not be as true today. That would be something we would need to look into a little more. But that was the history on the issue.

MR. PYENSON: Thank you.

MS. KELLEY: Mike, we can't hear you.

DR. CHERNEW: Okay. I keep inadvertently muting myself.

So we're going to transition to Round 2, and fortunately, Bruce, you can continue since you are a Round 2 person or reactor. And then we'll go to Marge. Marge, you will be next in line after Bruce, and then we'll work our way through the Round 2 queue. So, Bruce? And now, Bruce, we can't hear you.

MR. PYENSON: Thank you. I want to express my support for the work on this issue and fixing the benchmark process. I think it is very -- the work that Eric has done is very suggestive that the benchmarks for LIS are higher than they could be, and that the incentives to get to lower benchmarks are not as strong as they should be.

What I would -- in thinking about that, the concentration of LIS members in just a few plans, especially the PDP plans, is very relevant to the

discussion we had last month about concentration in health care on the part of organizations, and it's certainly the case that these members are sought after by certain companies who will also go out of their way to avoid losing -- bidding too high and potentially losing their members. So I think there's a real opportunity here because the members are so attractive to certain plans, and after all, the marketing expenses and the competition for the LIS has been greatly reduced by the nature of the organizations and the nature of the bidding process.

What I would like to see is a bit more work on how it is that some significant RD plans can offer enhanced benefits at significantly below the LIS benchmark, and that has to do with choice of formularies and other phenomena. But I think because the benchmarks are, after all, risk-adjusted, the differences suggest an underlying difference in business operations and incentives.

So I'm very supportive of this work. I think the direction and the proposals are good, and I'm eager to see this go to completion.

Thank you.

MS. KELLEY: Marge?

MS. MARJORIE GINSBURG: Thanks. Again, thanks for a wonderful report. My interest in this is fairly specific I think most of you know I'm actually a living and breathing SHIP counselor, and I deal with LIS clients frequently, particularly ones that I may help enroll in LIS because they're not on Medicaid. It's an extremely satisfying process to help people find drug plans that they're actually going to be able to afford given their high level of medications that they're taking.

I find this an exciting endeavor because it seems like there's so few ways we might actually use the concept of market competition to bring costs down. What an idea. It's been very hard to do in other domains, but I think this one definitely has potential, and I think the way it's been described in the report is spot on.

The issue about the concern about whether that would mean a reduction in the number of benchmark plans available, one of the other things that we do with clients -- all SHIP counselors do this -- is to use Plan Finder to make sure that the plan they're signing up for, in fact, is going to offer the medications that they have. And I think all of you know everybody's formularies are and can be

different. So just because they're an LIS client doesn't necessarily mean that, you know, one of the benchmarks is, in fact, going to offer the pharmaceutical coverage that they particularly need, which is why it's -- that whole concept of using Plan Finder is so important in helping people sign up and then helping people switch if, in fact, there's a better benchmark that's going to offer more comprehensive coverage.

So one of the concerns in the report was, Will this result in fewer benchmark plans being available? I think it said in the report -- and I know it's true for Northern California -- I think we have seven or eight benchmark plans. That's been pretty stable for the years that I've been doing counseling. But what happens if this drops to three or four plans? Does that then mean there's going to be a bigger struggle for people finding a good match with the drugs that they're on? Or, as it said in the report, that people, in fact, are going to need to be reassigned to new plans because they're going to lose the plan that they have grown to know and love?

I think these are still questions that need to be looked at, and I think somebody asked the question earlier

about how much money can we really save. I mean, if we do this, if we model this in a way that looks reasonable, what are we talking about how this is going to benefit the taxpayer? I don't think this is going to benefit the LIS beneficiary, and I don't support bribing LIS beneficiaries to pick lower plans. I just don't think that's a great idea. But I'd be very interested in knowing what do we expect this to -- how this might financially benefit the taxpayer.

So those are the outstanding questions. Very exciting work. I'm all for it. Thank you.

MS. KELLEY: Paul?

DR. CHERNEW: Thanks, Marge.

DR. PAUL GINSBURG: Thanks. Yeah, this is great work, and we definitely should be working on these issues. I had a thought as to whether we should think a little bigger. What I mean by that is that when Part D was designed, you know, the guiding force was to make this a competitive approach, competition among plans, and I think we went for a single market of both non-LIS and LIS probably to make sure that the LIS plans were good enough, because they were trying to appeal to the non-LIS

population.

What I'm thinking is that our attempt to do this with one unified market has really not worked out. And along with the options that Eric suggested, which I think have a lot of potential, we probably should consider actually breaking the two markets apart and using different approaches to competition. So for the non-LIS population, it'll be mainly driven by beneficiaries making trade-offs between a higher premium and broader choice of drugs or whatever. But for the LIS population, where we don't involve them today in making these trade-offs because of their very limited ability to pay, maybe we should just, you know, pursue it separately. There are other approaches to create a competitive market that are not driven by consumers but are still driven by bidding. And that's just something to think about as we go forward.

MS. KELLEY: Brian?

DR. DeBUSK: Thank you. I really enjoyed the work, Eric. I was reading through the paper. You know, this is really a classic exercise in game theory. It was really remarkable. And what really told the story for me was the clustering, the distribution, the frequency

distribution that you did showing how all the plans cluster right there are the benchmark. You clearly offered a dominant design, and plans are clearly taking advantage of that dominant design.

I liked a couple of -- several of the items in the paper, several of the ideas for how to basically disrupt that design. The ones I really wanted to focus on were the disproportionately auto-enrolling based on where the bid fell within the range. I really liked the idea of the lowest bidder getting -- I think you used 40 percent in the paper, but basically disproportionately allocating those auto-enrollments because, you know, Bruce has taught me one thing over the last four years, and that is that auto-enrollments are very, very valuable to these plans. He's taught me many things.

So I think the 40 percent auto-enrollment -- or stratifying the auto-enrollment I think is a great idea. I also think the idea put forth in the paper about not reassigning the beneficiaries to the parent company -- you know, I think the risk of all these beneficiaries slipping through a plan's fingers has a lot of risk there. So I think removing that option where, if they don't reach

benchmark status, their enrollees are redistributed, I think that would be a significant incentive to continue bidding competitively.

The final thing that I wanted to add actually wasn't in the paper, but it really complements these other two strategies. This de minimis option where if they're within 2 percent of the benchmark, you know, the plan basically just gets a do-over. That inherently creates an incentive to bid just a hair high. And one of the things I'd like us to consider in the paper is if a plan misses benchmark status, perhaps we don't just let them concede that 1 percent or that 2 percent and revert back down to the benchmark. Perhaps they actually do that with a modest penalty, so where they can buy back into the program, buy back in with maybe a 1 or 2 percent benchmark -- or premium that's below the benchmark. So basically you create a disincentive to try to win just a little -- to bid just a little high.

But, again, I think this is classic game theory, and I think the options that were put forth in the paper are very insightful, and I think they could incent competition among these plans.

Thank you.

MS. KELLEY: We have Pat next.

MS. WANG: Thank you.

So great work, Eric. On this Slide 15, I think the third bullet -- eliminate the ability of plan sponsors to inflate benchmarks -- this remains me of contract consolidation. It's like the one piece of sort of merger and acquisition and things that plans can engage in to benefit themselves kind of got missed. So I would be very in favor of this third bullet. I think it's straightforward.

The other issues, I just want to go backwards to the question that I raised in Round 1. So roughly half, a little bit less than half of LIS beneficiaries are enrolled in Medicare Advantage prescription drug plans, and so this discussion has really focused on the freestanding Part D plans, members in Medicare fee-for-service for medical services. Freestanding Part D plans, they're bidding behavior and a desire to use competition and other means to drive the bids down.

But as Eric explained earlier, this phenomenon and the experience on the freestanding Part D plan very

much affects what happens on the Medicare Advantage Part D side, and my concern and the reason I asked about MA-PD bidding behavior is I think that there may be different incentives that drive how a PDP bids versus how an MA-PD bids.

When you look at the consolidation of PDP LIS lives in six national plans, I can surmise -- and I don't think it's a stretch -- that there is an art form of formulary placement to maximize benefits and rebates to drive a certain level of premium.

On the MA-PD side, I can tell you at least my observation. There's a different set of incentives in how the basic plan, basic benefits might get structured, which has to do with Stars, medication adherence, avoiding medical costs that are avoidable and unnecessary, outcomes base. I think it's a different -- I think it might be a different -- I think it's definitely a different set of considerations. It's care management around the Part D and the medical benefit together.

So my concern about sort of focusing this way just on the freestanding PDP plans, which is great, needs to have some awareness of how it affects the MA-PD side. I

don't know the trend of MA-PD plans and how they are bidding the Part D basic benefit and whether there is a trend or not of them having to spend down Part C rebate dollars to match the benchmark that is being driven by the freestanding plans, for example.

So I would have a hesitation and sort of a time-out of rushing forward with being more aggressive on driving down the PDP premium by, for example, offering greater auto-enrollment. That's not an incentive that means anything to an MA-PD because what happens on the PDP world is dragging the MA-PD with it, and I just would want to know what that current relationship is and how more aggressive actions on the freestanding PDP side could ripple over.

Thanks.

MS. KELLEY: Bruce, did you want to get in on this point?

MR. PYENSON: Yes. Thank you.

I totally agree with Pat, and I think as the work develops, it would make sense to separate MA-PD from PDP for the reasons that Pat said.

I'd be interested in Paul's view of that since I

think he had an opinion about separating, separately viewing LIS from non-LIS but also separately viewing MA-PD from PDP.

DR. PAUL GINSBURG: I think it's a great idea and getting ready to say it.

MS. KELLEY: Dana?

DR. SAFRAN: Thank you.

And I apologize because I missed the first part of the discussion, but I just wanted to say that as I think I heard -- maybe it was Brian saying when I came back on. The clustering right around the benchmark is just really quite remarkable and suggests gaming that's going on.

So I have two things to comment on. One is I really liked the suggestion in the chapter about the possibility of a bidding process that would create the incentives that seem to be lacking right now to bid lower benchmark -- bid lower amounts to potentially lower the benchmark.

The other comment I had is just a small editorial one, and that is, I found myself struggling in the chapter because I hadn't seen an explanation early on about how the benchmarks get set. So I just kept trying to infer from

what I was reading about how the process goes. I think, unless I missed something, that it would be helpful to incorporate something a little bit earlier in the chapter about how the benchmark process works today.

But otherwise, it's great work, and I'm glad we're pursuing it. I think it's an important piece of work.

MS. KELLEY: David?

DR. GRABOWSKI: Great. Thanks.

Eric, great work. Really, really, like others, glad that we're pursuing this.

In terms of the options, I'll be brief here. I'm a fan to giving lower bidding plans a larger share of the auto-enrollments, so Bullet 1. I also like Bullet 3 in terms of eliminating the ability of plan sponsors to inflate the benchmarks after a merger or acquisition. It just seems really fraught with lots of potential for gaming to allow plans to inflate the benchmarks after these mergers. So I really like Policies 1 and 3.

I'm not as much a fan of Policy 2 and don't think we should pursue the cash awards, that I think we could go at that through giving the plans a larger share of the

auto-enrollments.

The only other comment I was going to make was just in response to Brian's suggestion, which I thought was awesome about the de minimis plans. Eric, you do the comparison with the game show, The Price is Right. If you go over on that show, you don't get a do-over. As Brian suggests, we're really giving a do-over here. So I like this idea quite a bit of having the plans that do want to buy back in to pay a penalty. I think that's a really elegant idea. So I want to just endorse that.

But thanks. Once again, I'm glad we're going down this path. Thanks.

MS. KELLEY: Larry, I think you are the last Round 2.

DR. CASALINO: Yeah. So I put my hand up just before David spoke, but basically, David said everything I was about to say. I completely agree with each point.

David, I think you said -- or if you didn't say it, I'll say it. I agree with Marge. I think the second bulleted recommendation, pay a cash reward, I would hope that we wouldn't have to do that if the first and third bullets of the elimination of de minimis helped.

Then I guess just the other thing I'd add, if it really looks like it doesn't make sense to analyze the freestanding plans and the Medicare Advantage plans together, quite obviously, we should do them separately, then, if we can.

MS. MARJORIE GINSBURG: May I make one more comment? Yes? No?

MS. KELLEY: Yes.

MS. MARJORIE GINSBURG: Okay. Nobody is kicking me out.

About the choice of a drug plan when you're in original Medicare versus MA plans -- and again, this is my experience -- people either come to us because they're in original Medicare, they get on LIS, and now they want to make sure they get a drug plan that's going to best serve them.

If people are already in an MA plan and now get on LIS, then there's the opportunity to make sure they're getting the best benefit from the drug plan that's associated with that MA plan.

But now they're faced with a dilemma. Are they going to change MA plans in order to get a better drug

plan? And I'm very enthusiastic about us moving forward and looking at these two, but I think they really use different. And the decision process for beneficiaries is very different. I'm not sure how that works out, and we definitely should pursue it.

But I just wanted to make sure we don't try to combine this issue into one pot because I don't think they fit into one pot.

Thank you.

MS. KELLEY: Mike, that's all we have.

DR. CHERNEW: Great. That's all we have for now. I'll keep watching the chat.

So a few things. The first is that I think we -- it's not surprising to me that the clusters around the benchmark, that is very common. You see that, for example, also in employer MA plans. I'm not sure I would call that "gaming" as much as responding to incentives, and this entire discussion is about how to set the incentives to get what we want to have happen. It's been a very rich discussion.

I hear basically three main goals. The first one is, in some sense, we don't want to drive the benchmark too

low because we don't want to have a disruptive reassignment, but we would like to shift people towards perhaps the lower bidding plan.

And I guess the core question -- and this will be something we'll discuss over the next several months -- is what we want to do with any associated savings. I have to say I don't have a strong opinion, but I am not amenable to sharing some of those savings with the beneficiaries per se if it can be done in an administratively simple way.

The broader point, I think, I'd like to make is that it is clear both there's enthusiasm and that we are at the beginning of the mountain. There's a lot to do here. Some of these things like separating out MA and MA-PD and PD plans, separating the LIS from the non-LIS market, I think, is going to require a lot of attention.

There's ways, for example, in which the connection of them helps provide some discipline for aspects of quality. That doesn't mean I think they should stay connected. It just means it's going to require some attention. So we are at the beginning, beginning of this process.

So I guess that is really all I have to say here.

Dana, I think you sent me a message about public comments. I think my comment about public comments is it's hard to work that out to the GoToMeeting, but we do look forward to hearing from members of the public. And there's a range of ways to do that. You can reach out to the staff in a whole variety of ways.

Hopefully, when we are in person, you will be able to make truly public comments to us, but we do pay attention to all of the comments that otherwise come in.

So, Jim, would you like to talk a little bit about the public comments?

DR. MATHEWS: So we do have an email set up on our website whereby you can submit comments on this meeting's agenda, and we do give those full consideration.

DR. CHERNEW: Absolutely.

So I think it's been a pretty robust conversation. I am going to pause for a minute to see if anybody else wants -- any other Commissioners want to jump in. Otherwise, I'm going to thank you all for a very productive and thoughtful day, and at 5:30, we will begin our virtual happy hour. I think that was the timing of it.

MS. KELLEY: 5:15, Mike.

DR. CHERNEW: Oh, 5:15. 5:15, we're going to begin our virtual happy hour. So let's all try and get appropriately happy by then.

All right. When I see the wave from Bruce and Pat, I know that's the wave.

All right. We will start again tomorrow morning. I believe it's 9:30, and again, thank you all for a great day. Thanks for everybody who attended, and please do send us comments through the website or contacting the staff. Thank you very much.

[Whereupon, at 4:31 p.m., the meeting was recessed, to reconvene at 9:30 a.m. on Tuesday, November 10, 2020.]

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
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P R O C E E D I N G S

[9:30 a.m.]

DR. CHERNEW: Good morning, everybody, and welcome to our Friday morning MedPAC session. We're thrilled to have you. I won't take much time with broad introductions. We are starting this morning with the topic of separately payable drugs, and I'm going to turn it over to Dan.

Dan, you are up.

DR. ZABINSKI: All right. Thank you, Mike. Good morning, everybody. To start, I'd like to thank Kim Neuman and Nancy Ray for the input and guidance that they have provided on this topic.

Today we're going to talk about how drugs are paid in the hospital outpatient prospective payment system, or OPPS, and discuss how that system could be improved. Our hope is that the policy changes that we're about to cover will have implications for how we think about separately paid items across Original Medicare.

I'd like to remind the audience that they can download the PDF versions of these slides using the handout section in the control panel on the right-hand side of the

screen.

Overall, the OPPS is a nuanced and complicated system, and the OPPS system of drug payment is no exception. Therefore, I think it will be helpful to provide an overview of what we'll be discussing.

We'll start by talking about the unit of payment in the OPPS, and we'll follow that with an explanation of how drugs are paid.

In the OPPS, most drugs are packaged into the payment of the related service, but some are paid separately, and we'll talk about the policies for separately paid drugs and the problems that we see with those policies. Then we'll talk about how the approach for separately payable drugs in the OPPS could be improved.

Even though the focus of this presentation is drugs, we think it will be helpful to first talk about payment bundles in the OPPS.

In the OPPS, most payments are for a primary service where primary services are the reason for a visit such as an MRI or a surgical procedure.

The OPPS uses bundled payments in which the cost of ancillary items are packaged with the primary service

into a single payment unit.

For example, suppose you're not feeling well and your chest feels tight and congested. So you go to an outpatient clinic, and the doctor orders a chest X-ray to check for pneumonia. In this case, the visit is the reason you're there, so it's the primary service and it's paid separately, while the chest X-ray is an ancillary, and its cost is packaged into the payment rate of the clinic visit.

Now, it's really important to understand that when an item is packaged, that does not mean there is no reimbursement to the provider for that item. Instead, the cost of the item is reflected in the payment rate of the related service with which the ancillary is used.

The payment bundles in the OPPS contrast with a fee schedule, in which everything has its own separate payment, including ancillary items.

The benefit of using payment bundles rather than a fee schedule is that bundles provide powerful incentives for providers to seek out the lowest-cost, most efficient way to furnish the primary service.

Now we'll turn our discussion to drug payment in the OPPS.

Many drugs in the OPPS are ancillary and are not costly in relation to the applicable primary service. The OPPS generally packages the costs of these ancillary drugs into the payment rate of the related service.

Under the OPPS, drugs are packaged if they do not meet certain cost thresholds or they are what CMS has defined as "policy packaged," which are drugs that function as supplies to a service.

Packaging ancillary drugs is generally beneficial because it provides strong incentives for providers to be efficient because the combination of inputs that a provider uses to treat a patient determines whether the provider experiences a financial gain or loss.

In addition, great care should be taken when deciding to pay separately for drugs rather than packaging them, because if we pay separately for a drug that is not clinically better than competing drugs that are packaged, Medicare would make a double payment -- one payment for the separately paid drug and one for the drugs that are packaged.

In contrast to packaged drugs, the OPPS does pays separately for many drugs, which means a drug gets a

payment that is separate from the payments for the services provided during the same visit.

Over time, the prominence of separately payable drugs has increased in the OPPS, with program spending increasing from $5.1 billion in 2011 to $14.8 billion in 2019.

Like most features of the OPPS, the policies for separately payable drugs were developed on an ad hoc basis. Specifically, the OPPS has two policies for separately payable drugs: pass-through drugs and separately payable nonpass-through drugs.

The reason that the pass-through policy exists is that during the development of the OPPS there was consideration to package all drugs. However, there were also concerns that for new drugs the needed cost and use data would not be available to include them in the payment rates of their related services.

So in response, the Congress created the pass-through policy, and payments for pass-through drugs began when the OPPS was launched in August 2000. This policy provides separate payments for new drugs, which mitigates providers' financial risk. Also, some stakeholders argue

that these payments maintain incentives for drug innovation by manufacturers.

In contrast, the separately payable nonpass-through policy began in 2004. The intent is to provide adequate payment for relatively costly drugs that are already established on the market. It excludes drugs that are ancillary, so the focus ends up being drugs that are the reason for a visit.

These two policies for separately payable drugs have different criteria for eligibility in the OPPS, and to some degree they serve different purposes.

For a drug to be eligible for pass-through payments it must be new to the market and have a cost that exceeds three thresholds that are related to the payment rate of the applicable primary service.

Having pass-through status has a definite time limit as drugs can be pass-through for two to three years. After their pass-through status expires, a drug either becomes separately paid under separately payable nonpass-through policy or it's packaged.

For a drug to be eligible for the separately payable nonpass-through policy, it must be a drug that is

established on the market rather than a new drug, and it must have a cost per day that exceeds a threshold, which is set at $130 for 2020, but CMS updates that threshold for drug price inflation each year.

It also cannot be a "policy packaged" drug, which are drugs, again, that function as supplies to a service and do not have pass-through status.

Now, there is no specified time limit for separately payable nonpass-through drugs. They can hold this status as long as their cost per day exceeds the $130 cost threshold. Any drug that does not meet the criteria for either the pass-through drugs or separately payable nonpass-through drugs is packaged in the OPPS.

A concern we have is that the criteria that drugs have to meet to be eligible for either the pass-through or the separately payable nonpass-through policy can allow drugs to have separately payable status even though they could be packaged without putting providers under excessive risk.

What we want to do is balance the benefit of packaging, which is that it promotes efficiency, while recognizing that some drugs should be paid separately.

In our June 2020 report, we had a chapter that identified features of an effective system for identifying drugs that should be separately paid, and there are two features of particular note.

One is that there is a strong rationale to pay separately for drugs that are the reason for a visit because these drugs are not ancillary to a service.

Second, there is a strong rationale for requiring that drugs that are ancillary to a service show clinical superiority over other ancillary drugs to have separately payable status for a limited time period.

Our immediate goal for the OPPS is to apply these two features to the separately payable nonpass-through and pass-through policies.

As we consider how to apply these two features to the separately payable nonpass-through and pass-through policies, it is helpful to recognize that OPPS drugs fall into two broad categories.

One category are drugs that are a reason for a visit. These drugs are not ancillary. They are high-cost; they typically treat a condition and are usually administered by infusion. Usually, the only service on the

claim is drug administration.

The other category are ancillary drugs. These drugs are not the reason for a visit and are adjunct to a service.

If we consider these two broad categories alongside the two desirable features presented on the previous slide, we reach two conclusions.

One is that the OPPS should pay separately for drugs that are the reason for a visit.

For drugs that are ancillary, the OPPS should try to package them as much as possible, keeping in mind that we should pay separately if packaging a drug exposes providers to excessive financial risk.

At this time, we believe the best policy is to keep both the separately payable nonpass-through and the pass-through policies, but we should modify them so that they are consistent with the two desired features discussed earlier.

For the pass-through policy, we should keep these current features: One is that a drug must be new to the market; and, second, the drug cost must be high in relation to the payment rate of the applicable service. Then pass-

through status would be limited to two to three years.

Changes that we believe should be made to the pass-through policy include:

Exclude drugs that are the reason for a visit. We say this because both the pass-through and the separately payable nonpass-through policy include drugs that are the reason for a visit. Pass-through drugs that are the reason for a visit would qualify for the separately payable nonpass-through policy in the absence of pass-through payments. Therefore, to simplify the OPPS system, we should restrict the pass-through policy to ancillary drugs, and this change would substantially reduce the number of pass-through drugs.

We should also require a drug to show clinical superiority over drugs included in the bundle of the applicable service. Without a clinical superiority requirement, a new drug could be granted pass-through status even though it has no clinical benefit over packaged drugs that have similar therapeutic uses. Under this scenario, Medicare makes a double payment when a hospital uses the pass-through drug -- one payment for the pass-through drug and one for the packaged drug that it is

replacing in the applicable service.

We want to be clear that clinical superiority requirements are used in several Medicare fee-for-service payment systems such as new drugs and devices in the new technology add-on payment, or NTAP, policy in the inpatient PPS.

Because the NTAP policy includes new drugs, we believe the clinical superiority requirements in the NTAP policy could be applicable to a clinical superiority requirement in the OPPS pass-through drug policy.

Relative to the pass-through policy, the separately payable nonpass-through policy is less complicated. Current features of the separately payable nonpass-through policy that should be continued are: It should focus on established drugs -- first of all, it should focus on established drugs, and also we should continue to use the cost per day threshold for eligibility, which is currently $130 per day, but we're open to changing that threshold. Also the focus should be on drugs that are not ancillary.

Changes that should be made to the separately payable nonpass-through policy include: explicitly

requiring a drug to be the reason for a visit, and expand it to include new drugs that are the reason for a visit. Currently, these drugs would be paid separately under the pass-through policy for two to three years.

On this slide, we summarize how the proposed changes to the pass-through and separately payable nonpass-through policies would affect the system of drug payment in the OPPS.

To obtain pass-through status, a drug would have to be new to the market, ancillary to a service, costly in relation to the applicable service, and clinically superior to competing drugs. A drug can hold pass-through status for two to three years.

To obtain separately payable nonpass-through status, a drug would have to be the reason for a visit, and cost per day must exceed some threshold, currently $130, but we are open to changing that.

Finally, packaged drugs are those that do not have pass-through status and are either a supply to a service or have cost per day less than the separately payable nonpass-through policy.

Now, the impact of our proposed policy changes

include that there be fewer pass-through drugs because the policy would be limited to drugs that are ancillary and also drugs would have to show clinical superiority to qualify.

Pass-through drugs that are the reason for a visit would be moved to the separately payable nonpass-through policy. And on net, you would have fewer separately paid drugs and more packaged drugs.

So our next steps for this work are to first respond to the Commissioners' comments and directions provided today.

If interest from Commissioners is sufficient, we will develop recommendations that would be presented in spring of 2021 that reflect the changes to the policies for separately payable drugs in the OPPS that we discussed today.

Finally, we have introduced the idea of adding a clinical superiority requirement to the OPPS drug payment policies, and we would like to hear Commissioners' thoughts on a broader application of clinical superiority requirements throughout Original Medicare.

That concludes the presentation. I'll turn

things back to Mike.

DR. CHERNEW: Dan, thank you. I think there are two Round 1 questions. I want to ask a Round 1 question first, though. Can you go back to Slide 13? Then we'll go to Bruce and to Larry.

So what I'm interested in understanding, in this process where are ancillary drugs that are high-cost but established -- or where are high-cost established ancillary drugs?

DR. ZABINSKI: They are packaged, and that's the current status right now under the OPPS.

DR. CHERNEW: Okay. Got it. And now we'll go on to Bruce and then Larry. Bruce?

MR. PYENSON: Thank you. Thank you very much for a terrific presentation, and I think this is the relevant slide for my question, Dan. The cost per day greater than a threshold issue, I understand that's at $130 today. And you've used the term "excessive risk for a provider." And I wonder if you could share some of your thinking on how do you determine what excessive risk is for a provider. It strikes me that's a very different amount for a small facility than for, you know, a facility with millions of

dollars of revenue. And how do you -- what sort of benchmarks have you thought about for coming to a threshold?

DR. ZABINSKI: Well, I mean, as you say, there's a lot to consider. The idea would be to compare, say, how much the drug costs in relation to the service and also how often it's used with the service. The less it's used with a service, the higher -- there's a tendency to have more risk unless it's packaged into the relevant payment rate for, you know, the related service.

I don't think there's any, you know, definite cutoff. I sort of think about it, you know, on average a provider would lose, say, 10 percent of the payment rate in relation -- for the related service. That starts to get into the range of excessive risk, I guess. You know, I'm basing that in part on what CMS does with the cost relative to the related service for pass-through drugs. There's a number of cost criteria, and one is that the difference between the cost of the pass-through drug versus the drugs that are in the payment rate of the related service, that has to be at least 10 percent, and that's where I draw that from. It's sort of to be somewhat consistent with what

already exists.

MR. PYENSON: And I'm wondering if someplace in the Medicare reimbursement program there's a notion of, say, two standard deviations or something like that, or outliers. We've certainly seen things like that, I think, for some of the accountable care organizations. It just seems to me the excessive -- what we're often characterizing as excessive risk maybe means something else.

DR. ZABINSKI: And one thing I think to keep in mind in all this, I've mentioned during the presentation that the system is pretty complicated, and while you want to do this appropriately and effectively, you also don't want to make it cumbersome and excessively complicated for anybody to understand. So you sort of have to balance things, I guess.

MR. PYENSON: Thank you.

MS. KELLEY: Larry?

DR. CASALINO: Thanks, Dan. Nice work.

My question is for the passthrough drugs. Let's suppose a clinically superior drug comes along. What happens? Do the bundles then go away completely? It's

sometimes the case that a drug may appear to be clinically superior on balance, but that there's different effect and side-effect profiles that might lead a physician with certain patients to still want to use the previous drug that was bundled. And would there still be the option to do that, or when the clinically superior drugs comes along, are there no more bundles anymore for that service and there's not really a way to use one of the previous drugs if you wanted to make it --

DR. ZABINSKI: No, you definitely would be able to continue to use the old drug. The cost of the old drug would continue to be reflected in the payment rate of the service.

The way passthrough payments work is this. Say you had some service and you got a drug package into it, and that packing that drug adjusts the payment of that service by $100. And then you got a new drug comes along that's clinically superior, and say it costs $120. The passthrough payment is that cost, that $120 minus the cost of the drugs that are already reflected in the payment rate of the related service. So the passthrough payment itself is actually $20.

DR. CASALINO: I see. So if you want to use the old drug, you just get the regular bundle of $100, say.

DR. ZABINSKI: Right. Exactly.

DR. CASALINO: If you want to use the clinically superior drug, you still get that same bundle plus $20.

DR. ZABINSKI: Right. And then once the -- yeah. Once the passthrough payment expires, you can package that new clinically superior drug into the payment rate of the related service.

DR. CASALINO: I see. So --

DR. CHERNEW: Yeah.

DR. CASALINO: Michael, just briefly and then a question, quickly.

So let's say the new drug, the two or three years are up, and now it gets packaged into the bundle. So now you've got $120, let's say, in there for the drug instead of $100. Wouldn't there be an incentive there to still use the old drugs and get the $120 and just put that $20 in your pocket?

DR. ZABINSKI: Yeah. What's going to happen is you're going to end up somewhere between $100 and $120, depending upon how often each drug is used with the

service. If it's 50 percent of the time, then you're going to end up halfway in between at $110. And, yeah, so then you'd have an incentive to use the lower-cost drug still because then you get a $10 savings, and that's the idea of package payments. You want the provider to think about not only what's best for my patient while keeping the costs down.

DR. CASALINO: This might not be a big deal. I'm talking about now just the packaging after the two or three years. This might not be a big deal if the cost difference is $10 or something like that, but if it were a really expensive drug and gets bundled in, then you'd have a strong incentive. Then the bundle becomes quite a bit more lucrative if you used a previous drug. Now, not many physicians would do that if the other drug is really superior in a particular situation.

DR. ZABINSKI: Right.

DR. CASALINO: It's an area to at least think about, I think.

DR. CHERNEW: Yeah. Larry?

DR. CASALINO: Yeah.

DR. CHERNEW: I'm sorry. Can I jump in?

DR. CASALINO: Please.

DR. CHERNEW: This is exactly the line of questioning and discussions, I think, we need to go on. I think you have essentially put your thumb on the crux of the issue in some ways.

The bundle, of course, reflects the average utilization, and there's an incentive to user the cheaper drug. And that's the way bundling works for everything. You always have an incentive to save money in the bundle, and this is just applying that to drugs. And the more people use the lower-priced drug, any individual person, the lower the overall price of the bundle, and the more they use the more expensive drug, the higher the price of the overall bundle. And you try and hope that the incentives are working so that they're only using the higher-priced drug when it's clinically indicated, and you hope that your quality metrics and physician professionalism maintains the use of that drug, but that's the sort of structure there.

The part that I think is also interesting is if you have the drug paid separately, then I think the physician gets the payment for the bundle, which reflects

the price of the old drug, and there's a separately payable drug payment for the new drug. So, in some sense, you're paying a bundled price that's reflecting the use of the old drug and the separately payable price as well.

Eventually, I assume what would happen, Dan, is if everybody switched to the new drug, the price of the bundle would actually drop over time because there's no longer any use of the old drug in the bundle. Is that basically right?

DR. ZABINSKI: I mean, well -- oh, I see what you're saying. Yeah. For a limited time, yeah. That would happen, and eventually, when the passthrough status of that new better drug gets used -- you know, as the passthrough status expires, then that new drug eventually becomes an old drug. And then it gets packaged.

DR. CHERNEW: Yeah. But for a while during the passthrough in some sense, there's some aspect of, quote, "double payment" because the bundle reflects the old drug and you're using the new drug. I think, again --

DR. ZABINSKI: Right, right.

DR. CASALINO: But, Mike, if I understood correctly, if I understood Dan correctly, it wouldn't be

extra or double payment in that situation because you're not getting the entire price of the new drug. You're just getting the extra price beyond what you get in the bundle already. It would be kind of a double payment if you got the full price plus the bundle.

DR. CHERNEW: I understand.

So back to Dan's example, if it's $100 and $120, the separately payable payment is the $20, not the $120.

DR. ZABINSKI: Right. But that points to why you want to have a clinical superiority. You don't want to pay that extra 20 bucks for something that's not giving you anything beneficial.

DR. CHERNEW: Right. I understand. That may be a whole Round 2 set of discussions, but that was useful, Larry.

Dana, while I've been rambling on, have -- oh, Brian, I see, has a Round 1 question. Are there other Round 1 questions first in the queue, Dana?

MS. KELLEY: Yes, we have quite a bit of list here.

DR. CHERNEW: Okay. So then, Dana, I'm going to let you go through the list.

MS. KELLEY: All right. Dana, you're next.

DR. SAFRAN: Thank you.

I have two questions. I think the first one is very simple. The second one might be a little more complex.

So the first question is in the paper, it refers to December 1996 as the time frame for defining what is new to market, and that just really caught my attention. I don't understand why new to market doesn't have some, you know, last X years definition to it.

And my second question is that you share with us the really significance rise in cost in spending for these separately payable drugs in less than a decade, from $5 billion to $14 billion. Can you say a little bit more about whether this is due primarily to increase in the volume or use of separately payable drugs versus the increase in price? I guess there's a third category that's kind of a subset of volume, which is there is more of them, and so that contributes to more volume.

And related to that, what do you expect the impact of these proposed changes to be on that rate of growth, the tripling in spending then?

DR. ZABINSKI: Okay. Let's see. Yeah. The 1996 new to market, I'm just pulling that off of the way CMS is defined what "new to the market" is, but when you think about -- see, when something gets passthrough status, it gets it and it just -- and you can't get that status again. So, as you go through time -- I hope I'm explaining this well. As you go through time, it's sort of like a new drug is one that has not had passthrough status before, essentially. So if a drug has had passthrough status, it can't be it can get it again.

So the 1996 is just a baseline when the whole program started in 2000, and CMS never updated it. But there's sort of a practical thing about this. As a drug's passthrough status expires, it can't have it again. So all the drugs that are going to be passed through are new drugs.

Did that answer the question?

DR. SAFRAN: As well as we probably can. Let's move on. Yeah. Thanks, Dan.

DR. ZABINSKI: On the spending, it's more -- the increase is more due to prices than volume. Volume has had an effect, but it's more basically new high-cost drugs. In

particular, the spending is really driven by new chemotherapy treatments or cancer treatment drugs. It's like in excess of 80 percent of the additional spending is on cancer treatment drugs, and it's mostly a price thing rather than a volume.

Then the expected impact of these changes we're discussing on spending, that's not going to be much. The big thing here is we're trying to introduce getting clinical superiority requirement for new drugs, and that's going to have some effect on spending but not a lot.

I think the bigger impact on spending can be through changing the way you pay for the drugs. Kim Neuman and Nancy Ray have been talking about with consolidated billing and reference pricing and other things over the last few years, and I think that our goal is to try to get those implemented through original Medicare eventually, but that's the better way to attack the spending issue.

DR. MATHEWS: Dan, let me jump in here, if I could, for just a second.

DR. ZABINSKI: Please do.

DR. MATHEWS: What Dan is trying to say is that when you look at the set of drugs that currently have

passthrough status that would become packaged if they were not clinically superior to an existing product in the bundle, that that is probably a relatively small set of drugs at the moment, and the savings from those specific drugs may or may not rise to a level of significance. Obviously, we would have to work with CBO should the Commission move towards a recommendation here to get a score.

But the larger issue here is to try and impose some drag on the price of future new products or even existing products that have passthrough status, whereby the dominant criteria now that Medicare uses to determine what is passthrough is, is it new, and is it expensive? And if the drug meets those criteria -- and I know there are others; I am oversimplifying here -- it will get passthrough status and be paid whatever it's paid.

What we are suggesting here through this policy is that with the implementation of a substantial clinical improvement criteria, that there would be fewer drugs in the future that can obtain passthrough status simply by being new and expensive. And that's the key feature of the proposal that we are talking about here with respect to

passthrough.

So it might not be a lot of money right now at this point in time, but ideally, there would be substantial benefits to the program in the future.

DR. SAFRAN: Yeah. Thank you, Jim. That sort of strikes again at the heart of my question or the second part of my question.

So, Dan, thanks for answering all that, and, Jim, thanks for the additional clarification. That's very helpful.

MS. KELLEY: Betty?

DR. RAMBUR: Thank you. Thank you very much for an interesting report.

I think this is a Round 1 question, and I apologize if this is obvious to everybody. But it's not obvious to me.

Regarding the clinical superiority requirement, it seems very logical, and I now understand better about the potential impact. But I'm muddled on the process for determining superiority and any regulatory or reporting burdens that are encompassed in that.

DR. ZABINSKI: Jim, do you want to handle that,

or should I take that?

DR. MATHEWS: Either way. If you want to make a run at it, I'm happy to let you do that. Alternatively, I could proceed, and you could correct everything that I get wrong. Why don't we do that, and you can add clean-up.

So, obviously, clinical superiority is a concept that's got a lot of variation in it, you know, condition, patient response, and we, if we were to proceed towards a recommendation here, would not necessarily be the arbiters of what constituted clinical superiority. But one could envision a scenario not unlike the NTAP process for the inpatient perspective payment system or other instances in Medicare where clinical superiority is used, where there is an application process, the manufacturer submits evidence on clinical superiority. It may not be for all patients, but for some subset of patients, there may be improved efficacy, fewer side effects, that kind of thing. And the Secretary could make a determination whether the evidence submitted in any way, shape, or form, met the criteria for substantial clinical improvement.

How did I do, Dan?

DR. ZABINSKI: Great. Better than I could.

Let's put it that way.

DR. RAMBUR: Thank you.

It seems to me thinking about clinician's perceptions of what's superior, et cetera, that that will take some attention and nuance to be precise and effective.

MS. KELLEY: Karen?

DR. DeSALVO: Thanks, Dana, and thank you, Dan.

The questions come up in the conversation. Jim, you mentioned it about if this is a strategy that will help us address launch price, and if there are other problems that we're trying to solve with these kinds of changes, do we think that it will keep prices flat for longer by having a pathway for them to be bundled? Just an affirmation that this is the strategy mostly about launch price, or are there other problems that we think we can solve if we move in this direction?

DR. ZABINSKI: Do you want to --

DR. MATHEWS: Since I got myself into this mess, I'll continue here.

So, arguably, there could be some effect on launch price. If there is now a requirement that something has to be superior in order to qualify for separate

payment, the fact that something is expensive in and of itself is no longer going to meet that requirement, and therefore, there may be less incentive to price things high at launch.

However, this would not completely eliminate those incentives because if something was innovative, more effective than an existing product, the Sovaldi being a primary example here, it could, indeed, be an extremely expensive product and on the basis of clinical superiority could qualify here. So this will not completely mitigate those incentives to price high, but it will at least impose a bar over which the manufacturer has to exceed in order to qualify for separate payment.

DR. CHERNEW: Jim, let me just say -- I'm sorry. I want to say one other thing. The right way to think through this discussion now is not that we are taking a big examination of the broad issues related to launch prices and drugs, although that is something that is quite interesting and may well be coming down the line. The way to think through this is to try and improve a relatively specific part of the way in which we pay for drugs.

That said, I agree with Jim. In some cases, it

will have that effect.

I think the fundamental problem, that incentives to set reasonable launch prices aren't strong enough yet, but we're not going to solve that problem with this alone.

DR. DeSALVO: Just a quick follow-up, what do we think is -- I'm not still clear about what problem this will solve, principally. It's not clear to me.

DR. MATHEWS: So a couple of things. One, in the materials, in the presentation, we point out the very rapid growth in spending for separately payable drugs under the OPPS, either through passthrough or separately payable non-passthrough. Ideally, this policy would impose some drag on that spending growth going forward.

The second thing that this would do is -- you know, currently, Medicare would be obligated to pay for something expensive and new and then continue to pay for that expensive thing once it rotated off of passthrough status to separately payable non-passthrough, and what this is signaling in a very small part of the Medicare program, you know, separately payable drugs for the OPPS, is that the fact that something is new and expensive is no longer going to suffice for it to receive separate and

preferential treatment that contributes to spending growth, that if something is going to be given that special payment treatment, it has got to be an advance in clinical superiority relative to the existing product.

So I'm not expressing myself articulately here, but in my mind, that is the most significant element of the policy that we are discussing.

DR. CHERNEW: Yeah. We're going a long time on Round 1, and I want to get to Round 2. Everyone, please, I know there's a list. Be cognizant of that in your comments.

The simple answer, Karen, is this a nibble at that problem, and that's what it tries to solve. And we can have a broader discussion about that.

Who's next, Dana?

MS. KELLEY: Marge.

MS. MARJORIE GINSBURG: My comment may, in fact, be more Round 2-ish than Round 1. I know it's unusual in the writeups we do that we include concrete examples of what we're talking about. To me, this is one of those topics where it would really help -- and I know it's hard, because if you give an example of what the status was in

2010, that's going to change dramatically from what it should be in 2012. But I think this is complex enough that it would help all readers to have specific examples of what we're doing now and what we want to change, in terms of actual clinical examples and using actual drugs.

That's all. Thank you.

DR. CHERNEW: Okay. Dana. I think we should move on. If that's not a question I think we should move on. Maybe there was. I'm just worried about time. I don't mean to cut off your answer, Dan, but we have probably four or five more Round 1's and then we still have Round 2.

MS. KELLEY: Okay. Paul is next.

DR. CHERNEW: I'm sorry. Was there a question, Marge, that you needed Dan to answer? I took that more as a general comment that examples would be good.

DR. ZABINSKI: It's something we can definitely do. I'm thinking immediately about each year there seems to be a new skin substitute that comes out and gets a separate payment. And there's a question of why. Without having to show any clinical superiority they automatically get a separate payment. And it's something we could talk

about.

DR. CHERNEW: We'll work on that. That's a good point for the chapter. Who was next, Dana?

MS. KELLEY: Paul.

DR. PAUL GINSBURG: Yeah. Thanks, Dana. A question is if under a separately payable non-passthrough drugs presumably we have situations where there are alternative separately payable drugs, say. For example, let's say there's a biosimilar that comes out for a drugs that's infused. So I take it our separately payable system just pays each one an amount based on its whatever, and we have no incentives at all for physicians to choose the less-expensive alternative.

DR. ZABINSKI: That's correct.

DR. PAUL GINSBURG: Yeah, and that's all I had.

MS. KELLEY: Okay. Brian.

DR. DeBUSK: Dan, one quick question. Let's say you had a $1,000 APC and $100 of that APC was contrast media. Let's say this is an imaging APC. If a passthrough status contrast media came along, say for $150, and I chose to use it, I would still receive the $1,000 for the imaging APC, but then I would be separately paid for the $150

additional contrast media. There is a true double payment there. Correct?

DR. ZABINSKI: No. What you end up, you get a $50 payment for the new contrast material. That is the difference between the old one and the new one.

DR. DeBUSK: Okay. So even if I -- you only pay on the differential now, so the actual amount that I would be paid would be the APC. So let's say I have a second APC that only has a -- it's a similar imaging procedure but it's a different APC, and it only uses $50, or it only has $50 packaged into it. Would I then receive a $100 payment if I used the same drug in that procedure?

DR. ZABINSKI: Yeah. I mean, I've thought about that myself and I actually investigated. It's really unusual to happen, if it ever happened at all. I never found a case where that happens.

DR. DeBUSK: Okay.

DR. ZABINSKI: And, you know, in all likelihood those two services, because they're similar, they would end up in the same APC.

DR. DeBUSK: Okay. I was just curious because in the June report, page 171, we do distinctly talk about the

situation would result in double payments by Medicare, a payment for the cost of the packaged drug and a distinct payment for the separately payable drugs. So there's really an overlapping payment, not a double thing.

DR. ZABINSKI: Well, to some extent. I mean, you think about if instead you had that new drug is packaged, its rate is going to be reflected in the payment rate of the service, and the addition to the payment rate is not going to be the full amount of that new drug. So there is some degree of double payment.

DR. DeBUSK: Okay. Thank you.

DR. ZABINSKI: -- amount of the drug itself, but there is a double payment.

DR. DeBUSK: Thank you.

MS. KELLEY: Bruce, did you have another question?

MR. PYENSON: Yeah, a very quick question. The test of clinical superiority, are you envisioning that happening before the decision is made for separately payable, or is that something like an evidence development test period?

DR. ZABINSKI: Personal preference is to require

it before the separate payment gets granted. That's just personal preference. But how that all works in practice, that's going to be a decision by CMS and Congress. It's basically outside our purview, I think. But Jim, you might want to add to that? Okay.

MS. KELLEY: Okay, Mike. Should we move to Round 2?

DR. CHERNEW: I had a list of people left on Round 1. Maybe I was confusing my Round 1 and Round 2. But if we're done with the Round 1 then absolutely, and I think Brian was the first speaker in Round 2.

MS. WANG: I'm sorry. I actually had a Round 1, Dana.

DR. CHERNEW: Yeah.

MS. WANG: I don't know if you saw me in there.

MS. KELLEY: I didn't. I'm sorry.

MS. WANG: Just really quick. May I? I'm sorry.

DR. CHERNEW: Absolutely, and I think Jonathan -- yes, Pat. Jonathan, were you Round 1 or Round 2?

DR. JAFFERY: Actually, my question got answered already.

DR. CHERNEW: Oh. Gold star, Jonathan. Pat,

you're up.

MS. WANG: Okay. This is really quick and it's foundational. I'm confused, Dan, about the relationship between, let's say, chemo agents that are administered under OPPS and subject to payment, and the same chemo drug that is paid for as ASP plus 6. Could you just clarify, is the ASP+6 only for a private physician office, because we're talking the same drugs here, right?

DR. ZABINSKI: Well, let's see. It gets really dicey, the chemo agents. The standard payment is ASP plus6 in the OPPS for it, unless it's paying through the 340B program then it's ASP minus 22.5.

MS. WANG: Okay. So I'm in a hospital clinic, I'm a physician administering a chemo agent. Is the ASP plus 6 in addition to the OPPS payment? I'm confused about the relationship.

DR. ZABINSKI: Well, no. What happens there is basically you have a drug administration service and then there's no drug cost reflected in that. And then you have the chemo agent. And the hospital gets paid ASP plus 6.

MS. WANG: Is the ASP plus 6 in addition to the separately payable amount?

DR. ZABINSKI: No. That is the separately payable amount.

MS. WANG: I see. Okay. Thank you.

DR. ZABINSKI: I mean, the hospital gets paid for the drug administration and the drug.

MS. WANG: At ASP plus 6. Okay, thank you. And so would the implications of a clinical superiority evaluation extend into the non-hospital world, into a physician office or cancer center, freestanding oncology center, in the way that -- if there's a determination made about clinical superiority of new drugs, do you see that as having any spillover effect to the non-hospital world?

DR. ZABINSKI: Well, it depends on -- you get into a lot of, you know, nitty-gritty details here. Specifically, we're thinking this would be applied only to the hospital, but in terms of decisions about what drugs to use, perhaps the hospital can have some influence on what their physicians choose to use. So I guess my answer is not directly but perhaps indirectly.

MS. WANG: Okay. Thank you very much. Thank you, Dan.

DR. CHERNEW: So I know Jim wants to jump in. I

want to say something first. When we say "clinically superior," do we mean clinically superior to what is in the existing bundle, or clinical superior to other potentially separately payable drugs? So if there's a biologic that has separately payable status and a biosimilar were to come out that was the same as the biologic, but clinical superior to what was before, there would be a separately payable status and there would be no connection between the prices of the biologic and the biosimilar. Is that basically right, Dan? And when we say "clinically superior" we mean relative to not the first biologic that's at the table but relative to something else?

DR. ZABINSKI: Yes. If I'm following you, yes, that's correct.

DR. CHERNEW: Okay. We'll ponder that later, but Jim, you wanted to say something before Round 2, and then I promise we'll get to Brian.

DR. MATHEWS: Yeah. So just to put a marker down with respect to the question Brian asked about the specific payment amount, whether the separately payable product gets the full separate amount, in which case it is a true duplicate payment, or whether it only gets a differential,

in which case it is a partial duplicate payment, I just want to pause there for a second, and we will loop back with you with a definitive answer. I want to make sure we get this right. So just to put a marker down that this response may be refined as soon as we can.

DR. CHERNEW: Okay. Now, the highlight of the session, Brian.

DR. DeBUSK: Ooh, that's pressure. Hey, Jim, first of all, thank you for doing that, because I had looked at the 2020 report it's pages 171, and then in TDAPA policy there's a similar issue that's discussed on page 189.

Anyway, first of all, thank you. This is a fascinating topic for me. Dan, great work and I really enjoyed your chapter. You know, there's a number of ways, as I was reading this chapter, to look at it, because we could look at this very, very narrowly as just an issue with transitional drug payments in APCs that already have those drugs packaged into them. But we can also look at it at a higher level. And as I mentioned earlier, for example, in the ESRD payment system the TDAPA has the same problem. I mean, TDAPA, you literally could be either

double paying or incrementally paying for the same drug, whether it's separately payable, even if there's something in that existing functional category used.

So this isn't, to me, just an OPPS issue. We have some similar challenges in the DRG system in inpatient. I would argue that even the direct practice expense component of the physician fee schedule has some of these elements.

So I think that this is a broad issue that spans several other payment systems, and I also think that it spans drugs and devices. So I'm hoping, first of all, I hope we dig into this more deeply, but I also hope that we do this more broadly, because I think this really leads us into the issue of how does Medicare feather new technology into really any payment system. So there are some very broad implications here, and I hope that we pursue those.

Now, getting back to the specifics of the chapter, I really think that, Dan, you and the staff have done a great job of trying to simplify a system that's been made needlessly complex. The separately paid, non-passthrough drugs, I mean, there really isn't a benefit to having a transition period there. If the drug, or the

device, for that matter, is the sole purpose or the principal component of the procedure, then I don't see the benefit of giving it this temporary passthrough status. I would just simply treat it as a separately payable drug and use their existing price mechanisms. As the drug is initially launched we would base reimbursement off of the WAC. Then, as we collect ASP data, we would transfer over to ASP-based reimbursement. All those mechanisms are in place, so that strikes me as a very clean solution.

Drugs that are packaged, existing drugs that are already packaged, also struck me as a very clean solution. I think packaging is the future, for all the reasons that have been outlined, not just in this chapter but also outlined in Chapter 6 and Chapter 7 of the June 2020 report. And, incidentally, I thought it was interesting that Chapters 6 and 7 really described the same issue, this issue of double payment or how to deal with new technology, back to back. So Jim and the staff, I think you have been leading us in this direction for some time now. Thank you. I think it's a great direction.

So let's talk a moment about what happens when a new drug is introduced into a bundle that already has a

portion of payment set aside for that drug category. First of all, I strongly support the substantial clinical improvement criteria. I think that is just great policy on a number of fronts. I do think it creates this issue, which is discussed in the paper -- I believe actually it's discussed in the June 2020 report -- about how would you address drugs that are clinically beneficial in different ways, because obviously the clinical benefits isn't a single dimension.

I think that that leads us into this issue -- and Jim, thank you again for researching this further -- how those differential payments would be established, because I would argue that we really want to only pay based on the strict differential between what's already factored into the bundle and what the proposed price of the new drug is. I think managing that gap would be very important, because if that gap becomes too large, for example, in TDAPA, you create an incentive to always use the new drug simply because you have some degree of overlapping payment, whether it's modest or whether it's great.

And then as you also mentioned in the discussion, once that incentive to use the new drug, the artificial

incentive, is in place, that usage starts showing up in cost reports, it starts getting repriced into the bundles. So what you have is an inflationary mechanism into the APC or the DRG or the ESRD bundle itself, or the dialysis bundle, I should say.

So I think this is really important to make sure that we do implement clinical superiority criteria and that we carefully manage those differentials. But I also think it's important that we look at this in a very broad spectrum. So I'm hoping that this permeates a lot of the work that we do, not just limiting it to the APCs and drugs used in APCs.

Thank you.

MS. KELLEY: Bruce?

MR. PYENSON: Thank you, Dan. I think this is a terrific chapter, and at the risk of expanding the scope further, I think it would be worthwhile to consider whether the proposal creates differential reimbursement with respect to physician office, since much of the topic at hand is chemotherapy. So I'd ask that that be part of the exploration.

In addition, I think there's an opportunity here

to have evidence development for some types of drugs with a conditional period. That's not going to apply to everything but I suspect there could be a transition period where a drug that gets covered while evidence is being developed and part of that process could also be a reduced reimbursement during that transition period, that might be considered part of the investment by the manufacturer in bringing a drug to market.

So I think there's opportunity here to think broadly, but the implications for physician office-based chemotherapy is something I think is worth paying attention to. Thank you.

MS. KELLEY: I think Dana Safran is next.

DR. SAFRAN: Thank you. Very supportive of the direction here, and I think my comments really just apply to the issue around clinical superiority. And so I think that, number one, the response that Jim gave to my earlier question really did affirm for me the importance of doing this because it does suggest the potential to begin to rationalize the kinds of prices that are being attached to new drugs that are coming to market.

One of the questions that I have -- I know it's

not an answerable one, so I'm just putting it in this part of our conversation -- is we're going to have to grapple with the question of how much clinical superiority counts as clinical superiority, and how is that related to how much of an increase -- you know, what the marginal pricing can be relative to the existing therapies?

I think I also to me -- and I think someone was just making this point; maybe it was Bruce. The amount of data that we'll have on clinical superiority at the time the drug is introduced will probably benefit from additional data being collected over the subsequent time period. So to me that suggests that at the same time that in the chapter we point to the need to collect information to know about the cost for when the drug gets incorporated into the bundle, we should also be ongoingly collecting the data that we need to ongoingly assess clinical superiority. And I recognize that that begins to open the door to something broader for clinical superiority assessment, and I don't think that that's a bad thing for the Medicare program.

So those are my comments. Thank you.

MS. KELLEY: Mike, I think you're next.

DR. CHERNEW: I am next. I'm going to say a few things, and then we can continue or move on to the next session. But let me make some broad points.

With regard to the structure of the chapter, I think we hear loud and clear that some specific examples matter in a range of ways, and there's some nuanced clarification about things like clinically superior to what, clinically superior to things in a bundle, clinically superior to other separately payable drugs, how is the thing working with particular cancer drugs and those different biologics, for example. All of that I think is a reasonable thing to work through in the chapter, and, Dan, you did an outstanding job with a very complicated topic, and we will try to be as concrete as possible in the examples moving forward.

I think the big conceptual issue is we're trying to balance some various things. One thing, of course, is we want to promote an incentive to keep spending down by avoiding drugs entering the system that are very high priced but not better, and I'm going to pause for a second, but I think, Dan, if I were to say that was the sort of elevator speech or the motivation for this, how close would

I be to right?

DR. ZABINSKI: Really close. I will say you're spot-on.

DR. CHERNEW: I'm going to stick with "really close." That being said, there's a very complicated process. There's the ASP plus 6 process and a whole slew of other things going on. So let me just say a few broad things. One of them is it's very important that I think Dan and the staff and many of you, certainly I recognize and feel strongly we need to preserve the incentive to innovate. It is important for a whole variety of reasons. So the goal is not to prevent innovation, and I think the proposal was constructed to do that. That's where you see things like clinical superiority.

The rub for me in part is, depending on how this is structured, we also want to promote competition amongst similar things. So, for example, if there's three biologics -- a biologic and three biosimilars, we don't want them all in their own separately separable payable categories with their own prices. I think the core mistake sometimes is we treat the cost of the drug as if it's actually a cost as opposed to it just being a price. And

when we set the price -- when we set the threshold for moving into a different category at a high price, there's incentive, I think, for organizations to potentially try and get into that separately payable category.

So there's a lot, I think, to be done to try and balance the incentives for innovation that are crucial, the incentives for efficient use, the incentives or efficient pricing. The challenge that I think I'll talk with the staff about -- and you can comment now or send messages later as it all sinks in -- is do we have this narrow type of recommendation that I think is an improvement in trying to solve a problem which we may or may not have convinced you of? Or do we wait to wrap this into a broader attempt to address a much, much, much bigger point? And, Brian, your comments I think were spot-on. This is not unique in a whole number of ways. In fact, I view this as a foray into all that's complex about a fee-for-service system, but we move into different alternative payment models and bundled systems and episodes. We have questions about how the episode payment is going to reflect new services. Amol, I imagine you spent a lot of time thinking about how that happens. This is just a subset of that kind of

question.

So let me pause for a second if anyone wants to say anything else. Otherwise, we'll move on to the next session, which is ESRD and Medicare Advantage. But let me just see if anyone has reactions to those big-picture things or thoughts now. And if you don't have them now but you have them later, please reach out.

[Pause.]

DR. CHERNEW: As the slide changed, Andy's making his point. So, Jim, I take from your silence you're fine with that as well. My comments were meant in some sense as my summary of at least what I am thinking now. Again, I will look forward to hearing from you, but I guess in the interim we'll move on to Andy and Medicare Advantage. This is maybe going once, going twice, going three times. And we are now on to Medicare Advantage and ESRD. Andy, you're up.

DR. JOHNSON: Thanks, Mike.

Good morning. This presentation addresses access to Medicare Advantage plans for beneficiaries with end-stage renal disease, or ESRD. I would like to thank Nancy Ray, Carlos Zarabozo, Luis Serna, and Eric Rollins for

their help on this topic.

The audience can download a PDF version of these slides in the handout section of the control panel on the right side of the screen.

The 21st Century Cures Act lifted existing limitations on MA enrollment for Medicare beneficiaries with ESRD, allowing those beneficiaries to enroll directly in an MA plan starting in 2021. Some observers expect that MA plans' coverage of cost sharing and the required cap on out-of-pocket expenses will attract a growing share of ESRD enrollees in the coming years. In today's presentation, I will review information about Medicare spending and coverage options for beneficiaries with ESRD.

Then we will move on to MA payments. I will start by reviewing how MA plans are paid for enrollees with ESRD and will share results of our analysis comparing MA payments with plans' medical costs for enrollees with ESRD.

We consider two payment issues: first, I will present information about the prices MA plans pay for dialysis; and, second, we discuss whether the statewide basis for Medicare payments may overpay or underpay some plans.

Finally, we turn to access to MA plans and consider whether plans' coverage of cost sharing or plans' networks for dialysis facilities could deter beneficiaries with ESRD from enrolling in an MA plan.

Treatment for ESRD requires dialysis to remove waste from the blood or a kidney transplant. Dialysis is usually provided three times per week. Patients with ESRD require many health care services, in addition to dialysis, and average Medicare spending for beneficiaries with ESRD is more than eight times the average spending for beneficiaries without ESRD.

This means that beneficiaries with ESRD are liable for substantial out-of-pocket costs, averaging about $13,000 per year. Many beneficiaries with ESRD have supplemental coverage from Medicaid, Medigap, or an employer-sponsored plan to help with cost sharing; however, these options are not available to all beneficiaries.

Prior to 2021, beneficiaries with ESRD were prohibited from joining most MA plans; however, they could remain in a plan, if they were already enrolled, or they could join a special needs plan. Even with these limitations, about 131,000 beneficiaries with ESRD were

enrolled in MA in 2019. That's about 25 percent of all Medicare beneficiaries with ESRD.

Beginning with coverage for 2021, the 21st Century Cures Act allows beneficiaries with ESRD to enroll directly in an MA plan. Because of this change, CMS expects an additional 83,000 beneficiaries will enroll in an MA plan over the next six years.

The agency expects additional MA enrollment because of the extra benefits that plans offer, including lower than fee-for-service cost sharing for most services; in particular, the cap on out-of-pocket spending is $7,550 for 2021 and is much less than the average out-of-pocket spending for beneficiaries with ESRD.

Medicare requires MA plans to offer the same benefit package to all plan enrollees.

In 2004, the Commission recommended that Congress allow all beneficiaries with ESRD to enroll in private plans, noting an improved risk adjustment system and a study finding equal or better quality of for most ESRD plan enrollees.

The Commission strongly supports beneficiaries' ability to choose among Medicare coverage options. Some

beneficiaries with ESRD may benefit from the substantial extra benefits that plans offer and the care coordination and cost-control tools that plans employ.

In recent years, we have tracked growth in an increasingly robust MA program, including growth in enrollment, increased plan offerings, and a historically high level of extra benefits. These indicators of a vibrant MA program set the context for considering the potential for expanded ESRD enrollment over the next few years.

Now let's review how MA plans are paid for enrollees with ESRD. Medicare payment is equal to an ESRD state rate multiplied by a risk score. The ESRD state rate is equal to the average fee-for-service Medicare spending for beneficiaries with ESRD in each state.

The risk score increases or decreases payment for enrollees based on their expected Medicare expenditures. The ESRD risk adjustment model is based on fee-for-service beneficiaries with ESRD and is separate from the other risk adjustment models.

Although plans do not submit a bid for enrollees with ESRD, CMS collects information about each plan's costs

and revenues for those beneficiaries through the bid payment tool. We used bid payment tool data to compare revenues with costs for enrollees with ESRD in each MA contract.

Now, on Slide 7, our analysis found that, on average, revenues were greater than medical costs for ESRD enrollees. This chart depicts the distribution of medical cost-to-revenue ratios across MA contracts.

Looking only at ESRD enrollment, a contract with costs that are equal to revenues has a ratio of 1.0. Each green bar shows the share of MA contracts within the cost-to-revenue range noted on the bottom, and the corresponding white bars show the share of MA enrollees with ESRD enrolled in those contracts.

The sum of the three white bars on the left indicate that 56 percent of MA enrollees with ESRD are in an MA contract with equal or smaller medical costs than revenues. However, the chart indicates a wide range of financial performance for enrollees with ESRD.

In a separate analysis of plans that exclusively enroll beneficiaries with ESRD, we found that those plans are generally profitable.

Although we find payments in the aggregate are adequate to cover medical costs for enrollees with ESRD, plan advocates have claimed that payments are not adequate for two reasons.

First, MA plans pay more for dialysis treatments because plans are not able to negotiate rates as low as fee-for-service Medicare. And, second, within-state spending variation and differences in the distribution of MA and fee-for-service enrollment across each state lead to MA payments that may be too low. We consider each of these issues over the next two slides.

To address the first issue, we evaluated dialysis prices using MA encounter data for 2018. You may recall that we previously found encounter data were not suitable for analyzing MA service use because missing and incomplete data introduce downward bias on utilization estimates.

Unlike analysis of service use, the distribution of dialysis prices is not necessarily biased by missing data. We assessed the extent of missing dialysis data and found that encounter data included about 80 percent of the dialysis treatments we would expect to observe, and we concluded that the encounter data were a reasonable basis

for this analysis.

Slide 9 summarizes our results. We found that MA contracts paid an average of about 14 percent more per dialysis treatment than fee-for-service Medicare rates in 2018, accounting for differences in age and wage index.

Dialysis prices in MA are a function of negotiations between plans and providers, and one reason for a high average price may be that consolidation in the outpatient dialysis industry hampers plans' ability to negotiate lower prices. Two dialysis companies operate 74 percent of outpatient dialysis facilities.

However, we find a wide range of dialysis prices per treatment with some MA contracts paying an average price below fee-for-service Medicare rates, covering 18 percent of MA dialysis treatments. And some contracts covering about 5 percent of MA dialysis treatments paid an average of 40 percent or more above Medicare fee-for-service rates.

Given the expectation for increasing ESRD enrollment in MA, the balance of negotiating leverage between MA plans and dialysis providers may shift. We will continue to monitor MA dialysis prices and consider whether

high prices lead to diminished access to MA plans for beneficiaries with ESRD.

The second payment issue is whether state-based ESRD payment leads to underpayment or overpayment for MA plans. The ESRD state rates are based on local fee-for-service spending for beneficiaries with ESRD.

Two studies of this issue found that some metropolitan areas had ESRD spending that differed from the state average and, therefore, differed from Medicare payments. The two studies found maximum differences in the range of 10 to 15 percent above or below the state average spending.

Payment accuracy requires balancing two factors. First, payment areas should be small enough to minimize spending variation within each area. And, second, payment areas need to include enough fee-for-service beneficiaries to maintain stable spending estimates over time.

We do not know whether there are sufficient data to use a smaller geographic unit as the basis for ESRD rates, but if the Commission is interested, we could explore an alternative basis for ESRD payments, such as MedPAC areas.

Now we turn to access to MA plans for beneficiaries with ESRD.

Although the 21st Century Cures Act eliminated enrollment barriers, some MA plans with financial losses for ESRD enrollees may seek to deter ESRD beneficiaries from enrolling in their plan.

We evaluated two strategies within the bounds of Medicare rules that could be used to deter ESRD enrollment.

One strategy is to allow high out-of-pocket spending for ESRD enrollees, diminishing beneficiaries' ability to reduce their cost-sharing liability by enrolling in an MA plan.

The second strategy is for plans to establish dialysis facility networks that do not provide adequate dialysis facility options.

First, we consider the level of cost sharing that MA plans impose for dialysis services. Plan cost sharing can vary by service category, and dialysis services have their own category. By law, plans can impose a maximum of 20 percent coinsurance for dialysis, equivalent to the dialysis cost sharing in fee-for-service Medicare.

We reviewed plan benefit package data and found

that 81 percent of plans imposed the maximum dialysis cost sharing, covering about 74 percent of enrollees with ESRD in 2020. These percentages have increased only slightly since the passage of the Cures Act, suggesting that high dialysis cost sharing has always been common for MA plans.

Considering cost sharing for all services, plans are required to offer a limit on the total out-of-pocket spending. The 2021 out-of-pocket cap limits spending to about 60 percent of the total out-of-pocket liability for the average beneficiary with ESRD.

That means the widespread use of high dialysis cost sharing may not deter enrollment in MA plans because the cap on out-of-pocket spending in place. However, if the cap were to be increased for ESRD enrollees, it would be detrimental to MA plan access. We will continue to monitor any changes to the out-of-pocket spending cap.

Next we turn to network adequacy. Two standards enforce the network adequacy requirement for most provider types.

The first standard establishes a minimum number of facilities or physicians per capita in a county. Second, a set of time and distance standards ensure that a

plan's network is consistent with the prevailing pattern of health care delivery in a community. Different standards are established for each facility type and physician specialty.

In recent rulemaking, CMS permanently replaced the time and distance standard with a plan's attestation that their network of dialysis facilities is adequate. CMS noted comments from stakeholders that dialysis providers may leverage network adequacy requirements in order to negotiate prices well above Medicare fee-for-service rates.

Please note that the last sub-bullet on Slide 13 is different from your mailing materials.

In the rulemaking, CMS stated that it will replace network adequacy evaluation with attestation for a specialty or facility type in circumstances where it may not be necessary to evaluate the number and accessibility of each of the provider types in a particular year. CMS apparently applied this provision to outpatient dialysis facilities for 2021, and so plans will not be evaluated on the minimum number of facilities per county standard but will attest to both standards for dialysis facilities. Neither of these changes apply to any other provider type.

In a comment letter, the Commission strongly opposed this change out of concern it could diminish access to MA plans for beneficiaries with ESRD.

If a dialysis facility is removed from a plan's network, patients may choose to continue receiving care from the facility rather than remain enrolled in the plan. The plan is also not likely to attract new enrollment from patients at the removed facility.

A plan's attestation does not provide any specific information about dialysis treatment options in a plan. When considering coverage options, beneficiaries are only certain about in-network dialysis facility options. Therefore, under the new rules, removing a dialysis facility from a plan's network could be an effective strategy for deterring ESRD enrollment.

If there is Commission interest, we can revisit this issue in a future meeting and consider whether further action is needed to maintain access to MA plans for beneficiaries with ESRD.

In this presentation, we covered a wide array of topics addressing MA enrollment for beneficiaries with ESRD, and we are looking forward to your discussion. In

particular, we would appreciate your feedback about pursuing future work in two policy areas. First, we could explore revising the ESRD state rates by using an alternative geographic unit, such as MedPAC areas. We would evaluate whether the available data would allow for smaller ESRD payment area and whether payment accuracy would be improved by doing so. Second, we could pursue changes to network adequacy requirements for outpatient dialysis facilities, such as reinstating the time and distance standards.

Thanks, and now I'll turn it back to Mike.

DR. CHERNEW: Great. That was terrific.

We have a few Round 1 questions. So I'll let us go through the list. I think the first person on the list was Jonathan. Am I right, Dana?

MS. KELLEY: That's correct.

DR. JAFFERY: Thanks.

Andy, great presentation. Thank you so much.

So my question is about the topic and the concept about the statewide variation and thinking about are we overpaying or underpaying plans. Do you have thoughts about some of the primary drivers of the variation? I

think in the reading, it mentioned about 30 percent of payments are for the dialysis payments themselves, which seem a little more fixed, but obviously, we see variation, a lot of variation in all sorts of things in Medicare and health care in general.

So do you have any thoughts about what's driving that in particular?

DR. JOHNSON: We haven't gotten into any of the specific variation within the ESRD state rates. I think for now I would only point to the geographic variation you're aware of, that all medical spending varies quite a bit by geographic area, and ESRD beneficiaries have a lot of spending. So the differences would be noticeable for this group in particular.

DR. JAFFERY: Okay. Thank you.

MS. KELLEY: Marge?

MS. MARJORIE GINSBURG: So maybe I missed this, but I'm curious. Were the MA plans supportive of the idea of allowing ESRD patients to be enrolled, or do they accept this kicking and screaming?

I have a hard time believing that MA plans can't make this work out to their advantage, but I am curious

whether the change in the rules about allowing ESRD patients to come to them directly was with their enthusiasm or resistance. Do we have any idea?

DR. JOHNSON: At least some share of plans do not seem to be supportive and have been pushing a lot of changes to the payment policy and suggesting that the payments are inadequate.

As to your other point, though, we did look at the types of plans that exclusively enroll ESRD beneficiaries, and they tend to make the finances work so that it does provide evidence that it's possible in at least some areas for some of the plans.

MS. KELLEY: Larry?

DR. CASALINO: Yeah. Andy, this may be a naïve question, but my understanding is that for most services in general, Medicare adjusts payments geographically on a national basis based on things like is the rent higher or their cost of space higher in City A than City B or County A or County B, are labor expenses higher or lower, and so on. So why are we talking about within state variation and prices at all? Why not just adjust geographically for costs on a national basis the way Medicare does for other

things?

DR. JOHNSON: I think the limitation has been the number of fee-for-service beneficiaries that are available to serve as the basis for a benchmark, and so far, CMS has used just states as the basis for that benchmark. So there is the same payment rate, the same base payment rate for an entire state, no matter where a plan is participating. Plans can have service areas that are county-by-county basis. So they might serve one metropolitan area and not the whole state, and another plan might serve a totally different metropolitan area. And if those areas have spending that is different from the state average, then the MA payment rates might be overpaying or underpaying relative to what the local rates are. But I think limitation is about the available ESRD enrollees and fee-for-service Medicare that serve as the basis for those rates.

DR. CASALINO: I see. So compared to the unit, which I think is the county that Medicare accounts for cost for other services, there wouldn't be enough ESRD patients in some counties to make that kind of calculation?

DR. JOHNSON: That's right.

DR. CASALINO: But why not just use -- why worry about ESRD patients as a specific group at all in this regard? Rents are rents. Labor costs are labor costs. Those are true whether it's ESRD beneficiaries or from other beneficiaries. I don't understand the special -- I still don't understand using different geographic areas than for the rest of Medicare.

DR. JOHNSON: So, currently, the entire payment system for ESRD enrollees is separate from the non-ESRD enrollee payment system, and so what I think you're asking is why isn't there just one payment system for everybody. And I'm not sure what the answer is, if that's your question.

DR. CASALINO: Yeah. And I won't editorialize, and I don't really know very much about this. But I think it's worth thinking about.

MS. KELLEY: Paul, did you have something on this point?

DR. PAUL GINSBURG: Yeah. It's a follow-up to Larry.

Larry, the big difference between MA rates and the rates that we pay hospitals or physicians is that MA

rates are capitated. So, in a sense, it's an entirely different thing, and we've always tied them to fee-for-service experience on a per-beneficiary basis. And that's why, historically, we've used the cap fee. You know, MedPAC has better ideas to do that in MedPAC areas, but I think that's why you're seeing statewide, presumably statewide payment back because the program started very small. Since it was only people, beneficiaries that were enrolled in MA that developed ESRD while they were enrolled, the number was small. There probably wasn't enough data in fee-for-service ESRD to use for that.

DR. CHERNEW: Yeah. I think what Paul is saying is that for hospitals, you're trying to adjust a price, and so you're looking at wage indices. In MA, you're trying to adjust for a spending, which is a price time to use. So the geographic variation in use gets captured in MA rate more so than just -- the differences in, for example, MA benchmarks normally across geographic areas isn't just the wage index. It reflects differences in utilization between different places, and that's the parallel to what's happening in ESRD.

I think, Paul, I can see you a little bit in a

small little square. If you nod, I think I'm just repeating what you said.

So I think that's why they're doing it differently because the use component is different.

DR. CASALINO: Mike, I don't want to prolong this, but I'll just point out that that basically rewards overuse or overutilization.

DR. CHERNEW: Yeah. Yes.

DR. CASALINO: Just for ACO rates and so on and so forth. But I don't think we should forget that.

So, basically, if you're in a state right now that has high utilization for any ESRD beneficiaries, they're going to pay more than if you're in a state where care is perhaps given better and more efficiently.

DR. CHERNEW: Absolutely. Which is the same -- the geographic panelists at IOM or National Academy of Sciences did this for Minneapolis and Miami, this exact same as you happen. If you're in a place with high home care use, the MA rate is much higher, for example.

DR. CASALINO: Right.

DR. CHERNEW: So we should move on. I think there's a few more Round 1's. I'm not sure I have it

exactly. I think we have --

MS. KELLEY: David is next.

DR. CHERNEW: Perfect.

DR. GRABOWSKI: Great. Thanks, Dana, and thanks, Andy, for a great chapter and great presentation.

I wanted to ask you just about -- I think this is really focused on Slide 9, just on that result that's in the headline there about -- oh, thank you -- MA contracts paid 14 percent more per dialysis treatment on average than fee-for-service. Andy, is that for the entire country? But this doesn't reflect where folks go for dialysis. This is within, within provider? Like how did you -- did you make sure to adjust for that? I just want to say more about what you did to get that number.

DR. JOHNSON: So we adjusted for differences in age and wage index. So it does take into account the wage index that would apply to the fee-for-service payment rates, but we first aggregated to the contract level and found an average for each contract and then overall average.

DR. GRABOWSKI: At that area level? Is that the calculation you made? It's not per sort of where folks are

actually receiving treatments? This is sort of at an area level and then aggregated up to the U.S.? Am I think about that correctly?

DR. JOHNSON: For the wage index adjustment in fee-for-service, ESRD, PPS, I think it's about 53 percent of the rate is adjusted by the wage index, and so we did the same thing but to back out the wage index from each of the MA payment areas so that we normalized -- or standardized the prices across the entire country and then compared the fee-for-service to MA averages.

DR. GRABOWSKI: Okay. Thanks.

MS. KELLEY: Pat?

MS. WANG: Thanks.

Andy, this is just a point of clarification. In the paper, on page 7, you talked about the ESRD subsidy, and for plans with ESRD payments that do not cover ESRD costs, this allows plans to draw down rebate funding to make up for the gap by reducing supplemental benefits. Is this specific to reducing supplemental benefits for ESRD patients or just for the entire Medicare membership enrolled by that plan?

DR. JOHNSON: It would be for the whole

membership of the plan.

MS. WANG: Okay. So a consequence of inaccurate payment or a gap in payment is that all members of the plan use supplemental benefits?

DR. JOHNSON: They could if the plan used this ESRD subsidy. It's optional for the plan, but they could use the rebate funding for the whole enrollment to reconcile any differences in their population.

MS. WANG: In the analysis that you did to match revenue to cost for the sample that you could simulate, I just -- and, again, this is on page 8 of the paper. You talked about average medical cost of 67/52 PMPM. Average plan revenue, 67/69. So the ratio was 0.997. Is that revenue the total premium received by the plan? I mean, where would admin or -- it includes, like, running the plan, doing care management. Is that included in this total revenue PMPM or not?

DR. JOHNSON: The revenue should be all of the money that the plan received from Medicare. On the cost side, it only includes the medical costs because --

MS. WANG: Okay.

DR. JOHNSON: So admin is not included in that,

and any --

MS. WANG: Okay.

DR. JOHNSON: -- profit, that would not be included like it is for normal.

MS. WANG: Okay. So a medical loss ratio of .997 means the plan is losing a ton of money. I just want to point that out because there's nothing about the cost of running the plan or doing care management in particular for a very high-need population. Okay.

The other thing I just was curious about -- I think you did an admirable job of trying to sort of piece together the information you had to do this cost-to-revenue analysis. It seems like about 25 percent of ESRD, people with ESRD are currently enrolled in MA. Under the current rules, where if you develop ESRD while you're an MA member, you stay in the plan.

Is there any reason to think that the profile of spending for members that have been in a managed environment might be different from members who might be coming in straight from fee-for-service and have unmanaged total health care costs? I just wondered. I mean, you had to use the information that you had, but I just wondered

whether you felt like this was a representative sample of ESRD spending in Medicare Advantage.

DR. JOHNSON: I think what you're asking is whether or not the spending profile would be similar among the fee-for-service patients, and I guess there are reasons why it could be different. I'm not sure that we've tried to quantify those.

MS. WANG: Okay. Final question. On the issue that was just being discussed before about the statewide average fee-for-service cost, has there been any effort to look? I realize that the number of enrollees is small, beneficiaries is small, but has there been any effort to look at variation in cost within a state, rural area versus major metropolitan area, or, you know, just even the grossest subcategories within state variation and spending?

DR. JOHNSON: So the two studies that I mentioned have done it for the fee-for-service population, and that's something that we could get into and try and do a more comprehensive national assessment. I'm not sure that any study has looked at the MA costs for a specific region.

MS. WANG: Okay. Thank you.

MS. KELLEY: Bruce?

MR. PYENSON: Thank you.

Andy, this is superb work. In my experience, ESRD is just about the most complicated area in Medicare Part A and B, and I'm sure Brian is going to ask you to integrate that with Part D, in which case this will be way off the charts on complexity, so terrific work.

I wanted to ask about -- I think it's Slide 13. I think it was 16 percent higher reimbursement, and I want to -- maybe it was not Slide 13, but Slide -- well, but my compliments on your use of the encounter data to finding a way to use that creatively and get useful information.

In my experience, many MA plans do not pay dialysis organizations using the Medicare bundle, just like some organizations don't pay hospitals using DRGs, and so this is kind of a geeky question. In particular, many MA organizations pay for ESAs and fused iron separately or perhaps other things.

In your use of the encounter data, were you able to spot that sort of thing? One of the reasons I'm asking is in looking at claims data from MA, I've seen much higher than 14 percent differential. So I'm curious, your thoughts about that, different kind of separately payable

but sort of a fee-for-service rather than bundle.

DR. JOHNSON: On the overall results, there certainly were some contracts that had an average price that they paid that was much higher. There wasn't as many, but the prices went several times more than the fee-for-service rate for some contracts.

The way we tried to capture the payments that plans made to the dialysis provider was using the type of bill code. So it wasn't specific to the ESRD bundle, included any of the payments that went through, and I think you're right that different plans used different methods of reporting -- or rather, the providers used different methods of reporting to the plan, what the costs were and what the claim was for. Sometimes it could have been for the ESRD bundle. Sometimes it could have been for dialysis and drugs separately, but as long as the payment was going to the facility, it was included. We used each beneficiary month as a unit to say that if a plan paid the facility any amount of money for this beneficiary in the month, that went into the calculation of payments per treatment.

MR. PYENSON: So the code you were using was a bill code, was a bill type, or --

DR. JOHNSON: It is the -- I know them as 72X codes, but I'll have to look up what the variable name is, type of billing and type of service.

MR. PYENSON: Since the encounter data is used for risk adjustment, are the drug claims, like for ESAs and IV iron, are those used for -- typically chaptered and used for risk adjustment?

DR. JOHNSON: I think they are. So you're asking, in the fee-for-service population, with ESRD, which was used as the basis for ESRD risk adjustment model, all of the spending for those beneficiaries would be captured.

MR. PYENSON: I'm thinking of the submission of encounter data for routine submission for MA plans for general risk adjustment.

DR. JOHNSON: So in the ERSD PPS and fee-for-service there is the case mix adjusters, the facility-level and patient-level adjustments, and you're wondering if plans tended to adjust their payments similarly to the fee-for-service? Is that --

MR. PYENSON: I'm wondering if routinely the plans would submit claims that just had a drug claim to capture diagnoses for a Part C drug claim.

DR. JOHNSON: I would have to go back and look.

MR. PYENSON: Okay. Thank you.

MS. KELLEY: Dana?

DR. SAFRAN: Thank you. Just two questions from me, and truly great work. One is related to the move to attestation. Can you help us understand a little bit more about the rationale and maybe justification for removing the time and distance standards and moving to attestation? And does it have any relationship to the increasing use of home dialysis? Is that part of what's behind it? It would be helpful to understand the rationale, and if it's not driven by home dialysis how does the increasing use of home dialysis factor into network adequacy considerations? That's my first question.

DR. JOHNSON: So the first part of the question, CMS didn't give a very specific rationale for eliminating the time and distance standards and replacing with an attestation, but they did note that several stakeholders found that dialysis organizations were using the network adequacy standards to leverage higher prices from the plans. So that does seem to be the main concern. And later CMS noted that the flexibility of replacing the time

and distance standards with attestation would allow plans to negotiate lower prices. That was what they said.

On the second part, for the minimum number of facilities per county, there wasn't an explanation given for that, and it was not noted that that would apply to dialysis facilities. And I should say I think this is the case that it applies to dialysis facilities. There is a rather non-transparent provision in the rulemaking that says we'll remove a specific facility type from the standards by excluding them from a specific spreadsheet, and on the spreadsheet dialysis facilities are not included in the standards.

For home dialysis, CMS did note that home dialysis is something that plans could use to help provide an adequate dialysis coverage. I think the concern is that home dialysis is not an appropriate treatment modality for all patients with ESRD, and so it certainly could help, and I think CMS wanted to push that, which makes sense. But it doesn't mean that home dialysis is a substitute for in-center dialysis for all patients, and I think I recently saw a figure -- I don't remember the exact number but the vast majority of patients who use home dialysis also use

in-center dialysis at some point over the lifetime of their treatment.

DR. SAFRAN: That's helpful. Thank you. The second question is the rationale related to how attestation could allow the plans to get better pricing, I have to say I don’t understand.

But my second question is related to the significantly higher pricing that you show us that MA plans are paying relative to fee-for-service. Given that extreme consolidation in the dialysis market with two companies really accounting for three-quarters of the market, is it possible to consider having MA plans leverage the Medicare fee-for-service negotiated rates for dialysis? I recognize that would be unprecedented. At least I think it is for how MA plans get pricing for their networks. But I just wanted to ask the question.

DR. JOHNSON: I think there is one precedent for that in MA policy which is for regional plans contracting with in-patient hospitals, and regional plans do not have a service area on a county-by-county basis. They have much larger areas. I think there are whole states or multiple states at a time. I have to double-check that, but by

agreeing to provide, or have a service area that is that large, the plan is allowed to say that this hospital is essential for network adequacy and we made a good-faith effort to contract with that hospital, and in the case that the negotiations fail the plan can say they are out of network but they will accept Medicare fee-for-service rates for payments. That's the one area I'm aware of.

DR. SAFRAN: Thank you.

DR. CHERNEW: Dana, I want to come back to that topic in Round 2, so I'll say something between the rounds. I think we have a few more people left in the Round 1, so I think it's Jaewon next.

MS. KELLEY: Yes.

DR. RYU: Yeah, thanks. I have two questions as well. The first is on, I think it was Slide 9, getting to the 14 percent average higher rate. And I think in the materials it's Figure 2. That 14 percent average, it looks like there's quite a bit of spread or distribution surrounding that average. Any observations or patterns that you can make based on whether it's market type scenarios or types of plans that are paying on the higher end of that average versus plans that are paying on the

lower end of that average?

DR. JOHNSON: I didn't do any specific analyses. There did seem to be not an obvious pattern to that. I think some of the larger insurers tended to be not on the very far right end but were also not exactly on the low end of the distribution, and there were smaller insurers spread throughout. So it did not seem to be a clear pattern, at least based on size of enrollment, and I didn't try and assess the services areas of individual plans. That would have been a much more difficult analysis.

DR. MATHEWS: But Andy, this is something we could do if the Commission were interested in exploring different geographic units as the basis for payment. We could dig into this more than we have for the purpose of this presentation.

DR. JOHNSON: Yes, we could.

DR. RYU: And then the second question was around the areas within the state that have over/under payment relative to the state average ESRD payment. And I'm just curious. I know that Jonathan asked a similar question, and I think Pat may have touched on it as well. But a slightly different was have you seen any difference around

plan behavior based on whether you're in an overpayment segment or section of the state or whether you're in an underpayment section of the state, and availability of MA plans to ESRD beneficiaries in those two different scenarios. Is there a difference?

DR. JOHNSON: We haven't dug into the within-state variation but I'll take this as a nod for interest in pursuing that work. We will try to answer that question. I think the one area where it seems to stand out is with the ESRD chronic conditions special needs plans. Those plans are only available in a few states, and the majority of enrollment is in California, which has one of the higher state rates. But I will say California, there is also variation within California, and I'm not sure whether or not the plans are operating in the parts of the state where they would get higher than average payments or lower than average payments.

DR. RYU: Thank you.

MS. KELLEY: Jon Perlin?

DR. PERLIN: Andy, let me also thank you for a terrific chapter. You know, I think the basic tension here is network adequacy and appropriate payments. My questions

were very, very similar to Dana's, in terms of trying to think through whether simply leveraging the fee-for-service negotiated rate would mitigate against the challenge on the one end of too broad a geography state rate and too narrow a geography. But at least to really a nuance on that question which is that as we think about the smaller geographic unit do we have any concerns, on page 13 referencing that, of sort of gaming to nominally meet the criteria but really not offering improved service, other than driving cost by being just outside of the particular lower pay geography and locating preferentially in terms of either a partial sort of plan for ESRD patients, and ultimately the impact on the location of the dialysis centers.

DR. JOHNSON: So I think that there are two issues that you mentioned initially, which was about MA plans being able to pay the fee-for-service rates to dialysis providers, which I think would help bring down some of the total medical costs. So on that medical cost-to-revenue ratio you see a lot of plans come down. But the ESRD state rates is the amount that Medicare pays to MA plan, and so there still could be a variation across the

state. More plans, I think, would fall into the category where the average state rate covered more of their costs, but there still would be some areas of the state where the geographic spending is higher at an ambient level and the state average might be too low.

DR. PERLIN: Okay. I appreciate that. I'm just wondering about the fungibility of geography if you go to smaller units, in terms of optimizing the rate. I'm trying to think, if one wanted to optimize, there may be very strange behaviors around the geographic boundaries.

DR. JOHNSON: I think that's a good thing to be concerned about, and if the rate was to be smaller than the state level, I mean, I think that would be an improvement on that dimension overall, where there might be issues right now where the parts of the state with higher spending are less well covered for ESRD, MA plans of those areas is less, especially for the ESRD C-SNPs. There would be an incentive to enroll more ESRD enrollees in the parts of the state where the average spending is lower than the out-of-state average.

DR. CHERNEW: I think that was the end of Round 1, and so I'm going to jump in. Dana, was I right about

that?

MS. KELLEY: That's correct.

DR. CHERNEW: So we're going to go to Round 2 in a second, first to Jonathan and then to Amol, but let me make a general point about this. Some of this came up in the Round 1 questions about policy options, but you'll see what I'm hoping to get out of this Round 2.

My personal view is that a lot of these axis issues arise because the plans are finding it impossible to serve dialysis patients, and a lot of the reason why that's true is because they're paying higher than fee-for-service prices. And I think the core problem is that because there's simply not enough competition in the dialysis market because of the consolidation of the dialysis market, which makes it different than a lot of other places, which means the pricing part is very different.

My general view, and this is what I'd like to hear, is we need to solve those problems together. If we spend a lot of time promoting access, in other words, forcing plans to serve people in markets that just aren't profitable, without allowing them to narrow their networks, to do something else, which is hard to do, I think it's

going to be very hard to move forward.

So my personal view is while there is a lot to discuss, we're going to need to figure out how to do something, that I think Dana and Jon were talking about, which is not easy, with how to address the market power issues that are occurring in the dialysis market, which are making it complicated to run a good MA ESRD program. And I'm worried about trying to solve just one piece of this, because I think it's going to really have to come together more holistically.

So we're going to move on. I think, Jonathan, you're next. But what I'm looking for out of this is to understand if we should take snippets of problems to try and solve or try and address what I think is the root cause and then how to go from there.

Jonathan?

DR. JAFFERY: Yeah, thanks, Mike, for that intro, and again, Andy, thanks for the presentation and the excellent report. And I think, Andy, you mentioned at some point near the end of your presentation that this presentation explored a wide array of topics, I think that you said, which I think has been clear in our discussion.

And, you know, as I think through this and as I've listened to the questions and comments the other Commissioners have made, I think my thinking is very similar to what a lot of people have said. I'm going to see if I can tie those together and actually if it sort of aligns with what Mike was just saying about it's hard to kind of tackle each of these sort of separately. They really have some interplay.

And I think it's important to reflect on this population of patients and the whole ESRD payment system as being somewhat unique, as Bruce was talking about, the complexity of it. But it's a pretty unique set of patients in terms of what their needs are. I think we have a lot of examples of subsets of patients that get this kind of intensive treatment multiple times a week, for indefinite periods of time.

And the other pieces that are unique, I think within that it uses up a significant chunk of Medicare spending. Andy, you can correct me, but I think it's about 7 percent, and it's been at that rate, more or less, for as long as I can remember, so for probably decades.

And then the other very unique thing is what Mike and Dana and others have mentioned, is that there is

nowhere else where we have something this level of market consolidation, so we have a really different dynamic than anything else.

So as I think about that there are two or three things that had come up in my thinking. And so, first of all, in terms of patient access, most of the questions didn't talk a lot about the travel, the time and distance requirements, but I think that's pretty key. As you pointed out, while there are -- and Dana had commented about this too -- there are probably good reasons for us to try and encourage more home dialysis use than we have in this country. We're not going to be in a situation where it's appropriate for everybody. It just isn't.

And so we have a lot of beneficiaries who, especially in rural areas, may be traveling far distances, over difficult terrain, during periods of the year where there's a lot of inclement weather, and to get to a lifesaving treatment three times a week is just not really very easy, if you've got to travel far. So I think it's really important that we go back to our previous comments, as a Commission, to really support those things.

And that said, this gets into this interplay, if

health plans are forced to utilize, or to be able to have a broader network, and there are such intense market consolidation, then they may be at a disadvantage in terms of prices. So I do think that this is a situation that might be unprecedented but one that we should really explore, this idea of utilizing fee-for-service payments for this population.

I think the other thing that had come up in some of the comments or, rather, the Round 1 questions has to do with the variation. And so while we do have sort of an immediate concern and issue around the fact that at the state level it creates some distortion so that some plans may be getting overpaid and some getting underpaid, I think what I'm hearing and what I was concerned about coming is, you know, what exactly are the justifications broadly for this degree of variation? So there are wage index issues, and there's risk adjustment, and that certainly makes sense. But as we see across Medicare and health care spending broadly, a lot of this is utilization patterns that may not be justified. And if only about 30 percent of payments are for the treatments themselves, there's a lot of variation that we may want to think about how we move

towards more of a national benchmark. And this has a broad applicability for things we've talked about in MA plans overall and in ACOs. It is hard to understand why long term our targets for all these models should vary so widely and go beyond some of the labor costs and things that exist at the local and regional level.

So just to sum up, I think that in the short term, I certainly favor reinstating the time and distance requirements because I think that's a big issue for beneficiary access. And at the same time, even if we're thinking about longer term how to get at more of a national benchmark, there's opportunities to think about a smaller unit. The state-based payment may not be -- clearly has some issues.

I think in conjunction with that, exploring a cap on payments or using the fee-for-service payments as the model for payments here makes sense. And I do think longer term I'd love to explore some of the basis for the wide geographic variation in spending, and perhaps the ESRD population gives us an opportunity to explore that in a relatively contained number of beneficiaries where we have high spending, lots of utilization, and actually a fair bit

of clinical data that's collected already because of the ESRD requirements.

So it's definitely a complex topic, and, again, I think these topics do interact, intersect, and it's going to be hard for us to tackle them independently. But together hopefully we can come up with something pretty cohesive. So thank you for the opportunity to comment.

MS. KELLEY: Amol.

DR. NAVATHE: Great. Thank you. Andy, fantastic job with the paper and publication. Really good.

I'm thrilled that we're taking something like this on. I think this is sort of an exemplar of MedPAC looking forward and anticipating issues as they're potentially arising, which I think is really great.

There's clearly a lot of dynamic effects here that I think potentially are going to complicate things and may change some of the association and some of the relationships that we're observing. And so I think that piece is worth noting. I think it is noted in the paper. I think it's worth noting while we're speaking as far as any recommendations or further work that we do here.

First let me register my support for the

recommendations or the approach and discussion points that you've outlined here. I think I have a couple of additional points that are worth diving into perhaps.

So first is kind of getting a fact right, if you will. So I appreciate the innovative way that you have viewed encounter data to infer the prices on the dialysis side. I think it would be worth figuring out if there's a way to dig more deeply into that because what we're finding there is a linchpin for basically almost everything else, and I outlined up front that it's kind of hard to separate payment from network adequacy from these other issues, cost sharing, et cetera, et cetera. So that's really important.

The reason I say that is because I think there is some evidence, even some of our own work has shown that, in general, the adherence, if you will, to dialysis sessions, or the number of dialysis sessions per beneficiary are higher in Medicare Advantage, certainly in SNPs but also Medicare Advantage more broadly. And so if that is, in fact, true, then some of the assumptions that I believe that were used to get that 14 percent number may actually have some variance around them, which would actually drive toward smaller price effects, I believe, than we're noting.

So that may be hard to solve, but I think it's worth just throwing out there, given that it's so fundamentally important to all of our inferences. If there's anything that we can do to dig more deeply into that piece, I think that would be important.

The third piece I think is largely building upon a lot of what -- the questions I think we're hinting at in Round 1, and Jonathan also indicated, you know, in the figure where we look at the variation of the cost-revenue ratio, obviously a lot of variation. I think it would be really important to understand more deeply what that variation looks like, how much of that variation is within state, within market even, versus across market. Are there other MA contracts in the same area which have a lot of variation? And I think taking that one step further, which is what are the characteristics of those markets, what are the characteristics of those contracts that we can observe them in terms of enrollment of number of ESRD beneficiaries, in terms of, you know, rural versus urban. I think there's a lot of pieces here that are important, and since we're supporting -- registering our support for pursuing this work, I think additional data work there I

think would really help us understand better what some of the dynamics are and, therefore, you know, wrap our hands around this, if you will.

I think it's going to show us that rural areas are a particularly challenging piece here, at least any markets that include rural areas. That's one of the reasons that I think out of the box I'd support, as Jonathan does, the sort of network adequacy requirements reinstating the time and distance standards.

There's going to be clearly a trade-off here between trying to precision payment, if you will, versus sample size issues, and I think exploring that area or other geographic units is worth doing. I think even in light of Jon Perlin's concern around some of the potential gaming that could happen around those units, I think still there's probably a lot of benefit trying to see if we can get some of those payment elements more precise, if you will.

One broad point here is I think -- and this is perhaps touching a little bit on what Larry was talking about earlier on around, you know, having a different way that we pay here. I think the ESRD population is pretty

different than other populations and largely, you know, vulnerable to a lot of challenges, both clinical, socioeconomic, and otherwise. So I think having an approach here that is heavily focused on protecting the ESRD beneficiary is paramount, in my opinion. And so I support the Commission sort of kicking it in that direction, and whatever we can do, I think the analysis that you've done, for example, on the impact on cost sharing itself is also really important. It's very likely that the ESRD beneficiaries would hit the cost-sharing limit, you know, for the next month right away, and I think addressing those issues is also an important piece, I think, of stitching together payment elements that Mike commented on, but I think pulling all this together.

One thing that does strike me that I highlighted earlier on is that some of these dynamics could change actually considerably. So if we have an influx, an impressive influx of ESRD patients into MA that previously were not there, that could change some of the market power negotiating dynamics. And I think it's worth making sure we're on top of that. And so one thing I wondered here is, in addition to the sort of straw man potential

recommendations that we're putting here, could we also make a more concerted effort to push for greater monitoring around specific aspects? This is likely to be a moving target, and I think if we can push, you know, through whatever way, even if it's indirectly through Medicare, CMS, to more aggressively monitor this around specific dimensions that we are outlining in the paper, I think that could also do a lot of good.

So thank you so much. I think it's a really important population, really an exemplar example of an issue of looking forward here and anticipating what might be coming, and thanks for listening.

MS. KELLEY: Paul?

DR. PAUL GINSBURG: Thanks. You know, I think we had two lead comments that I thought were very valuable. I just wanted to bring up our way of -- you know, a context of this that ESRD patients in MA started very small because they had to be in the plans, and this has grown over time, and we'll have a major expansion. I think this changes a lot of things.

You know, as far as payment rates, we've said that it's the market power that leads to higher payment

rates in MA ESRD for dialysis, although Amol had really good comments about understanding this better. But I was thinking that we have lots of hospitals who serve Medicare patients who are very dominant in their markets. They may be the sole hospital. They may be a must-have hospital, like in Boston, you know, most employer-based coverage has to include the Partners hospitals in their networks; otherwise, it's just not attractive. And this would be relevant to MA enrollees as well. But you don't see these hospitals charging large premiums to MA plans for enrollees that use those hospitals. So there's something in -- I think the principle that the payment rates that fee-for-service Medicare has achieved, you know, should translate to the providers that MA plans use, and I don't think there's any exception to that, except for the dialysis treatments.

Another thought is that as far as the statewide, I think I misspoke before saying that it was a small number of ESRD enrollees. I think the problem and perhaps the reason why CMS went to state rates initially was that there just may not have been enough ESRD beneficiaries in fee-for-service to actually get accurate numbers at the county

level, which is our system. And I think by using a MedPAC area, there may very well be sufficient sample size -- or I should say population size to get accurate estimates. And I think that it's really in the interest of the program to line up MA ESRD as much as possible with the rest of MA practices in Medicare.

I'll just stop there.

MS. KELLEY: Brian, did you still want to comment?

DR. DeBUSK: Yes, thank you, Dana. I just want to mention again really meaningful work, great chapter, well written. I wanted to comment on the issue of MedPAC units.

First of all, I think they should be used here in the ESRD payment calculations instead of state-level data. But I also wanted to advocate for using MedPAC units broadly throughout MA, because I think -- and this is my inner Jon Christianson speaking, but as MA penetration rates get higher and higher in counties, the fee-for-service data in highly penetrated MA counties is going to become more and more fragile. So I think this idea of moving the MA ESRD payments and MA in general toward MedPAC

units is a huge step in the right direction.

I also do favor looking at network adequacy and looking at some of the cost-sharing provisions just to make sure that the MA plans aren't dissuading MA enrollment. But the one thing I would ask is I hope as we do this, we make sure we're not overconstraining these programs, because in such a highly consolidated market, forcing network adequacy requirements, forcing new cost-sharing provisions or more restrictive cost-sharing provisions, I'm just afraid we might be overconstraining this problem. And as we do it, hopefully we could explore -- and I don't know if there's a precedent for this. I don't know if there's any type of statutory authority for this. But I wonder if dialysis providers that provide a certain mix -- provide services to a certain mix of Medicare patients or some other constraint, if they could be required to accept rates that are closer to Medicare rates for these MA patients.

You know, Bruce and I have talked about this before about MA being able to access Medicare rates for out-of-network patients, but I don't know what's out there, if there's as pathway to getting these dialysis facilities to accepting Medicare rates or something closer to Medicare

rates for MA.

That was it. Thank you.

MS. KELLEY: Pat.

MS. WANG: Thanks. I echo everybody's praise for your work, Andy. This is a really important paper, and it's a really important topic for us to be taking up at the dawn of greater enrollment in MA of ESRD patients.

So as a basic principle, many of the dilemmas that have been described and the relaxation of time and distance requirements are all sort of circling around this issue of, you know, the costs are too high, the payments are too low, and so people are responding in different ways to try to give plans more flexibility or what have you. I'm glad we're talking about this because the answer to this issue is for payments to be accurate. It's just a fundamental principle. Payments have to be appropriate for the members served, and I think some of these issues start to fall away.

On the issue of statewide costs, I endorse what others have said. I think it's very important to see whether or not that can be broken down into smaller units. It's not just the dialysis costs. It's all of the other

input prices of physician services, hospital services, ambulatory care. I mean, there's just a lot of variation, I think, in the input price in addition to differences in utilization that should be explored, and I just think the cost variation across a gigantic state with potentially tens of millions of people in it, or even smaller, just really needs to be broken down to a smaller level.

On the issue of the dialysis centers, I think it's a very important conversation, and the requirement that ESRD beneficiaries have access two to three times a week to life-saving treatment is, in my mind, very similar to requiring access to inpatient services for which we have default rates. Brian referred to it as "out of network." But the existence of a default rate in the absence of a negotiated rate, the default rate being Medicare fee-for-service, brings people to the table, and I think between that and the example that Andy gave of regional PPOs, there might be justification in this case to employ that principle. It's just consolidation coupled with the essentiality of access to these services really might justify that sort of approach.

I just want to thank you for the work, Andy, and

I think that there's a lot more to be done. Thanks.

MS. KELLEY: Larry.

DR. CASALINO: Yeah, I have a comment that leads to a question. The comment is on the time and distance, time and distance standards. This is different for dialysis patients than many other beneficiaries, I think. It's not just a matter of convenience. I don't know how many Commissioners and staff know somebody who was on dialysis. My mother was on it for ten years. And particularly in elderly beneficiaries, dialysis sessions are not a trivial thing. There's massive fluid and electrolyte shifts, and at the end of the session, you often don't feel very well at all, really for the whole day, and certainly not in the hours immediately after the session. Having to drive some extra distance, especially if the weather is bad, is potentially life-threatening for the beneficiary and for anybody else who happens to be on the road or near the road. So it's not just a question of convenience. It's really a question of life and death in a way. So I recognize the problems with reinstating the time and distance standards, but I think I would favor that.

But my question is this -- a large part of the

conversation that we're having we wouldn't be having and Medicare wouldn't have to worry about if there wasn't such consolidation among dialysis providers. And so my question is a general one for Jim, for Mike, for whoever. If MedPAC identifies a problem or problems caused by consolidation, one approach is to kind of twist ourselves in knots trying to deal with that and accepting the consolidation as an accepted fact. From a broad policy point of view, which I realize exceeds MedPAC's powers, your solution should be to not have so much consolidation.

So if MedPAC identifies consolidation as a problem, what, if anything, can MedPAC do or who can MedPAC talk to, what can MedPAC publish? Obviously, this is a job for the antitrust agencies, but this problem is not unique to dialysis, but it's particularly acute in dialysis. What can MedPAC do, if anything, when deleterious effects of consolidation are noted?

Jim, I'd love to hear your comments on it.

DR. MATHEWS: Well, I was hoping Mike would jump in here.

DR. CHERNEW: Well, I was hoping you would. Actually, I was muted when I tried to say something, and

then I realized that the better part of discretion is to keep yourself on mute.

So I think that's a really good point, Larry, and I think this is true in a lot of areas. The honest answer is I don't think we have a ton of direct levers beyond our general contacts with people in the world and shedding light on the issue. We can deal much more easily with how Medicare pays when the market powers affecting Medicare per se, and this seems to be one area where that's true. I see many fewer levers for dealing with broader antitrust issues. Frankly, we're not the only agency that has that problem. Once there's a lot of consolidation having happened, even the agencies you mentioned have a hard time figuring out what to do to unravel them.

And this is a much bigger issue that we can shed light on, particularly how it affects the Medicare program and the Medicare beneficiaries, but I don't see an easy answer. It's certainly something that we will discuss, and having the discussion here about the role of price, and Paul's point about well, why is it here and not in hospitals, is a useful continuation of our discussion, which we will have.

That's why you should have gone first, Jim.

MS. KELLEY: Shall I move on?

DR. CASALINO: Jim, are you going to respond?

DR. MATHEWS: No. I have nothing more to add.

DR. CASALINO: Then just very briefly, one function I think MedPAC can serve is to try to be an early warning system about consolidation, because Mike's right, I think. Once there is a lot of consolidation even the antitrust agencies can't do very much about it, generally speaking.

So I think, as a general principle, if MedPAC identifies areas in which consolidation looks like it's becoming a problem, it would be interesting to know. Surely we can put that in a report, but are there other actions MedPAC can take -- letters to Congress, letters to the antitrust agencies. And then once there is established consolidation, again, perhaps that could be called out more clearly in reports, and then again there's the letter to Congress, or I don't know if it's beyond the balance for MedPAC to write letters to antitrust agencies.

But let's face it. Consolidation is one of the responses of the health care system, and to treat it as an

accepted fact, especially when it isn't already a fact, as it is now in dialysis, and then just try to work around it in ways that are unnecessarily convoluted because of the consolidation, I think is maybe not the best way to go.

DR. MATHEWS: So I guess maybe I will add a comment or two here. First and foremost, you know, in the conduct of all of our work, when we -- and by "we" I mean I -- try to be cognizant of our statutory mandates. You know, we are asked to weigh in on issues specific to Title XVIII of the Social Security Act, and as part of our mandate we are required to make examinations of how the Medicare program interacts with the outside world.

So it's not a question that we can only narrowly focus on Medicare, and we need to be cognizant of the impacts of external forces, such as consolidation, on the program. But, you know, our statutory charge is the Medicare program, and I am not sure we necessarily have the leeway to start writing letters to the FTC or other entities with antitrust obligations and authorities.

I agree with Mike that in instances where we do see trends in consolidation, and particularly instances where those trends are at least influenced by Medicare

payment policies, we do report them out and we develop payment policies to address them. Over the years we have observed successive waves of hospital acquisition of physician practices -- cardiology, orthopedics, now oncology -- and in the course of observing those trends we have identified site-neutral payment policies as a solution that makes it less lucrative for the parties involved to engage in those transactions.

And obviously we can continue to do those kinds of policy responses, but I think we need to be very, very cautious about being the entity that serves, you used the phrase earlier, "early warning system" for Congress, for policymakers in general, about these broader market forces of which Medicare is influenced by and subject to, but not necessarily the driver.

DR. CASALINO: Just one quick response here and then I'll shut up. I agree that when we see Medicare policies that seem to be promoting consolidation that we want to call that out, and we have, right?. But it does seem to me it's symmetrical. If we see consolidation that affects Medicare, probably we should at least call that out pretty explicitly. And I'll stop there.

DR. CHERNEW: So just to give everybody a check as we hit noon, I don't get the full list. I have three people on the list. We have 15 minutes. Dana, your turn to call the next person.

MS. KELLEY: We have four people on the list. Bruce is next.

MR. PYENSON: Oh, thank you. I agree with the comments that the other Commissioners have made. I would just want to reiterate my support for looking at changing the network rules so that dialysis centers could be considered out of network and MA plans could take advantage of the fee-for-service rates there. I suspect that our analysis of the encounter data is perhaps dramatically understating the higher amount that Medicare Advantage pays the DOs.

I would identify the Medicare cost reports of the dialysis organization as another potentially valuable source for insight.

I do want to comment on the benefit design issue. My impression is that a large portion of patients, Medicare beneficiaries receiving chronic dialysis, are dual eligibles, and the benefit design issues for them are

perhaps different.

I would also like to suggest that, anecdotally, dialysis organizations very frequently waive member cost sharing. So although I think the discriminatory benefit design concern is real, it perhaps take a different dimension for patients receiving dialysis than, say, patients on chemotherapy who might be subject to high co-insurance for Part C drugs.

But overall I think moving ahead on looking at, as Mike characterized it, the supply problem, would be very fruitful, and I think it might even be a model for dealing with other kinds of concentration in other areas.

So, Andy, terrific work. You've got lots of followers here. Thank you.

MS. KELLEY: Jon Perlin.

DR. PERLIN: Yeah, let me add to the accolades for a really thoughtful piece of work, and also begin with very clear support for the recommendations.

I would just note that my Round 1 question about how policy could incentive strange geographic behaviors, in an attempt to resolve issues with network adequacy, particularly time and distance, it was really aimed at

concerns that you could actually yield a different set of strange network adequacy challenges, and Larry Casalino spoke eloquently, to the clinical fragility of these patients. Particularly, if you think about going to a dialysis center, the point that the patient is going to the dialysis center, they are already feeling ill because they're carrying toxins, and when they leave the dialysis center they're feeling poorly because they've just had these massive fluid shifts. So distance is just critical.

With that in mind, I think we do need to use the smaller geographic areas so we can assure the network adequacy. I think this issue of consolidation may actually be understated. On page 1 of the reading materials, there is the comment that 74 percent of the outpatient dialysis centers are operated by two companies. That does not include the percent where the payment doesn't go directly to those centers but, in fact, to nominally some other entity that, in fact, is contracting with one of the two companies that are the substantially vertically integrated dialysis providers.

So this is an issue that we're tapping into. Out of network or other mechanisms for fee-for-service may be

the most practical approach.

And third, I just wanted to make a point that, you know, one of the good things that occurred in the last year, folks like Jonathan Jaffery may know the details better than I might, was the Executive order that really facilitated living donor transplant and mechanisms to increase transplantation. You know, being able to get a transplant, when possible, is freedom from all of the liabilities that we're trying to address here, in terms of assuring adequacy of dialysis. Don't get me wrong -- there will be a group of patients who won't qualify, don't qualify, don't want, can't take transplantation.

But I would encourage us, in not this section but in our broader policy, to think about how our policies fall together such that there is incentivization toward the most liberating form of renal replacement, which is transplantation.

So, in summary, I support this approach, would be on the lookout for unintended consequences based on the sections. If we can overcome that through fee-for-service or rate access, that would be temporizing and really finally encourage a broader policy perspective. Thanks.

MS. KELLEY: Jaewon.

DR. CHERNEW: Thanks, Jon. We have -- yeah, we have Jaewon and then I think Dana, you're going to finish the session, because we're just about at the time. Jaewon.

DR. RYU: Yeah. So as far as the alternative geographic unit I agree with many of the comments that have been said.

I think the network adequacy and the time and distance reinstating, I completely, or I should say Larry and Jon Perlin's comments totally resonate with me as far as the clinical importance to the beneficiary for the time and distance. But I do hesitate here, and it has to do with -- and I think you referenced it in the chapter -- the balance of negotiating leverage between the plans and the dialysis providers. I think Jon Perlin used a great term, "temporizing" measures to kind of mitigate or offset considerations along those lines, whether it's, you know, Dana's suggestion or on the fee-for-service rates. I think in the absence of some other solution like that I do get concerned, because I think what we could have as an unintended consequence, because there isn't the right balance in that negotiating leverage, I think you could

have consolidation in the dialysis centers space lead to consolidation in the MA plan space.

Because the nature of who's going to be able to contract with the dialysis carriers at a sustainable level, I think that's something we just need to think through. And again, that's in the absence of some other solution like, you know, what Dana has proposed, and others. But if we don't have something like that, I think that's more concerning.

MS. KELLEY: Dana?

DR. CHERNEW: Thanks, Jaewon.

DR. SAFRAN: Yeah, thanks, and I'll be very, very brief. You know, Jaewon's comments just before me are interesting and I think thought-provoking. I would still weigh in with support for reinstating the time and distance standards. You know, I just am very concerned about attestation is the mechanism for ensuring network adequacy.

And, you know, my question earlier indicated, and as some of my colleagues have pointed to, I would really think that we should pursue this option of MA plans being able to leverage the Medicare fee-for-service negotiated rates, given both the consolidation and the small numbers

issue that they face.

So those are my comments. Thank you.

DR. CHERNEW: Great. Deep breath. This is the going once, going twice comment.

Okay. So we've had a lot of discussion this morning about two really important issues. In fact, I think as these meetings go, we were early on in a lot of these chapters, which means there's a lot of different directions for us to go back and grapple with, which we will do.

My summary for this particular session is, we really do need to think holistically about how the access and the payment models work and overall the role of MA for ESRD, given these market dysfunctions, and we will do that. I do think it's important to make sure that beneficiaries have access to the care that they need, but we have to figure out how to do that in an efficient way. I probably should have said the exact same thing for the separately payable drugs discussion.

But I will leave this with just a thank you to the staff for outstanding work again. Thank you to all of my fellow Commissioners who, as always, provide insightful

comments that we will have to really take to heart. And I do want to say to the public there are many ways to reach out and give your comments to us. You can do it through the website. You can reach out by email, I think, to the staff. We very much do want to hear feedback from those of you that have been listening to this discussion. And these are the beginning of the chapters where we are going, and so we will continue, I think, on both of these paths for separately payable drugs and MA and ESRD, so you will certainly hear more from us.

So with that I will say thank you again to my Commissioners. Have a wonderful Tuesday. See, that's a joke because I said it was Friday at the beginning of this meeting. It isn't, by the way. But have a wonderful Tuesday afternoon, and we will all be in touch. Thank you.

Jim, any closing comments?

DR. MATHEWS: Nope. Do it again in December.

DR. CHERNEW: Stay safe.

[Whereupon, at 12:13 p.m., the meeting was adjourned.]