MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Thursday, January 12, 2023
10:00 a.m.

COMMISSIONERS PRESENT:

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AGENDA PAGE

P R O C E E D I N G S

[10:00 a.m.]

DR. CHERNEW: Hello, everybody. For those of you at home, thank you for joining us. This is our January MedPAC meeting so first, Happy New Year. Second, as is always the case, this is one of the more important meetings as we vote on the update recommendations. We have discussed the recommendations at some length, and so what we're going to do today, again as is the norm, is we're going to go through each of the sectors in somewhat different fashion. But we're not going to start with hospitals, and for hospitals and physicians we will have an abbreviated session, followed by a set of votes.

So I'm going to turn it over to Alison to take us through the material.

MS. BINKOWSKI: Thanks, Mike, and good morning.

The audience can download a PDF version of these slides in the handout section of the control panel on the right-hand side of the screen.

This and the subsequent payment adequacy presentations recap our December presentations and have been updated with newer data. For each sector we have

updated our margin projections to reflect CMS's most recent market basket forecasts. However, in most sectors, this newer data did not materially affect our projected margins.

As requested in December, this presentation also includes more detail on potential options for transitioning towards better targeted payments to Medicare safety-net hospitals. Other additional details requested by Commissioners during the December meeting are noted in the updated mailing materials.

Before turning to our assessment of the adequacy of fee-for-service Medicare payments to general acute care hospitals, we first provide some context. To reimburse general acute care hospitals for their facility costs, fee-for-service Medicare generally sets prospective payments rates under the inpatient prospective payment systems and the outpatient prospective payment system.

In 2021, the fee-for-service Medicare program and its beneficiaries paid IPPS hospitals $107.9 billion dollars for inpatient stays, as well as an additional $8.3 billion dollars in uncompensated care payments. The fee-for-service Medicare program and its beneficiaries also paid hospitals $49.9 billion dollars for outpatient

services, as well as an additional $16.4 billion for separately payable drugs.

As a reminder, to assess the adequacy of Medicare payments, in each sector we examine indicators in four different categories: beneficiaries' access to care, the quality of care, provider's access to capital, and Medicare payments and providers' costs.

As we described in December, despite the coronavirus pandemic, for hospitals our four categories of payment adequacy indicators were generally positive in 2021, though preliminary data suggests some indicators declined in 2022.

I won't repeat all of the payment adequacy indicators, but some highlights include fee-for-service Medicare beneficiaries maintaining good access to hospital care, including a positive marginal Medicare profit of 8 percent on inpatient and outpatient services; mixed quality relative to 2019, including declines in patient experience measures; a record high operating margin in 2021 of 8.7 percent, though preliminary data suggests hospitals' operating margin declined in 2022 closer to the 2019 level and a minority of nonprofit hospitals' bonds were

downgraded in 2022; and an increase in IPPS hospitals' aggregate Medicare margin in 2021, but we project the 2023 Medicare margin will decline to -10 percent, reflecting, in part, higher than expected input cost increases.

With that summary in mind, we turn to considerations for the draft recommendation.

In considering these payment adequacy indicators and their implications for the draft recommendation to update 2024 hospital payment rates, the draft recommendation seeks to balance several objectives. These include to maintain Medicare payments high enough to ensure beneficiaries' access to care; to maintain payments close to hospitals' costs of efficiently providing high-quality care; to maintain fiscal pressure on hospitals to constrain costs; to minimize differences in payment rates across sites of care, consistent with our site-neutral work; and to avoid implementing large, across-the-board payment rate increases to support a subset of hospitals with specific needs.

To balance these objectives, the draft recommendation reads:

For fiscal year 2024, the Congress should update

the 2023 Medicare base payment rates for general acute care hospitals by the amount specified in current law plus 1 percent.

We estimate that the draft recommendation will increase Medicare spending by more than $2 billion in 2024 and by more than $10 billion over five years, relative to current law. We also expect this recommendation will help maintain general acute care hospitals' willingness to treat Medicare beneficiaries and beneficiaries' access to care. However, this update may not be adequate for Medicare safety-net hospitals with a poor payer mix.

DR. STENSLAND: The draft update recommendation Alison just read applies to all general acute care hospitals. However, some hospitals have unique challenges, such as high shares of low-income Medicare patients. These hospitals may need additional assistance, because, as we discussed in November and December, the current system of disproportionate share and uncompensated care payments do not adequately address issues associated with low-income Medicare beneficiaries.

A new Medicare safety-net payment system could improve financial security for hospitals with challenging

payer mixes that include high shares of low-income Medicare beneficiaries.

There are five potential concerns with the mechanisms used to distribute current safety-net payments. First, DSH indirectly subsidizes Medicaid. Higher shares of Medicaid patients results in higher Medicare inpatient payment rates. Second, DSH shares are negatively correlated with Medicare shares. This means that hospitals with high shares of Medicare patients tend to receive lower DSH add-on payments.

Third, DSH payments are inpatient-only. Fourth, last month the Commission discussed focusing Medicare payment on care for Medicare beneficiaries. Large uncompensated care payments violate this principle when they are not tied to the volume of Medicare patients served. Fifth, current uncompensated care payments are distorted to paying greater amounts to hospitals that have few fee-for-service patients and relatively more Medicare Advantage patients.

To address these concerns we developed the Medicare Safety-Net Index that we discussed last month.

The Medicare Safety-Net Index is computed as the

sum of three factors. First the hospitals' LIS share, meaning the share of inpatient and outpatient Medicare claims that are for beneficiaries receiving the low-income subsidy. Second, uncompensated care costs as a share of total revenue, and third, one-half of the Medicare share of inpatient days. The rationale for this particular formulation of the index is discussed in the June 2022 report to the Congress.

The purpose of adding in Medicare shares is to acknowledge that Medicare profit margins are substantially below where they were when the DSH program was enacted in 1985. It also eliminates the Medicare subsidy of Medicaid and aligns Medicare funds more directly with the costs of serving low-income Medicare beneficiaries.

This brings us to the draft Medicare safety-net recommendation. In substance it is identical to what we presented in December, but the wording has changed a bit to improve clarity. It reads:

In fiscal year 2024, the Congress should begin a transition to redistribute DSH and uncompensated care payments through the Medicare safety-net index; add $2 billion to the Medicare Safety-Net Index pool; scale the

fee-for-service MSNI payments in proportion to each hospital's Medicare Safety-Net Index and distribute the funds through a percentage add-on to payments under the inpatient and outpatient prospective payment systems; and pay commensurate MSNI amounts for services furnished to MA beneficiaries directly to hospitals and exclude them from MA benchmarks.

The change to the Medicare Safety-Net Index, including adding $2 billion in MSNI funding, would increase Medicare spending by between $750 million and $2 billion in 2024, and by $5 to $10 billion over five years.

We expect the recommendation to improve the financial stability of some safety-net providers.

In addition, as we said in our June 2022 report, the safety-net add-on should not affect beneficiary cost sharing, the idea being that beneficiaries going to Medicare safety-net hospitals should not pay more in cost sharing than patients going to hospitals that serve few low-income patients.

Most hospitals will see an increase in Medicare revenue under our recommendation, but there will be material reductions in payments to some hospitals that

currently receive high Medicare uncompensated care payments but serve few Medicare patients. Therefore, the policy should be transitioned over a number of years.

The transition to the MSNI payments could be eased by two aspects of the policy we have discussed. The first is that the full $2 billion of additional funding would be included in the MSNI pool of dollars in the first year of the program.

The second is that the shift of funds currently distributed as DSH and uncompensated care payments to the MSNI would occur slowly over several years, such as three to five years. Alternatively, a transition could be managed through a stop-loss policy so that no hospital would experience changes, positive or negative, in Medicare payments of more than 5 percent in any one year due to the transition to the MSNI.

Both approaches would allow time for the hospitals facing the most substantial revenue reductions to try and augment revenues from existing sources and request financial support from state and local governments, as warranted. The portion of these hospitals that have high cost structures may also be able to improve efficiencies.

So that brings us to a summary of the two recommendations for you to vote on. I will now pass it back to Mike to kick off your discussion.

DR. CHERNEW: Jeff, thank you, and I think Jonathan, you are first in the queue. Just to remind everybody, we're going to get a set of comments, then we're going to go around for just a roll-call vote. Jonathan.

DR. JAFFERY: Thank, Mike, and thanks, Alison and Jeff, and everybody. This was a really well-done chapter and presentation.

I just wanted to make a couple of quick comments about something that's sort of in the broader sense I think I still have some concerns about that we talked about at previous meetings. It sort of gets to some of the stuff on Slide 4 about some of the considerations, so this is maybe about some other principles, and it really gets to things that Jaewon and others have talked about for a long time now, about leading versus lagging indicators.

So I think about some of the things on here, several of the bullet points, efficiently providing care, things like fiscal pressure on hospitals concerning costs. I mean, I think most hospital operators would argue that

those are here. They're not even lagging at this point. And I think a big one for me is that first one, about ensuring beneficiary access to care, and I have a lot of concerns about the leading versus lagging pieces there.

On the previous slide you show the occupancy at 65 percent, and as we know across the board this is not true. And I know that's not what you're saying, but it really does come into play for access to care for a lot of people, for a lot of hospital leaders. And I'll talk about being above 100 percent capacity. And in particular, when we think about the recognition of the need to maintain access to capacity, I guess I'm not seeing a big string of how these things are real. There are struggles between these things. Maintaining capacity and being super-efficient, those are tradeoffs that we have to think about, particularly as we fill this public space more for health systems.

But that said, I also really appreciate the language that has been added to the chapter around, you know, that sort of speaks to policymakers' need to take into a holistic view of what's happening in the marketplace. So thanks for that, and I look forward to the

rest of the discussion.

DR. CHERNEW: Lynn.

MS. BARR: Thank you for this incredible work. I just have a couple of quick comments. I think in the chapter it would be important to reiterate how we got here, that the DSH formula doesn't work. I saw in a lot of comment letters people were like supporting DSH. We couldn't differentiate the hospitals using DSH, and I think putting that data back up in the front of the chapter is really important to go this is how we got here. DSH doesn't work.

And I agree we shouldn't support Medicaid and uncompensated care, but I agree with Jonathan's comments. We have to worry about access. And I particularly continue to be concerned about the government hospitals, and would suggest that there is some way to just exempt them from this program, you know, and let things figure themselves out and then maybe we can think about what we have to do with the government hospitals later.

But I'm very in support of this. Thank you very much for this incredible work.

MS. KELLEY: Greg.

DR. CHERNEW: And Greg.

MR. POULSEN: So Mike and Jim received a suggestion from me earlier, and some might have called it a diatribe, but it essentially wanted to call out the impact that docs and hospitals have had over this last year, both from the residual COVID issue but also because of really unusual levels of input cost increases. And I encourage that we include that in the chapter so that people would recognize two things, one, that we recognize how challenging it has been, and two, that the recommendation that's being made takes that into consideration, which I think is really important. And I think that they received that the way I meant it, so thank you for that. And with that I think that we are in a good place.

The other thing I just wanted to mention is regarding the safety-net issues. Different communities approach meeting the needs of the underserved in different ways, and I think that the move that is being proposed here is effective in more accurately reflecting the different approaches that are being made, all of which may have different values but aren't equally recognized in the DSH approach. So I like this very much.

MS. KELLEY: Amol.

DR. CHERNEW: I was just going to say Amol.

[Laughter.]

DR. NAVATHE: I love being called on twice.

So thanks for this great work. I also think we're landing in a terrific place, and I agree with my fellow commissioners really. I think Greg's point around acknowledging the uncertainty here and the impact, particularly initially through COVID and now on input costs, is certainly important. And I think we did obviously take that into account in making this recommendation, so it would be nice to really make that very explicit as well as Jonathan's point, which is there is uncertainty here. We do have this tension around leading and lagging indicators. And so ongoing work, obviously, will, monitor that over time, which is, I think, really fundamentally important.

On the safety-net side, I am certainly very supportive of the safety-net work. It's an important area. Obviously, the hospitals here provide really fundamentally important care.

I think one of the pieces that I just wanted to

highlight that I feel is a very, very major improvement in terms of how these funds end up getting targeted and reaching the safety-net is that there is a direct incentive to care for patients who are in the safety-net, or in the formula, if you will, or low-income Medicare beneficiaries. And that was not the case in the previous system, and we should want that. We shouldn't want hospitals and physicians, and whomever really, to have the marginal incentive to say that if I care for this patient, I will be financially better off than I would if I didn't. And that was not the system, or is not the system that's currently in place.

So I think that point, while it is, to some extent, a subtle policy point, is a major point in terms of what we're trying to accomplish. So I just wanted to highlight that again as a really major improvement and I'm very glad to see that move forward.

DR. CHERNEW: Dana and then Robert.

DR. GELB SAFRAN: Yeah, thanks. Just a brief comment. I am also very supportive of this work. I feel good about where we're landing.

The comment I wanted to make was building on

something that Lynn was saying in her suggestion, which I really support. I'm really glad that we made the change, which might seem small but I think is extremely important, to the labeling of our safety-net index to a Medicare Safety-Net Index, and with Lynn's suggestion about really putting forward some of the data about why DSH doesn't work for this.

I think the flip side of that, which I would really encourage us to make explicit, is that we aren't saying that the hospitals that are the gap between our index and the DSH don't need additional support. What we're saying is that there has been a cross-subsidy that happens through Medicare when we use DSH, and that's something we can't do anymore.

I think making that really explicit sort of calls out the policy problem that's out there to be dealt with, that has been kind of riding along unaddressed because Medicare has been kind of absorbing that. So I just think it's worth calling out that cross-subsidy issue, and that this is a very important policy issue. We're not backing away from it but it's not Medicare's to solve. Thanks.

DR. CHERNEW: Robert.

DR. CHERRY: Thank you. I just wanted to let everyone know that I enthusiastically support the Medicare SNI model. It's not perfect, as we know, but it goes a long way to optimizing access to care among the most vulnerable population.

As we start to optimize the model over the years, again like some other Commissioners, I feel we should focus on public hospitals that are already serving in a safety-net capacity but are not fully integrated into the model. Otherwise, this is a really good step forward.

DR. CHERNEW: Thank you.

I'm going to pause for one second to see where everybody is.

All right. That was the last comment. I appreciate all of them. I think they very accurately capture the tone that both I feel and that we had in our previous discussion in December and hopefully where the chapter is getting to. There's still edits ongoing to the chapter to reflect some of these, and they have been quite helpful. So thank you for the comments that were sent in the interim.

Dana, do you want to go? We're going to do --

we're going to do this Recommendation 1 roll call, Recommendation 2 roll call. That's the process.

MS. KELLEY: Okay. For Recommendation 1, which reads "For fiscal year 2024, the Congress should update the 2023 Medicare base payment rates for general acute care hospitals by the amount determined under current law plus 1 percent."

Voting yes or no. Lynn?

MS. BARR: Yes.

MS. KELLEY: Larry?

DR. CASALINO: Yes.

MS. KELLEY: Robert?

DR. CHERRY: Yes.

MS. KELLEY: Cheryl?

DR. DAMBERG: Yes.

MS. KELLEY: Stacie?

DR. DUSETZINA: Yes.

MS. KELLEY: Marjorie? Marge. Sorry. Just reading the list.

MS. GINSBURG: Yes.

MS. KELLEY: David?

DR. GRABOWSKI: Yes.

MS. KELLEY: Jonathan?

DR. JAFFERY: Yes.

MS. KELLEY: Kenny?

MR. KAN: Yes.

MS. KELLEY: Amol?

DR. NAVATHE: Yes.

MS. KELLEY: Greg?

MR. POULSEN: Yes.

MS. KELLEY: Betty?

[No response.]

MS. KELLEY: Betty, why don't you give us a thumbs-up? Perfect. Or down, of course. Thank you for the thumbs-up.

[Laughter.]

DR. CHERNEW: Betty was caught in the flight situation that arose yesterday, and so, hopefully, she will someday get here. But, in any case, thank you, Betty. We are sorry for your travel hazards.

MS. KELLEY: Wayne?

DR. RILEY: Yes.

MS. KELLEY: Jaewon?

DR. RYU: Yes.

MS. KELLEY: Dana?

DR. GELB SAFRAN: Yes.

MS. KELLEY: Scott?

DR. SARRAN: Yes.

MS. KELLEY: Mike?

DR. CHERNEW: Yes.

MS. KELLEY: All right. For the second recommendation, which reads: "In fiscal year 2024, the Congress should begin a transition to redistribute DSH and uncompensated care payments through the Medicare safety-net index, or MSNI; add $2 billion to the MSNI pool; scale fee-for-service MSNI payments in proportion to each hospital's MSNI; and distribute the funds through a percentage add-on to payments under the inpatient and outpatient prospective payment systems; and pay commensurate MSNI amounts for services furnished to MA beneficiaries directly to hospitals and exclude from MA benchmarks."

Voting yes or no. Lynn?

MS. BARR: Yes.

MS. KELLEY: Larry?

DR. CASALINO: Yes.

MS. KELLEY: Robert?

DR. CHERRY: Yes.

MS. KELLEY: Cheryl?

DR. DAMBERG: Yes.

MS. KELLEY: Stacie?

DR. DUSETZINA: Yes.

MS. KELLEY: Marge?

MS. GINSBURG: Yes.

MS. KELLEY: David?

DR. GRABOWSKI: Yes.

MS. KELLEY: Jonathan?

DR. JAFFERY: Yes.

MS. KELLEY: Kenny?

MR. KAN: Yes.

MS. KELLEY: Amol?

DR. NAVATHE: Yes.

MS. KELLEY: Greg?

MR. POULSEN: Yes.

MS. KELLEY: Betty?

[No response.]

MS. KELLEY: Okay. That was a thumbs-up from Betty.

Wayne?

DR. RILEY: Yes.

MS. KELLEY: Jaewon?

DR. RYU: Yes.

MS. KELLEY: Dana?

DR. GELB SAFRAN: Yes.

MS. KELLEY: Scott?

DR. SARRAN: Yes.

MS. KELLEY: Mike?

DR. CHERNEW: Yes.

MS. KELLEY: Okay. Thank you very much.

DR. CHERNEW: All right. You know, I appreciate the clapping. It is a -- I will say, since we have a second before, about the transition, we'll take a quick break and transition to physicians. But for those at home, this has been, as I knew going into the year, one of the most challenging years for both update recommendations and I think for the industry writ large. So I just want to give a personal thanks to the Commissioners and their attention to this and the staff and their work on this as we work through what I think is a really -- to use a Poulsen term, turbulent challenging time for providers, and we really are aware of that and trying to do a balance of

very difficult environment, given the tasks that we have at hand. And I think we've ended up acknowledging both the importance of supporting hospitals that serve a lot of low-income Medicare beneficiaries and because we're doing basically -- adding to the update, recognizing that there is some more resources that are needed in the hospitals. So, actually, we've tried to balance all of that.

So, again, thank you all for your help and attention and comments on this, and I do think we've ended up at a quite reasonable place. So I do appreciate that.

So let's take a break. We're a bit ahead of schedule, but that's fine for me. Let's take a five-ish-minute break, and we'll come back, and we will do the physician stuff. And, again, Jeff and Allison, really thank you.

[Recess.]

DR. CHERNEW: Okay. Welcome back, everybody. Thank you. We are now going to continue our update recommendation work, moving to the physician and other health professional services chapter. And so, with that, I am going to turn it over to Rachel.

MS. BURTON: Good morning. In this presentation,

Geoff and I will recap two draft recommendations related to payments for physicians and other health professionals.

I will talk about what percent to update 2024 payment rates by, and Geoff will talk about new safety-net add-on payments.

The audience can download an abbreviated version of these slides in the "Handout" section of the webinar's control panel, on the right side of the screen.

To give some quick background, Medicare's physician fee schedule pays for about 8,000 types of clinician services, delivered in a wide variety of settings -- including in hospitals, nursing homes, and doctors' offices. 1.3 million clinicians billed Medicare's physician fee schedule in 2021, including a variety of types of non-physicians.

Spending by the Medicare program and its beneficiaries on clinician services totaled $92.8 billion in 2021, which is up from $84.7 billion in 2020 but still less than was spent in 2019.

To ensure clinicians remained viable sources of care during the pandemic, Congress provided them with pandemic relief funds that more than offset their losses

from Medicare and other payers.

This graph shows the cumulative effect of Congress' changes to clinician payment rates since 2017, including temporary increases relative to prior law that were enacted two weeks ago in the Consolidated Appropriations Act, 2023.

We only reflect updates that are specified in law. We do not capture the additional adjustments to payment rates that CMS makes to maintain budget neutrality when payment rates for individual codes are increased or decreased.

This graph shows that in recent years Congress temporarily increased payment rates due to the pandemic, and also in an attempt to offset payment rate reductions that occurred when CMS raised payment rates for evaluation and management visits.

The two arrows in our graph show Congress' recently enacted, temporary increases for 2023 and 2024. These increases each apply for only one year and will cause payment rates to decline more gradually than they otherwise would have under prior law.

This slide recaps our assessment of the adequacy

of payments for clinician services.

Access to care appears good, with beneficiaries continuing to report access that is comparable to, or better than, the privately insured.

Quality of care is not factored into our assessment, due to the pandemic.

In terms of clinicians' revenue and costs, the growth in clinicians' input costs, as measured by the Medicare Economic Index, or MEI, is projected to grow rapidly in 2022 through 2024, at rates not seen for many years. CMS' latest projections are that the MEI will grow by 4.7 percent in 2022, 3.9 percent in 2023, and 2.9 percent in 2024.

Payments per beneficiary for clinician services declined in 2020 but fully rebounded in 2021. Commercial payment rates for clinician services continued to be higher than Medicare rates in 2021. And physician compensation from all payers grew by 3 percent per year, on average, from 2017 to 2021.

In summary, most of our indicators suggest that payments have been adequate, but rising clinician input costs are a concern.

This leads us to the Chair's first draft recommendation, which reads: For calendar year 2024, the Congress should update the 2023 Medicare base payment rate for physician and other health professional services by 50 percent of the projected increase in the Medicare Economic Index.

This draft recommendation is motivated by our concern that clinicians may not be able to absorb projected increases in input costs at current payment levels. But it also acknowledges that our indicators suggest payment rates are currently adequate.

Since clinicians' practice expenses account for about half of the MEI, this draft recommendation is designed to reflect the growth of clinicians' practice costs.

If payments are increased by our recommended percentage, it will increase Medicare spending by $750 million to $2 billion over one year, and by $5 to $10 billion over five years.

Our recommendation should maintain beneficiaries' access to care, and providers' willingness and ability to furnish care.

I'll now turn things over to Geoff to discuss new safety-net add-on payments.

MR. GERHARDT: In the June 2022 report to Congress, the Commission laid out a framework for supporting safety-net providers.

During this cycle, we applied the framework to physicians and other clinicians. As part of this work, we noted that clinicians are prohibited from collecting the 20 percent Part B cost sharing from most beneficiaries who are dually enrolled in the Medicaid program.

In addition, almost all state Medicaid programs make reduced cost-sharing payments, or do not make any cost-sharing payments, on behalf of dually enrolled beneficiaries. We estimate that the combination of these two policies results in clinicians not collecting approximately $3.6 billion in revenue they would have received otherwise.

Because they generate less revenue, treating beneficiaries with lower income may be financially burdensome for clinicians. This financial burden could cause some clinicians to cut back on the number of low-income beneficiaries they treat or avoid them altogether.

This may help explain why surveys show that lower-income beneficiaries report having more difficulty accessing care compared to other beneficiaries.

Finally, we observe that targeted financial support for safety-net clinicians does not currently exist in fee-for-service Medicare.

This leads me to our second draft recommendation.

The Congress should enact a non-budget neutral add-on payment, not subject to beneficiary cost sharing, under the physician fee schedule for services provided to low-income Medicare beneficiaries. These add-on payments should equal a clinician's allowed charges for these beneficiaries multiplied by: 15 percent for primary care clinicians, or 5 percent for non-primary care clinicians.

The recommended add-on payments could be made on a lump-sum basis rather than applied to individual claims. This would be consistent with how other fee schedule add-on payments are administered and help make the safety-net add-on transparent to clinicians.

It is the Commission's intent that safety-net payments would not be available to Medicare Advantage plans, either through direct payments by Medicare or

including the cost of fee-for-service payments in MA benchmarks.

Finally, it is worth noting that budget neutrality adjustments would not apply to the safety-net policy, which means the cost of the add-on payments would not be offset by reducing payment rates elsewhere.

In terms of implications, relative to current law it has been estimated that the draft recommendation would increase Medicare spending by more than $2 billion during the first year of implementation and by more than $10 billion over the first five years.

We expect that the recommendation will maintain or improve access for beneficiaries with lower income. And we expect that the safety-net payments would maintain or increase clinicians' willingness to treat low-income beneficiaries.

That concludes our presentation. I'll leave you with a summary of the two draft recommendations and hand things back to Mike.

DR. CHERNEW: Geoff and Rachel, thank you.

I think if I have this right, we're going to again go around for just one set of comments, and, Lynn, I

think you are first. Is that -- yes. I think we have Lynn, Scott, Cheryl.

MS. BARR: I've been working out on wrist weights so I could hit that comment button first, so I guess it's working.

DR. CHERNEW: Only good for a game show.

[Laughter.]

MS. BARR: If only. So thank you very much for this terrific work, and I do support the recommendations.

I think that in the chapter, as you're giving your overview, it helps to give some context in that overview of why you picked 50 percent of the MEI. I think it's actually a really good logic, but I struggled to find -- you know, it's way down in the text, and a lot of people will react immediately to the number. So I think we should tell them why we did it up front.

And then one other question about the chapter. It talks about the MIPS adjustment, you know, is typically only 2 percent, you know, because CMS gets to monkey with it. Are we past that point now where CMS can monkey with the MIPS adjustment? Because that was -- so that was a temporary thing. I believe that has expired, so we should

be in full MIPS now, I think. But it wasn't clear in the chapter, so just a comment for clarification. Is it going to be 9 percent this year or not?

MS. BURTON: I could get back to you on that. I don't have that at my fingertips.

MS. BARR: Okay. I think it is, so hopefully that will make a difference in terms of income, and we should be thinking about that as well, because the 2 percent has been the main problem with MIPS, I think, in my opinion. It's not enough money to make people want to do anything.

Thank you.

MS. KELLEY: Scott?

DR. SARRAN: Yeah, I strongly support this excellent work. I think it unequivocally moves us in the right direction and takes some very big steps.

I just want to highlight work that I think still remains to be done in subsequent cycles, and when I think about where the gap or gaps really are, I think it's around small primary care independent practices. I think we've fixed or are in the process of fixing through a lot of this work much of the other problems in much of the other -- or

many of the other settings. But the big, I think, round peg/square hole is small primary care practices with respect to two major issues.

One is that what we really want, I think, from primary care is excellent chronic disease management. We can get acute minor illness management at Walgreens, CVS, et cetera, and they're probably better at it, frankly, with the lower cost structure. But what we really want and need, particularly with an aging population, is excellent chronic disease management, and that by definition and by lots of proof is a team sport. It has to be a team sport, multilevel professionals. And that's not compatible with how small primary care practices who get any revenue stream, any material revenue stream via fee-for-service are paid.

The second problem is, as we discussed earlier, the administrative burden of many of the well-intentioned programs currently in place to drive at excellent chronic disease management such as MIPS and all the various ACO programs. So it's just to tee up. That is, I think, still sitting out there, the small primary care practice, how do we support them -- and not just support them, but support

them in delivering the kind of care we want and need.

MS. KELLEY: Cheryl?

DR. DAMBERG: Thank you. This is great work, and I'm very supportive of the recommendations in this chapter.

I just wanted to briefly note, you know, per the data, access has been declining between 2017 and 2021 more broadly, and I do think that this Medicare safety-net payment add-on will be critically important in terms of promoting greater access, especially for low-income populations, who I think historically have really struggled with access issues.

So I think kind of over the long haul it will be important, if this were to go into effect, to monitor the impact of it. But I think it's directionally correct.

MS. KELLEY: Okay. I have a comment from Betty that I will read: Great work. Thank you. The notation related to incident-to billing not fully reflecting the workforce composition and NP/PA contribution may seem like a minor point, but it is very important because the loss of MDs from primary care is even more significant than the data would otherwise reveal.

Similarly, the need for Congress or CMS to

develop a mechanism to clarify primary care versus specialty care practice across clinician types, including NPs and PAs, is essential and likely would more clearly illustrate the flight from primary care, even among those explicitly prepared for it -- for example, family nurse practitioners.

And the next comment is from Amol.

DR. NAVATHE: Thanks. Fantastic work, as usual. I wanted to make just hopefully two quick points.

One is I'm really glad that we're recognizing again, like in the prior sector, the input cost uncertainty here and, therefore, adding an update beyond the current law.

The second point is safety-net work I think here is really foundational. I think we -- there's a strong recognition that has existed for a number of years around the hospital safety net. I think this is a really major step forward to recognize the outpatient or the ambulatory safety net. And I think there's empirical evidence from the work that MedPAC has done and that others have done that the pattern of care for low-income beneficiaries is actually quite different in that they receive a lot of the

specialty care through facilities as opposed to in the outpatient ambulatory setting. And there's also empirical evidence that suggests that outpatient engagement with primary care and specialists for things like E&M visits, which are about chronic disease management, oftentimes do have a relationship with avoiding preventable hospitalizations and other care.

So I think this is a major step forward to improve access for this type of care in the ambulatory setting, and I'm really proud that MedPAC is pushing this forward.

Thanks.

MS. KELLEY: Larry?

DR. CASALINO: Thanks, Dana. Thanks to the staff for this very carefully done work, in particular for the second recommendation for higher payment rates for physicians caring for low-income patients.

You know, in terms of the first recommendation, the payment update, I recognize that, as a MedPAC Commissioner, my responsibility is to think about what's best for the country and not to try to maximize physicians' income. So I will vote for the Chair's recommendation, and

in part because I strongly support the safety-net recommendation. But a few points briefly.

I agree with Lynn that the rationale for giving one-half of the inflation update of the MEI should be more clear. You do have to kind of look for it.

So looking forward to future years and to the Commission's work, I want to very briefly state three things.

I'm not terribly happy with the one-half of MEI increased recommendation even though it's a bit higher than current law, because, again, it's only half of inflation cost, and the practice costs are only half of what physicians take in in revenue. The other half is for physicians' time. And we're not really recommending any increase for that. So in terms of this will -- the incentive is more inflation, this will reduce physicians' net income.

The other thing is the recommendation also keeps the facility fee extra payment for hospital-based physicians, which I don't favor.

The second point, I would strongly recommend that the Commission start a body of work looking into

potentially fundamental revisions in the way physicians are paid. There are just too many problems with the current way of paying physicians, and one symptom of that or sign of that is that practically every year there has to be some kind of patch. This has been going on for decades into the way physicians are paid and the physician payment rates, and that needs to be fixed.

It hasn't been mentioned, so I'll just mention it. There is no built-in inflation adjustment for physician payment unlike pretty much all other sectors, and that's not so much of a problem when inflation is 1 or 2 percent, but we've seen now that that's not always the case, and that's a problem.

MIPS is obviously very administratively burdensome. Scores don't correlate well with better measures of performance. That's a problem. The Commission has recommended ending the MIPS program. And the relative value system still tends to overvalue procedures over E&M, even with the recent changes.

Then the last thing I would say, like Scott, I would like to see MedPAC take a line of work thinking about ways in which Medicare could reduce the administrative

burden on physicians. I think quite a few physicians and probably especially primary care physicians would say, you know, we can give up the 1 or 2 percent extra payment if you would make our lives so we don't have to spend a couple of hours a day or more doing things that we don't think add any benefit to patient care at all. So that would be a nice line of work for us to undertake.

Thanks.

MS. KELLEY: Robert?

DR. CHERRY: Yes. I wanted to thank the staff for the excellent work.

My comments are related to Draft Recommendation 2.

I do support the differential add-on payment where primary care is getting more than non-primary care physicians. I do think -- and consistent with my prior comments -- that the 5 percent number is a bit on the low side. I think it is important for communities that are vulnerable that we retain, you know, specialty care so that primary care physicians have access to, in a multidisciplinary team-oriented fashion be able to treat patients that have a number of chronic conditions.

In addition, also, it just creates access to care that I think over the longer term would be beneficial.

It's not enough to cause an unfavorable vote on my part, but I do think that sort of in future years we need to consider closing a gap a little bit and making sure that that specialty care is also taken into consideration so we can make sure that it's available to these communities.

MS. KELLEY: Dana?

DR. GELB SAFRAN: Yeah, thanks.

I also will be strongly supporting the recommendations.

I just wanted to add some additional comments and support around the safety-net recommendation in particular. Like Amol and other Commissioners, I really am pleased to see us expanding some of our thinking about safety net and compensation down to the ambulatory level and specifically at the physician level.

And I particularly like that, that the way this is structured, it really, I think, reinforces incentives to create access for low-income beneficiaries, and I think that's just terribly, terribly important and very glad to

see us doing it.

The thing that hasn't been said that I just want to flag is it does kind of double down on a fee-for-service mentality at a time that this Commission has been trying to advance alternative payment models. However, I recognize that it's really those alternative payment models are in place with systems, not individual clinicians. So what I like about it from the perspective of APMs and reinforcing APMs is it gives the physicians' organizations, to the extent that they're part of a larger organization that's doing APM contracting, at least no incentive to cherry-pick against low income and perhaps the incentive to favor low-income beneficiaries.

But, that said, I think it should go hand in hand with the kinds of incentives we've talked about in other conversations to make sure that APM contracts are structured in a way that care for and quality for lower-income beneficiaries is really supported. So we've talked about various mechanisms for that around, you know, up-front additional funds for vulnerable populations or organizations serving those or enhanced bonuses and rewards.

But I think I just wanted to make the point that coupling those together with what we're doing here but not feeling like that's enough is really important.

And the final thing I'll say is I like -- I think it was Cheryl who mentioned the importance of monitoring the impact of this on access. I'd like to see us doing that in a way that differentiates access in fee-for-service versus APM models to see if there's anything important to be learned there from the signals and any differences.

But I'd also say let's monitor the impact on outcomes for low-income beneficiaries because we know access is necessary but not sufficient, and I think as we do that, we'll learn what is this helping us to accomplish, but what are the gaps that are left for us to solve with other levers.

Thank you.

MS. KELLEY: Kenny?

MR. KAN: Thank you for a fabulous chapter. I am supportive of both recommendations.

Regarding Recommendation No. 2 on the clinician safety-net payments, I especially like the suggestion that the payments be made on a lump-sum basis. Such lump-sum

payments would be consistent with the way how payments are currently being made under, like, the health professional shortage area, and it will be easy for clinicians to understand and less -- and also less better symptoms to administer. So thank you for that.

DR. CHERNEW: So, if I'm correct, Kenny had the last word.

MS. KELLEY: Yes.

DR. CHERNEW: Great. So, again, thank you all for your sets of comments, and, Dana, now we're going to go around. We're going to go around for Recommendation 1 and then around for Recommendation 2 in a roll call.

Dana.

MS. KELLEY: Okay. Voting on Recommendation 1, which reads: "For calendar year 2024, the Congress should update the 2023 Medicare base payment rate for physician and other health professional services by 50 percent of the projected increase in the Medicare Economic Index."

Voting yes or no. Lynn?

MS. BARR: Yes.

MS. KELLEY: Larry.

DR. CASALINO: Yes.

MS. KELLEY: Robert?

DR. CHERRY: Yes.

MS. KELLEY: Cheryl?

DR. DAMBERG: Yes.

MS. KELLEY: Stacie?

DR. DUSETZINA: Yes.

MS. KELLEY: Marge?

MS. GINSBURG: Yes.

MS. KELLEY: David?

DR. GRABOWSKI: Yes.

MS. KELLEY: Jonathan?

DR. JAFFERY: Yes.

MS. KELLEY: Kenny?

MR. KAN: Yes.

MS. KELLEY: Amol?

DR. NAVATHE: Yes.

MS. KELLEY: Greg?

MR. POULSEN: Yes.

MS. KELLEY: Betty, can you give a thumbs-up or down? Betty votes yes.

Wayne?

DR. RILEY: Yes.

MS. KELLEY: Jaewon?

DR. RYU: Yes.

MS. KELLEY: Dana?

DR. GELB SAFRAN: Yes.

MS. KELLEY: Scott?

DR. SARRAN: Yes.

DR. CHERNEW: Michael.

MS. KELLEY: I'm sorry. And Mike?

DR. CHERNEW: Yes.

[Laughter.]

MS. KELLEY: I don't know how I could have left you out. Okay.

DR. CHERNEW: I know, the appendage to the whole set of things.

Now we're going to do it again.

MS. KELLEY: Recommendation 2, which reads: "The Congress should enact a non-budget-neutral add-on payment not subject to beneficiary cost sharing under the physician fee schedule for services provided to low-income Medicare beneficiaries. These add-on payments should equal a clinician's allowed charges for these beneficiaries multiplied by 15 percent for primary care clinicians or 5

percent for non-primary care clinicians.:

Voting yes or no. Lynn?

MS. BARR: Yes.

MS. KELLEY: Larry:

DR. CASALINO: Yes, enthusiastically.

Just one note. I think the "or" should be "and," shouldn't it?

MS. KELLEY: Noted.

DR. CASALINO: That's kind of important, actually.

[Laughter.]

MS. KELLEY: All right. Noted.

Robert?

DR. CHERRY: Yes.

MS. KELLEY: Cheryl?

DR. DAMBERG: Yes.

MS. KELLEY: Stacie?

DR. DUSETZINA: Yes.

MS. KELLEY: Marge?

MS. GINSBURG: Yes.

MS. KELLEY: David?

DR. GRABOWSKI: Yes.

MS. KELLEY: Jonathan?

DR. JAFFERY: Yes.

MS. KELLEY: Kenny?

MR. KAN: Yes.

MS. KELLEY: Amol?

DR. NAVATHE: Yes.

MS. KELLEY: Greg?

MR. POULSEN: Yes.

MS. KELLEY: Betty, a sign? Betty votes yes. Wayne?

DR. RILEY: Yes.

MS. KELLEY: Jaewon?

DR. RYU: Yes.

MS. KELLEY: Dana?

DR. GELB SAFRAN: Yes.

MS. KELLEY: Scott?

DR. SARRAN: Yes.

MS. KELLEY: Mike.

DR. CHERNEW: Yes.

MS. KELLEY: All right.

DR. CHERNEW: So, again, thank you all, particularly to Rachel and Geoff.

I will add for those at home that we have worried a lot about the broad reform to the physician fee schedule, the physician and other health service professionals' fee schedule, and we are very much thinking about how we will engage in a much more comprehensive assessment of what we do going forward for future cycles. I think that's going to be an increasingly important thing.

And I might add, to Dana's point about APMs, this interaction is one that is particularly important in how we pay for health services in general and how the professional side interacts with the APM side is important.

We are now working in an update recommendation world, which is inherently in this fee-for-service space, but it is not that we actually are trying to, in any way, double down on fee-for-service.

So, with that said, we're going to take another -- let's take a 10-minute break, and then we'll be back -- a real 10-minute break, not like a 15-minute 10-minute break, and we'll be back at about 10 after 11:00 to go through the other sessions in our expedited process.

[Recess.]

DR. CHERNEW: Okay, everybody. Now we are going

to go through the first of what will be several expedited sessions. They will differ from what we just did in the physician and hospital side, in that we are not going to have a round of comments. We're going to go through the materials and then we're going to go through the roll calls. That decision was made, for those of you at home, because of the general consensus that we had at the past meetings, so we are ready to move along, and I guess as the sessions would suggest, in an expedited way.

So Nancy, I'm going to turn it to you, and we'll go from there.

MS. RAY: Good morning. The audience can download a copy of today's presentation on the upper right-hand side of the screen.

During the December 2022 meeting, we discussed the adequacy of Medicare's payments for outpatient dialysis services. There was strong consensus around the draft recommendation. Today's presentation is an abbreviated version of what was discussed in December. Additional detail can be found in your briefing paper.

In 2021, there were roughly 332,000 fee-for-service dialysis beneficiaries, 7,880 dialysis facilities.

Total Medicare fee-for-service spending was about $10.0 billion for dialysis services.

The indicators assessing adequacy are generally positive, and you have seen all of this material in December. Between 2020 and 2021, there was a net increase of roughly 120 facilities, and the growth in dialysis treatment stations exceeded the growth in the number of fee-for-service and MA dialysis beneficiaries.

Looking at volume changes, the decline in the number of dialysis fee-for-service beneficiaries and treatments between 2020 and 2021, is largely attributable to the change in the statute that permits, as of January 2021, ESRD beneficiaries to enroll in Medicare Advantage plans, as detailed in your paper. We don't see this as a negative indicator of access.

The 20 percent marginal profit suggests that providers have a financial incentive to continue to serve Medicare beneficiaries.

Moving to quality, between 2020 and 2021, the percent of dialysis beneficiaries using home dialysis continues to increase. That is a good trend, and consistent with prior year trends. However, monthly ED

visits and hospital readmissions declined while monthly all-cause hospital admissions and mortality modestly increased.

Regarding access to capital, indicators suggest it is robust. An increasing number of facilities are for-profit and freestanding. Private capital appears to be available to the large and smaller-sized multi-facility organizations.

In 2021, the aggregate Medicare margin is 2.3 percent. The 2023 projected aggregate Medicare margin is -0.4 percent.

Based on our findings that suggest that outpatient dialysis payments are adequate. The draft recommendation reads:

For calendar year 2024, the Congress should update the 2023 Medicare end-stage renal disease prospective payment system base rate by the amount determined under current law.

This draft recommendation will have no impact relative to the statutory update. We expect beneficiaries to continue to have good access to outpatient dialysis care and continued provider willingness and ability to care for

Medicare beneficiaries.

And now I turn it back to the chair.

DR. CHERNEW: Nancy, thank you, and Dana, I think now we're just going to go to through. Is that --

MS. KELLEY: Yes. All right. The recommendation reads: For calendar year 2024, the Congress should update the 2023 Medicare end-stage renal disease prospective payment system base rate by the amount determined under current law.

Voting yes or no. Lynn?

MS. BARR: Yes.

MS. KELLEY: Larry?

DR. CASALINO: Yes.

MS. KELLEY: Robert?

DR. CHERRY: Yes.

MS. KELLEY: Cheryl?

DR. DAMBERG: Yes.

MS. KELLEY: Stacie?

DR. DUSETZINA: Yes.

MS. KELLEY: Marge?

MS. GINSBURG: Yes.

MS. KELLEY: David?

DR. GRABOWSKI: Yes.

MS. KELLEY: Jonathan?

DR. JAFFERY: Yes.

MS. KELLEY: Kenny?

MR. KAN: Yes.

MS. KELLEY: Amol?

DR. NAVATHE: Yes.

MS. KELLEY: Greg?

MR. POULSEN: Yes.

MS. KELLEY: Betty, can you give us a sign? Betty votes yes.

Wayne?

DR. RILEY: Yes.

MS. KELLEY: Jaewon?

DR. RYU: Yes.

MS. KELLEY: Dana?

DR. GELB SAFRAN: Yes.

MS. KELLEY: Scott?

DR. SARRAN: Yes.

MS. KELLEY: And Mike.

DR. CHERNEW: Yes.

MS. KELLEY: Okay.

DR. CHERNEW: Thank you. And now I guess we're going to move to Kim and we're going to do hospice.

MS. NEUMAN: Yes. Good morning. Next, we will discuss hospice. First, we'll review indicators of hospice payment adequacy and the hospice aggregate cap, and then the draft recommendation for 2024.

We discussed these issues in more detail at the December meeting and there's more information in your mailing materials. Those materials were updated to reflect the December discussion. For example, we included additional information about the hospice quality reporting program and CMS's efforts to develop future quality measures.

In 2021, over 1.7 million Medicare beneficiaries, including nearly half of decedents, received hospice care from over 5,300 hospice providers, and Medicare paid those hospices $23.1 billion.

This next chart summarizes our indicators of hospice payment adequacy, which are generally positive. The supply of providers continued to grow in 2021. The number of hospice users and total days of care were stable. In-person visits per week increased slightly between 2020

and 2021. The share of decedents using hospice declined, reflecting the continued effects of the pandemic on death rates and patterns of care, not payment adequacy. Length of stay also declined slightly. Marginal profit was 18 percent.

While quality is difficult to assess, the most recent CAHPS data were stable, and visits at the end of life were stable in 2021, after a slight decline in 2020.

Access to capital appears adequate. We continue to see significant provider entry, almost entirely by for-profit providers, and financial reports indicate the sector is viewed favorably by investors. Provider-based hospices have access to capital through their parent provider.

In terms of margins, different from other sectors, we have an estimated 2020 margin because data on the hospice aggregate cap lags. The 2020 aggregate Medicare margin was 14.2 percent, and the 2023 projected margin is 8 percent.

Switching gears to the hospice aggregate cap, the cap limits total payments a hospice provider can receive in a year. It is an aggregate limit, not a patient-level limit. If a provider's total payments exceed the number of

patients served, multiplied by the cap amount, the provider must repay the excess to Medicare. Hospices that exceed the cap have long lengths of stay and high margins.

Each year since March 2020, the Commission has recommended the hospice cap be wage adjusted and reduced by 20 percent. Changing the cap in this way would make it more equitable across providers and would focus payment reductions on providers with the longest stays and high margins.

So that brings us to the draft recommendation. It reads:

For fiscal year 2024, the Congress should update the 2023 Medicare base payment rates for hospice by the amount specified in current law and wage adjust and reduce the hospice aggregate cap by 20 percent.

In terms of implications, the draft recommendation would decrease spending relative to current law by between $250 million and $750 million over 1 year, and by between $5 billion and $10 billion over 5 years.

In terms of beneficiaries and providers, we expect that beneficiaries would continue to have good access to hospice care and that providers would continue to

be willing and able to provide appropriate care to Medicare beneficiaries.

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

DR. CHERNEW: And I'm going to turn it over to Dana to go through the vote.

MS. KELLEY: Okay. Voting on the recommendation, which reads:

For fiscal year 2024, the Congress should update the 2023 Medicare base payment rates for hospice by the amount specified in current law and wage adjust and reduce the hospice aggregate cap by 20 percent.

Voting yes or no. Lynn?

MS. BARR: Yes.

MS. KELLEY: Larry?

DR. CASALINO: Yes.

MS. KELLEY: Robert?

DR. CHERRY: Yes.

MS. KELLEY: Cheryl?

DR. DAMBERG: Yes.

MS. KELLEY: Stacie?

DR. DUSETZINA: Yes.

MS. KELLEY: Marge?

MS. GINSBURG: Yes.

MS. KELLEY: David?

DR. GRABOWSKI: Yes.

MS. KELLEY: Jonathan?

DR. JAFFERY: Yes.

MS. KELLEY: Kenny?

MR. KAN: Yes.

MS. KELLEY: Amol?

DR. NAVATHE: Yes.

MS. KELLEY: Greg?

MR. POULSEN: Yes.

MS. KELLEY: Betty? Is that a thumbs up? Thank you. Betty votes yes.

Wayne?

DR. RILEY: Yes.

MS. KELLEY: Jaewon?

DR. RYU: Yes.

MS. KELLEY: Dana?

DR. GELB SAFRAN: Yes.

MS. KELLEY: Scott?

DR. SARRAN: Yes.

MS. KELLEY: And Mike.

DR. CHERNEW: Yes.

MS. KELLEY: All right then.

DR. CHERNEW: Great. Nancy and Kim, thank you both very much. I think we're going to do a brief staff shuffle. So we have Kathryn and Evan and Jamila coming to the table.

DR. CHERNEW: All right. And we are to pick up now with skilled nursing facilities, and that's going to be Kathryn. So Kathryn.

MS. LINEHAN: Good morning. I will recap the payment adequacy indicators for skilled nursing facility services that you saw and discussed in December and then I will present the draft recommendation for your vote. More detailed information is in your paper.

This slide provides a snapshot of the SNF sector in 2021. That year, the Medicare program spent $28.5 billion on SNF care. These payments were made to about 15,000 providers, most of which also provide long-term care. Those services are largely covered by Medicaid, and they make up the bulk of services that the sector provides. Medicare SNF care makes up a small share of most nursing

facilities' volume, about 10 percent of days, and a larger share of revenue.

In 2021, about 1.2 million beneficiaries, or 3.4 percent of fee-for-service beneficiaries, used SNF services.

In summary, our indicators are generally positive. The supply of facilities declined less than 1 percent. Declining volume reflects declining demand due to a number of factors and not the adequacy of Medicare's payments. The high marginal profit of 26 percent indicates providers had a strong incentive to treat Medicare beneficiaries.

Our quality measures in 2021 indicate improvement compared to 2020, but the pandemic and PHE-related policies complicate our interpretation of rates and trends.

SNFs have adequate access to capital, and this is expected to continue. The total all-payer margin increased compared to 2020.

The average Medicare margin in 2021 was high, and for relatively efficient providers was even higher. The projected margin for 2023 is 10 percent. This is a change from 11 percent reported in December because we updated our

projections of cost growth to reflect the most recent market basket estimates for 2022 and 2023.

This brings us to the draft recommendation. It reads:

For fiscal year 2024, the Congress should reduce the 2023 Medicare base payment rates for skilled nursing facilities by 3 percent.

In terms of implications relative to current law, this recommendation would lower program spending by over $2 billion in 1 year and by over $10 billion over 5 years. Given the high level of Medicare's payments, we do not expect adverse impacts on beneficiaries. Providers should continue to be willing and able to treat beneficiaries.

And with that, I'll turn things back to Mike.

DR. CHERNEW: Thank you so much. Again, we are going to go through the votes, so Dana.

MS. KELLEY: All right. Voting on the recommendation, which reads:

For fiscal year 2024, the Congress should reduce the 2023 Medicare base payment rates for skilled nursing facilities by 3 percent.

Voting yes or no. Lynn?

MS. BARR: Yes.

MS. KELLEY: Larry?

DR. CASALINO: Yes.

MS. KELLEY: Robert?

DR. CHERRY: Yes.

MS. KELLEY: Cheryl?

DR. DAMBERG: Yes.

MS. KELLEY: Stacie?

DR. DUSETZINA: Yes.

MS. KELLEY: Marge?

MS. GINSBURG: Yes.

MS. KELLEY: David?

DR. GRABOWSKI: Yes.

MS. KELLEY: Jonathan?

DR. JAFFERY: Yes.

MS. KELLEY: Kenny?

MR. KAN: Yes.

MS. KELLEY: Amol?

DR. NAVATHE: Yes.

MS. KELLEY: Greg?

MR. POULSEN: Yes.

MS. KELLEY: Betty? Betty votes yes.

Wayne?

DR. RILEY: Yes.

MS. KELLEY: Jaewon?

DR. RYU: Yes.

MS. KELLEY: Dana?

DR. GELB SAFRAN: Yes.

MS. KELLEY: Scott?

DR. SARRAN: Yes.

MS. KELLEY: And Mike.

DR. CHERNEW: Yes.

That was well done. It was indeed expedited. I want people to understand that that, in no way, reflects assessment of the importance of the sector. It has really been a challenging time for SNFs, and I think the discussions we have had have illustrated that and the work that you've done, the staff has done, has really been outstanding.

DR. CHERNEW: But with, really, two brief comments, we are going to move on to home health, and I think that's going to be Evan.

MR. CHRISTMAN: Good morning. Next, we will review the indicators for home health using the same

framework you saw in the other sectors. The Commission expressed a consensus supporting the draft recommendation presented in December. This presentation summarizes information that was presented in more detail at that meeting, and there is more information presented in the draft paper for you for this meeting.

As an overview, Medicare spent $16.9 billion on home health services in 2020. There were over 11,400 agencies. The program provided to 3 million beneficiaries. And in addition, 2021 was the second year of changes to the home health PPS required by the Bipartisan Budget Act, a 30-day unit of payment and the elimination of therapy visits as a payment factor in the case-mix system. The Commission provided a preliminary analysis of the impact of these two changes in our March 2022 report.

Finally, I turn to the summary of the indicators. Overall our indicators are positive. Ninety-eight percent of beneficiaries live in a ZIP code with two or more home health agencies in 2021. Total volume decreased, but per capita volume increased, and agencies had a positive Medicare marginal profit of 25.9 percent in 2021.

For quality of care, the pandemic and public

health emergency-related policies affected our ability to measure quality in this year.

For access to capital, the large for-profit agencies continue to have adequate access to capital, and we expect this to continue, and the all-payer margins were positive in 2021, at 11.9 percent.

For payments and costs, Medicare margins in 2021 were 24.9 percent, and the relatively efficient provider had a median margin of a little over 28 percent, and we project margins for 2023 of 17 percent.

This brings me to the draft recommendation. The recommendation reads:

For calendar year 2024, the Congress should reduce the 2023 Medicare base payment rate for home health agencies by 7 percent.

In terms of spending impact, we expect that relative to current law spending would decrease by $750 million to $2 billion over 1 year and over $10 billion over 5 years.

For beneficiary and provider implications, we expect that access to care should remain adequate, and it should not affect the willingness of providers to serve

beneficiaries, but it may increase cost pressure for some providers.

This completes my presentation.

DR. CHERNEW: Evan, thank you, and I think we now know the drill. Dana.

MS. KELLEY: All right. Voting on the recommendation, which reads:

For calendar year 2024, the Congress should reduce the 2023 Medicare base payment rate for home health agencies by 7 percent.

Voting yes or no. Lynn?

MS. BARR: Yes.

MS. KELLEY: Larry?

DR. CASALINO: Yes.

MS. KELLEY: Robert?

DR. CHERRY: Yes.

MS. KELLEY: Cheryl?

DR. DAMBERG: Yes.

MS. KELLEY: Stacie?

DR. DUSETZINA: Yes.

MS. KELLEY: Marge?

MS. GINSBURG: Yes.

MS. KELLEY: David?

DR. GRABOWSKI: Yes.

MS. KELLEY: Jonathan?

DR. JAFFERY: Yes.

MS. KELLEY: Kenny?

MR. KAN: Yes.

MS. KELLEY: Amol?

DR. NAVATHE: Yes.

MS. KELLEY: Greg?

MR. POULSEN: Yes.

MS. KELLEY: Betty? Betty votes yes.

Wayne?

DR. RILEY: Yes.

MS. KELLEY: Jaewon?

DR. RYU: Yes.

MS. KELLEY: Dana?

DR. GELB SAFRAN: Yes.

MS. KELLEY: Scott?

DR. SARRAN: Yes.

MS. KELLEY: And Mike.

DR. CHERNEW: Yes.

And this brings us -- again thank you. Another

very challenging sector -- this brings us to, I think, last but not least, in our expedited session, we're going to go to Jamila, and we're going to talk about rehab facilities. Jamila.

DR. TORAIN: Thank you.

Good morning. We continue with the update to Medicare's payments to inpatient rehabilitation facilities. We will review the indicators for IRF using the same framework you saw in the other sectors.

The Commissioners expressed a consensus supporting the Chair’s draft recommendation presented in December. This presentation summarizes information that was presented in more detail at our December meeting, and there is more information presented in your mailing materials.

Here's a reminder of the IRF industry in 2021. In 2021, there were about 1,180 IRFs and about 335,000 beneficiaries had 379,000 stays. Medicare spent about $8.5 billion on IRF care provided to fee-for-service beneficiaries, and Medicare accounted for about 52 percent of IRF discharges.

In summary of the materials we discussed in

December, our four categories of payment adequacy indicators for IRFs are generally positive.

First, in terms of fee-for-service Medicare beneficiaries' access to care, IRFs continue to have capacity that appears to be adequate to meet demand. The marginal profit for freestanding IRFs was 41 percent.

Second, in 2021, the pandemic and public health emergency-related policies affect quality measures and interpretation of trends.

Third, IRFs maintain good access to capital markets. The all-payer total margin for freestanding IRFs was 14 percent.

Fourth, Medicare payments and IRF cost indicators were positive. In 2021, the aggregate Medicare margin was 17 percent, 20.4 percent for the relatively efficient provider. We project a margin of 11 percent in 2023.

And so that brings us to the update for 2024. The draft recommendation reads: "For fiscal year 2024, the Congress should reduce the 2023 Medicare base payment rate for inpatient rehabilitation facilities by 3 percent."

To review the implications on spending, relative to current law, spending would decrease by between $750

million and $2 billion in 2024 and by between $5 billion and $10 billion over five years.

On beneficiaries and providers, we anticipate no adverse effect on Medicare beneficiaries' access to care. The recommendation may increase in financial pressure on some providers.

With that, I will close. Thank you.

DR. CHERNEW: Jamila, thank you. That was really well done, and, Dana, again.

MS. KELLEY: All right. Voting on the recommendation which reads: "For fiscal year 2024, the Congress should reduce the 2023 Medicare base payment rate for inpatient rehabilitation facilities by 3 percent."

Voting yes or no. Lynn?

MS. BARR: Yes.

MS. KELLEY: Larry?

DR. CASALINO: Yes.

MS. KELLEY: Robert?

DR. CHERRY: Yes.

MS. KELLEY: Cheryl?

DR. DAMBERG: Yes.

MS. KELLEY: Stacie?

DR. DUSETZINA: Yes.

MS. KELLEY: Marge?

MS. GINSBURG: Yes.

MS. KELLEY: David?

DR. GRABOWSKI: Yes.

MS. KELLEY: Jonathan?

DR. JAFFERY: Yes.

MS. KELLEY: Kenny?

MR. KAN: Yes.

MS. KELLEY: Amol?

DR. NAVATHE: Yes.

MS. KELLEY: Greg?

MR. POULSEN: Yes.

MS. KELLEY: Betty?

[No response.]

MS. KELLEY: Betty votes yes.

Wayne?

DR. RILEY: Yes.

MS. KELLEY: Jaewon?

DR. RYU: Yes.

MS. KELLEY: Dana?

DR. GELB SAFRAN: Yes.

MS. KELLEY: Scott?

DR. SARRAN: Yes.

MS. KELLEY: And Mike?

DR. CHERNEW: Yes.

And so that brings us to the end of what was a particularly expedited session. So, again, thank you all, and understand that the expedited nature of those votes were reflective of our consensus, not anything else.

UNIDENTIFIED SPEAKER: [Speaking off microphone.]

DR. CHERNEW: Yes. That's how we got to our consensus.

And I might add, thanks to the staff -- Kathryn, Evan, and Jamila -- for really outstanding work. We really do appreciate it.

And so we are now going to break, and we are going to have lunch. And we will be back at -- do you want to start a little early?

UNIDENTIFIED SPEAKER: [Speaking off microphone.]

DR. CHERNEW: Okay. We're going to still come back at 1:15 where we will talk about our status report on Medicare Advantage.

So, again, for those at home, please, we do look

forward to your public comments. You can reach us at meetingcomments@MedPAC.gov or through the website at MedPAC.gov/meeting, and again, we really do look forward to your comments and take them seriously. So we appreciate the time that all of you at home have spent with us, and we will be back at 1:15 to discuss MA.

So, again, thank you.

[Whereupon, at 11:36 a.m., the meeting was recessed for lunch, to reconvene at 1:15 p.m. this same day.]

AFTERNOON SESSION

[1:16 p.m.]

DR. CHERNEW: Hello, everybody. Welcome to our afternoon January session. We have several important topics. We're going to talk about Medicare Advantage, behavioral health services, and telehealth. I'm looking forward to a pretty rich discussion, and we're going to let Luis kick that off with Medicare Advantage. Luis?

MR. SERNA: Good afternoon. This presentation updates our findings on the status of the Medicare Advantage, or MA program. 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.

I am going to present our analysis of the MA enrollment, plan availability, and payment for 2023. As part of a congressional request, I will present two methods for comparing MA and fee-for-service spending. First, I will present our analysis using MedPAC's long-standing prospective method. Second, I will present a new retrospective method using actual fee-for-service spending and payments to MA plans. Then Andy will give you an update on MA risk coding intensity and summarize our

ongoing concerns about MA quality.

In 2022, 49 percent of Medicare beneficiaries with both Part A and Part B coverage are now enrolled in MA plans, a substantial and growing difference from 26 percent in 2011. In 26 states, the majority of eligible Medicare beneficiaries are now enrolled in an MA plan. At current trends, the majority of all eligible beneficiaries will be in an MA plan in 2023.

The Affordable Care Act established changes to MA payment rates, essentially phasing in a reduction of MA payment rates by 10 percentage points between 2011 and 2017. Despite some initial projections that the decrease in MA payment rates would result in enrollment declines, MA enrollment has continued to grow rapidly. In 2022, MA enrollment grew 8 percent to about 29 million enrollees. The proliferation of MA enrollees has coincided with an increase in the number of plans bidding.

Medicare beneficiaries have a large number of plans from which to choose, and MA plans are available to almost all beneficiaries. For 2023, nearly 100 percent of Medicare beneficiaries have at least one plan available. Ninety-nine percent have a zero-premium option that

includes the Part D drug benefit, up from 98 percent in 2022. The average Medicare beneficiary can choose from 41 plans sponsored by eight organizations in 2023. The number of plans available increased relative to 2022.

I'll now briefly go over the MA payment system. More detailed information is available in your mailing material.

The key concepts are that plans submit bids each year for the amount they think it will cost them to provide Part A and B benefits. Each plan's bid is compared to a benchmark, which differs by geography and plan quality rating. For nearly all plans, Medicare pays the bid plus a rebate, calculated as a percentage of the difference between the bid and the benchmark. Plan rebates may go toward lower beneficiary cost sharing for A and B services, supplemental benefits, or enhanced Part D benefits. Plan rebates may include plan administrative expenses and profits.

The average rebate that plans have available for extra benefits in 2023 has increased to $196 per member per month, a record high and a 19 percent increase relative to 2022, which was previously a record high. While MA rebate

dollars can be used to provide cost-sharing reductions as a means of competing with Medigap coverage, plans have allocated smaller shares of rebate dollars toward reducing beneficiary cost sharing and premiums.

As rebates have increased, MA plans have allocated the largest share of additional rebate dollars toward other supplemental benefits, such as gym memberships and discounts on dental services. Coverage for these supplemental benefits varies widely by plan, and data on their use is unavailable, making it unclear whether these benefits are being administered efficiently for both beneficiaries and the Medicare program.

The level of rebates, now at 17 percent of total payment, reflects MA plans' ability to reduce the growth in their bids relative to the growth and in payment benchmarks.

To assess how the lower relative bids compare with fee-for-service spending, we used the same long-standing prospective method that MedPAC has used for many years. We use plans' projected enrollment, spending, and risk scores from their bids to estimate projected MA payments.

Our fee-for-service spending estimate uses CMS's projected fee-for-service spending that is the basis for MA benchmarks and therefore directly inform plan bids and MA payments.

Our comparison aligns standardized fee-for-service spending in each county with each plan's projected county enrollment and risk scores and subsequently includes our most recent estimate of coding differences in MA.

These steps help us account for differences in health status, geographic enrollment patterns, services covered in each program, and diagnostic coding differences.

Our prospective method finds that because benchmarks have been much higher than fee-for-service spending, lower plan bids have not translated to Medicare savings. Without accounting for coding differences between MA and fee-for-service and any favorable risk-adjusted mix of beneficiaries in MA plans, we estimate that benchmarks will average 109 percent of fee-for-service spending. This is represented by the blue line.

When we look at overall bids relative to fee-for-service, represented by the white line, we see a decline from 85 percent in 2022 to 83 percent in 2023. As shown in

your mailing materials, even in the lowest spending areas, most MA plans bid below their local fee-for-service spending.

Payments, represented by the green line, will average 101 percent of fee-for-service spending, which includes quality bonuses that account for 3 to 4 percent of MA payments.

As Andy will discuss later, overall payments to MA plans will be about 6 percent higher than fee-for-service after accounting for our most recent estimate of coding practices by MA plans that result in higher risk scores. This is represented by the dotted line in red. The 6 percent higher payments translates into a projected $27 billion in 2023. This would be even larger if the favorable mix of beneficiaries in MA plans were taken into account.

MedPAC's long-standing prospective method shows that overall, while the relative level of plan bids continue to decline, the Medicare program has not shared in these projected efficiencies through program savings.

Our long-standing method of comparing MA payments to fee-for-service spending has some limitations because it

relies on CMS and plan projections, includes beneficiaries that are not eligible for MA enrollments, and uses an MA coding intensity estimate from two years prior. We have consistently noted this and approximately correct for it when we publish this comparison.

This year, as part of a congressional request, we conducted a retrospective analysis that compares actual MA plan payments in 2017, 2018, and 2019 with actual fee-for-service spending for MA-eligible beneficiaries. Similar to our prospective analysis, to compare MA payments with fee-for-service spending, we aligned actual standardized fee-for-service spending in each county with each plan's actual enrollment and risk scores for enrollees in the county. More details on our method can be found in your mailing materials.

Our retrospective analysis shows that our long-standing prospective method has produced a reasonably accurate comparison. As with our prospective analyses, a retrospective comparison shows that MA payments were higher than fee-for-service spending from 2017 through 2019. In fact, our estimates were nearly the same as the prospective estimates we originally published.

We will update our retrospective analysis with more years of data as that data becomes available.

Now Andy will discuss our findings on MA coding and summarize our concerns with MA quality.

DR. JOHNSON: I am now going to turn to risk adjustment and coding intensity in Medicare Advantage. Your mailing materials explain how risk scores adjust payments to MA plans to account for the health status of plan enrollees. Today we are going to focus on risk adjustment's biggest flaw: differences in diagnosis coding.

MA plans have a financial incentive to document more diagnoses than providers in fee-for-service Medicare, leading to larger MA risk scores and greater Medicare spending when a beneficiary enrolls in MA.

For 2021, we find that MA risk scores were about 10.8 percent higher than fee-for-service beneficiaries with comparable health status. The Secretary is mandated by law to reduce MA risk scores to account for the impact of coding differences. The adjustment of 5.9 percent only partially offsets the full impact. The remaining difference caused 2021 MA risk scores to be about 4.9

percent higher, generating about $17 billion in payments to MA plans, in excess of what Medicare would have spent for the same beneficiaries in fee-for-service Medicare.

This figure shows coding intensity and the adjustment for coding intensity over time. We have presented this chart for the past few years, and it is explained more fully in your mailing materials. This version has been updated for 2021.

The main points are that MA coding intensity continues to grow over time, and the adjustment does not fully account for coding intensity's full effect. Excess payments become larger each year not only because the share of unaddressed coding intensity continues to grow, as represented by the green portion of the bars, but also because the share of Medicare beneficiaries enrolled in MA continues to increase rapidly.

This chart shows payments to MA plans due to coding intensity in excess of the adjustment. We find that these excess payments totaled $80 billion from 2007 to 2021, which is the sum of the light green bars.

To estimate excess payments in 2022 and 2023, we assume that coding intensity will be the same as it was in

2021, even though all evidence suggests that it will higher. Despite this assumption, MA enrollment and aggregate spending continue to grow, adding an estimated, nearly $44 billion during these two years. In total, we estimate that MA coding intensity will have generated nearly $120 billion in excess payments to MA plans, with more than one-third of these excess payments occurring in 2022 and 2023.

For years, we have documented variation in coding intensity by looking at MA contracts. This year we aggregated our results to each MA organization. Each gray column shows one MA organization's coding intensity relative to fee-for-service. In 2021, coding adjustment of 5.9 percent, in blue, generates payment inequity by penalizing MA organizations, left of the dashed line, and failing to account for overpayments to MA organizations, right of the dashed line.

Our evaluation of coding intensity by MA organization highlights two new findings. First, there is a 9-percentage-point spread in average coding intensity among the eight largest MA organizations. These organizations cover about 77 percent of all MA enrollees.

Average coding intensity is about 15 percent above fee-for-service levels for three of these organizations and ranges between 6 and 10 percent above fee-for-service for the other five. All eight of the largest MA organizations had coding intensity greater than the 5.9 percent coding adjustment, and therefore, all received aggregate excess payments due to coding intensity.

However, these differences in coding intensity offer some organizations a competitive advantage over other organizations. The advantage provides higher-coding organizations with larger payments than lower-coding organizations than they would receive for the same enrollees. The higher-coding organizations can also offer more extra benefits simply due to their coding efforts.

Second, we find that MA organizations offering plans primarily in California and Florida account for 12 of the 14 highest-coding MA organizations, shown in the yellow box. California and, to a lesser extent, Florida are known to use a form of provider payment capitation called the "delegated model." In this model, a plan fully delegates the responsibility for health care delivery and associated financial risks to a medical group or an independent

physician association.

Capitated arrangements transfer the financial incentive to document more diagnosis codes from the plan to the provider. Providers diagnose conditions during health care encounters with plan enrollees and have direct access to enrollee medical records. Thus, capitated providers are able to document even more diagnosis codes than the plan could have documented, and in cases like California and Florida, shown here, capitated providers appear to be aggressively documenting more diagnosis codes and increasing MA risk scores.

We don't know whether the MA organizations we identified here use the delegated model, but we did find that the five highest-coding California or Florida organizations use capitation for nearly all payments to providers, and use of capitation among the other California or Florida organizations is generally correlated with their level of coding intensity.

In 2016, the Commission recommended a change to the coding intensity adjustment that would address both excess payments and the competitive advantage that some organizations have due to coding. The Commission's

strategy first focuses on addressing underlying causes of coding intensity by removing health risk assessments from risk adjustment and using 2 years of data to improve diagnostic documentation and then applying a flat adjustment to account for any remaining effect of coding intensity.

Since our recommendation, the OIG has highlighted the use of chart reviews and health risk assessments as significant underlying causes of coding intensity. Based on OIG's findings, we calculate that nearly two-thirds of excess payments to MA plans are due to chart reviews and health risk assessments.

Furthermore, MA plans use health risk assessments and chart reviews to differing degrees, which contributes to the variation in coding intensity across MA plans and organizations. Eliminating these underlying causes is a necessary component of fully addressing MA coding intensity.

Now we'll move on to a summary of quality in Medicare Advantage. Clearly, the enrollment trend showing large year-over-year growth in the share of Medicare beneficiaries choosing an MA plan demonstrates that some

baseline level of quality is being met. However, through work over several years, the Commission has concluded that MA quality cannot be meaningfully assessed through the current system, and it should not be used as the basis for distributing bonus payments.

Your mailing material cites prior Commission reports explaining the many flaws of the quality bonus program, which include assessing quality for large contracts with dispersed enrollment, using too many measures, and not providing beneficiaries information about plan quality in their local market.

Despite these issues, the MA quality bonus program now accounts for at least $15 billion in annual bonus payments to MA plans above the revenue that plans require to provide the Part A and B benefit.

In our June 2020 report, the Commission recommended replacing the quality bonus program with a value incentive program that would focus on local markets, use a smaller number of measures, and distribute plan-financed rewards. Over the next analytic cycle, we anticipate continuing work on our MA value incentive program.

To summarize, the MA program is extremely robust. If the current trend continues, the majority of Medicare beneficiaries with Part A and B will be enrolled in Medicare Advantage in 2023. Plan offerings and extra benefits continue to increase, such that the average beneficiary now has a choice of 41 plans, and the average MA enrollee has access to $2,350 in annual extra benefits. Payments for these extra benefits now represent 17 percent of all payments to MA plans. However, Medicare continues to pay MA plans 6 percent more than fee-for-service Medicare for similar enrollees, or an estimated $27 billion in 2023. These overpayments worsen Medicare's fiscal sustainability and demonstrate significant flaws in the payment system.

Over the past few years, the Commission has made recommendations addressing flaws in the coding intensity adjustment, the quality system, and the way benchmarks are set.

One topic not discussed today is MA encounter data, where the Commission has also recommended ways to improve data completeness. Reforms on these policies are urgently needed.

That concludes our presentation, and I'll turn it back to Mike.

DR. CHERNEW: Thank you both. Given that the Medicare Advantage program is a growing and I think roughly half, maybe a little bit north of half, actually, part of the Medicare program, I think this is increasingly central to how the Medicare program functions. And so, just for those at home, we are not going to have recommendations on Medicare Advantage this cycle. We do have a set of recommendations that Andy and Luis referred to, but we are going to continue to focus on this.

So I am looking forward to all of this discussion as we go through, and so, Dana, let's start with Round 1, and I think it's Kenny.

MS. KELLEY: Yes. Kenny?

MR. KAN: Thanks, Dana.

On Slide No. 8, I believe that the analyzed 106 percent 2023 data point on the dotted red line is based on 2023 MA benchmarks, which are impacted by 2022 star ratings. Stars is very complicated. So the 2022 star ratings are impacted by a CMS relaxation of quality reporting rules for 2020 due to the pandemic. So star

ratings subsequently drop in 2023, and this will impact 2024 payment year and the benchmarks when we do this same analysis a year from now.

So it appears, then, that the 6 percent differential benefitted from a nonrecurring change in CMS policy in 2023 as the star -- the 2024 average stars rating dropped from 4.37 to 4.15 per Oliver Wyman, which I've shared with the staff.

How material was the change, and could we please note the issue and the materiality of the issue up front in the March chapter?

MR. SERNA: So, to the extent that the change in star ratings from 2021 star ratings to 2022 star ratings affected payments in the subsequent year, that would be reflected in the base, the base comparison, which is the green line. So, if you see from 2022 to 2023, it's pretty flat. So the magnitude, to the extent there was a magnitude, I don't think we can isolate whether it was strictly from the stars or how much of it was from the stars. It was pretty minimal from 2022 to 2023.

DR. CHERNEW: Yes. So let me add that there's two parts to this. One is, I think, the factual reporting

of the numbers, which reflect one-time things or otherwise. And I think, Kenny, you're not disputing that part. And the second part is the inference that you draw from the numbers that you see, and I think any one-time thing, that would be a question.

I think it is fine that in the chapter we acknowledge that there were some changes to the quality program that would influence those numbers. But I think what's clear, if you look at the red line, the blue line, the green line -- if you look at the lines, this program has pretty stably been a few percentage points above fee-for-service since -- I don't know, this was close to where it was, I think, probably when I was on the Commission back, you know, years ago. So I think the specific numbers, you know, all these will change, but I think the general inference from the chart is that, on balance, we believe -- "we" being MedPAC -- that collectively Medicare Advantage is getting paid more than comparable beneficiaries would have been paid had they been in fee-for-service.

And I guess I'm going to say one other thing. I just want to emphasize that you guys said -- I'm

emphasizing this for folks at home. We get a lot of comments, and, by the way, we like all the comments, and a lot of those comments have involved things like how people that are in A or B but not both are treated in the comparisons. And in the retrospective method where you mentioned in your presentation -- this is amongst Medicare Advantage eligible beneficiaries -- that is equivalent to people that have both A and B. So the extent to which the critiques have come in -- and we have been saying this for a while -- it doesn't make that big of a difference. We now are presenting a set of numbers that shows you when you restrict a comparison to both A and B patients, we don't see a big change in our basic conclusions.

I just wanted to emphasize that. That wasn't really a Round 1 question. If there was a Chair, they would have cut me off, but there wasn't. So I think we're going to go --

MR. KAN: Thanks, Mike. I have a second question if I may.

DR. CHERNEW: Yeah.

MR. KAN: Okay. On the same slide, I believe there is tremendous diversity and heterogeneity among MA

plans. So I work as an actuary at a small nonprofit regional MA plan who place in the 95 percent quartile, and we struggle financially. I suspect that the numbers, especially the 106 and the 101 on that slide on page 8, could vary significantly by quartile level. Would it be possible to show this by quartile in the March chapter or future work?

MR. SERNA: So we can -- definitely in the report, we do report out numbers by quartile. We report beds. We have in the past reported benchmarks in overall payments by quartile. That's something we can look into doing again this year.

MR. KAN: Thank you.

DR. JOHNSON: Coding intensity does play a big part of that, especially in the 106 number. That would be harder to break out by quartile, just to set expectations.

MR. SERNA: Yeah, that's one large limitation to looking at anything by quartile, was that we don't have code intensity estimates at that level.

MS. KELLEY: Okay. Marge had a Round 1 question.

MS. GINSBURG: Yes, thank you. Page 2 of the materials that were sent out, about halfway down it says,

"Instead, Medicare spends 6 percent more per MA," blah, blah, blah. The next sentence: "That difference translates into a projected $27 billion in 2023. This would be even larger if the favorable mix of beneficiaries in MA plans were taken into account."

I just didn't understand this. The sentence made it sound as if, oh, does that mean we're doing something right that this number would be even larger if, dot, dot, dot? But I don't understand the part "if the favorable mix of beneficiaries...were taken into account." I wonder if you could explain more what this means.

MR. SERNA: That's explained later in the chapter, and what that basically means is that the risk-adjusted spending of beneficiaries that enter MA, we've observed -- and we're looking into it more, but the risk-adjusted spending tends to be lower relative to the rest of the fee-for-service population that remains in fee-for-service. And that's something that we're looking into. But if that holds and if that's a consistent pattern, then that basically means that risk scores are overpredicting spending for MA enrollees relative to those who are in fee-for-service. But, again, that's something that we didn't

focus on in this chapter, but we wanted to allude to it, that we're looking into it.

MS. KELLEY: Lynn?

MS. BARR: Thank you. A great report.

So on page 14, we talk about the coding intensity. Would you be able to break that apart by type of plan, so provider-based plans versus non-provider-based plans? Because I'm curious as to sort of seeing what that looks like in terms of coding intensity. I'd somehow want to take Florida and California and label them differently, you know, so like a double label of those, because obviously there's so much money to be made in those environments that I can see providers actually doing those kinds of plans in those states, but outside of that, I'm curious because, you know, a lot of the provider-based plans aren't doing all that well, and I'm curious as to how that graph would look. Would you be able to do that?

DR. JOHNSON: That is something we can look into. I don't think there's a definitive list of which plans are provider-sponsored or not, but I know that some other research has been done. We can try and replicate what other people have done to identify those types of plans.

MS. KELLEY: Amol is next.

DR. NAVATHE: I had three questions. The first one is on page 4 of the mailing materials -- and we've used this language repeatedly, and this is referencing the rebates, that plans can devote the rebate to lower cost sharing, lower premiums, or supplemental benefits, and plans retain administrative costs and profit on most of these benefits. I was wondering if we have a sense of what the formula is, what the magnitude is on this, plans can retain administrative costs and profit on those benefits.

MR. SERNA: So in the past, we've reported what the plan projections were for those administrative costs and profits, and we can think about noting that again. But it's typically in the range of 10 to 15 percent.

DR. NAVATHE: Ten to 15 percent of the total rebate?

MR. SERNA: On those services, so on those -- so plans cannot profit or admin load on Part D premium reductions or Part B premium reductions, but on supplemental benefits, on cost-sharing reductions, they can.

DR. NAVATHE: On cost-sharing reductions they

can.

MR. SERNA: Correct.

DR. NAVATHE: So it's on the premiums.

MR. SERNA: That's correct.

DR. NAVATHE: Got it.

DR. JOHNSON: And they can load on the Part D side for Part D cost sharing.

MR. SERNA: Correct.

DR. JOHNSON: In one of the two sectors, there is loading on everything but the Part B premium reductions -- Part B as in "boy."

DR. NAVATHE: Okay, great. I think if that could be added as a footnote, it would be helpful.

The second question is on Slide 4 -- I think this is where we're showing access -- access to plans is robust. And I was curious if you could -- I think you did comment on this in the mailing materials, but I was hoping you could recap for us here. This sort of suggests that there's a lot of choice and there's a lot of competition in these markets. But my understanding is that, in fact, that's highly variable and that the market can be very concentrated. So is that correct? And how would you

characterize that?

MR. SERNA: So I think right now -- it is in the mailing materials, but you have a situation where you have both. You have highly concentrated markets, but you also have a lot of choice. So the average beneficiary typically is going to have a choice of plans sponsored by eight organizations, and that was for 2023 and 2022. While the markets are heavily concentrated, there are a lot of plan choices available, both at the insurer level and the actual plan benefit level.

DR. NAVATHE: So this might be a little bit more than a Round 1 question, but I'm curious if you can speculate on what's happening in the market that we're landing there. If we have eight choices but two or three of them are dominating the market, is that a reflection -- I'm kind of -- well, instead of my speculating, I'm curious if you can speculate what might be going on there.

MR. SERNA: So we talked about it a little bit in the chapter when we looked at concentration nationally and then we looked at concentration locally. It appears that at least some of what's happening is that plans are entering new markets and gaining market share in those

markets where some plans have had a stronghold on those markets for a long time. And now that you have more market entrants, you have them taking up a larger share of those markets.

Now, they're still highly concentrated, but the amount of concentration, locally at least, has slightly decreased in recent years.

DR. NAVATHE: Okay. And is there a sense that because of rules around plan consolidation and how stars works and such that there is any advantage, if you will, that accrues to national versus regional plans in that?

MR. SERNA: So we have seen a pattern of the national plans having a larger market share nationally, and if the market share locally, if it's becoming less concentrated, that would suggest that the national plans are entering new markets.

DR. NAVATHE: Okay, thanks. One last question. If we can go back, I think it's Slide 8 -- on Slide 8 and Slide 10, I think we show the different MA versus fee-for-service comparisons, and this is somewhat related to Kenny's question and Mike's comment. But I was just curious if you could clarify for us.

So here we have in 2023 an estimate of 106 percent, and I believe this is the -- well, maybe you can help me, but I thought this was a prospective method. And if we look on Slide 10, then we have an estimate that I believe is 102 percent. So this is simply a year difference, this is 2019, and we have 102 percent, but whereas in the prior graph we're charting that out. Is that the main difference there?

MR. SERNA: That's --

DR. NAVATHE: The methodology is the same and --

MR. SERNA: Right. So for the retrospective analysis, our most recent year is 2019 because of data availability.

DR. NAVATHE: Got it. So that's where we can compare retrospective with prospective.

MR. SERNA: That's correct.

DR. NAVATHE: Got it. Okay. Thank you.

MS. KELLEY: Dana?

DR. GELB SAFRAN: Thank you. Really excellent work and always a very important chapter.

My question relates to the information you shared on Slide 16 around delegation in Florida and California,

and it might be a multipart question, but let me start by asking: How did you decide that delegation in particular was the issue that was different in those two states and accounting for this?

DR. JOHNSON: That is some speculation on our part because it is known, especially in California, that it is in some parts of the state, especially in the southern part of the state, it's the predominant model being used. We don't have a list of, you know, these plans have X share of their payments to providers under a delegated model, but we do have that under a capitated model. So sort of putting the two together, saying that these plans do use a lot of capitation, as they report in some data sets, and we know that it is common -- it's the delegated form of capitation in these areas. So we think that's what's going on, and it was pretty apparent that -- we didn't, you know, quantify this, but the levels of capitation -- plans that use more capitation in other states aren't showing up on the very right end of this slide, too. So it's really the California more capitated plans that are on the right end -- California and Florida, more capitated plans that are --

DR. GELB SAFRAN: Yeah, and I wonder, it sounds

like you have some data limitations, but I do wonder what data do you have that could inform this question of how plans are incentivizing providers around coding, because delegation might be one -- might be even the most extreme approach to that. But, you know, any kind of risk sharing arrangement, you begin to have those incentives. So do you have any of those data that would allow you analysis?

DR. JOHNSON: Right now, I think the best data we have has the share of payments to providers that are under some capitated model. There's a little bit more detail that we could look into, but we'll have to think about that some more, I think.

DR. GELB SAFRAN: Okay. And then the last part of this is: Did you consider in whatever modeling you were doing other characteristics of what's different about those plans in those two states? And it might not be the same for both states. You know, for example, one state might have, you know, a ton of -- to, I think it was, Lynn's point -- provider-sponsored plans and another state might have a ton of some other attribute, maybe it's for-profit plans that really drive this in their provider contracts. Did you consider other things?

DR. JOHNSON: We haven't dug into that yet, but that is a good suggestion. The one thing I will say is that especially the plans in the yellow box are -- most of them have almost all of their enrollment in California or in Florida separately so they tend to be either regional or at least focused on those individual states. But we can look into some of the other characteristics.

DR. GELB SAFRAN: Great. Thanks, Andy.

MS. KELLEY: Cheryl?

DR. DAMBERG: Thank you. This was a great chapter, a lot of information packed into it. I have a couple of questions.

One, there's a statement about margins being higher in SNPs, and I guess I was trying to understand why that might be the case and whether you could unpack that a little bit.

MR. SERNA: I don't think we know for sure. It's been a consistent pattern since we've been reporting margins, that the margins of special needs plans, writ large, whether they're D-SNPs, I-SNPs, C-SNPs, tend to be larger than traditional MA plans.

I don't know if you want to add anything to that,

Andy?

[No response.]

DR. DAMBERG: Then, I was also really intrigued by the -- it was in the slide deck. I guess it's Slide 6, about the rebates having doubled since 2018. I guess I'm trying to understand the factors that are driving that doubling. So I'm assuming some of it's tied to fee-for-service benchmarks being too high. Right? Is that like the primary driver, or are there other things that we should be considering as we think about, you know, these rebate amounts and -- I don't know, this may be the wrong term, whether they're appropriate, like how big they should be, how that money should be used.

MR. SERNA: Right, so this goes back to the recommendation we had in 2021 to address benchmarks so that overall -- there were a number of things that we incorporated, such as using the A-B population, using markets instead of counties. But we did recommend that the overall level of benchmarks should be reduced by at least 2 percent. What's happening with the rebates is kind of -- there's misalignments between plans' risk-adjusted bids and the benchmarks, and, increasingly, they are diverging over

time.

DR. DAMBERG: Yeah, it's really significant. And then my last comment about rebates -- and this relates to the quality bonus payments and how they're determined. Did the Commission or staff talk about not pegging the bonus payment to the rebates so there wouldn't be that differential, essentially inflate bonus payments? Was that ever discussed or considered?

DR. JOHNSON: I don't think we discussed that as part of the recommendation. We do have a separate recommendation to replace the quality bonus program with a local quality measurement that would distribute money within a local area among the plans that operate there. We didn't quite do what you said, but we've sort of addressed the issue in two different areas.

DR. DAMBERG: So that wouldn't be tied to the rebate at all, what you're just describing.

DR. JOHNSON: Correct. Those are two separate --

DR. CHERNEW: So let me just add one other thing that may or may not be clarifying, and we'll see if Andy and Luis correct me.

One of the challenges is it's easy to think that

any supplemental benefits or cost-sharing reductions or whatever come out of the rebate, because in some nominal sense they do. But there's some leeway in how all those things are costed, and so I think a fair bit of the extra benefits is actually financed through parts of the bid and not just the rebate. So the rebate I think is a reasonable measure of generosity of what's going on, and the growth in the rebate from the slide I think actually -- I'll be careful here -- gets a lot of people's attention. And it's very clear, if you just look at the level of benefits that people are getting, they're getting a lot more, whether that's measured by how you see it in an anything sense or if you just look to see what's happened to the premiums they're paying, the propensity to get benefits. You see much more there. But it's not all directly through the rebates, so there's some fungibility. So the big difference, if we were, for example, to put the quality under versus above, whether it's rebate or not, it would be taking money away, and one way or another -- the bids would adjust, things would happen -- you would see some reduction in benefits. Whether it be financed through the rebate or through some other things --

DR. DAMBERG: Right, right.

DR. CHERNEW: -- is a little bit hard to say.

DR. DAMBERG: Okay.

DR. CHERNEW: I feel like I'm in some sort of, you know, oral exam here.

[Laughter.]

DR. CHERNEW: But I think that's basically right.

I think we have Larry and then I think we have Scott. Is that right? And then I want to move to Round 2, because we do have a Round 2, and we will be pressed for time. Larry?

DR. CASALINO: Yeah, I have several what I think are pretty quick Round 1's. I just want to clarify a little bit about the California groups -- I don't know that much about Florida -- and the phrase "provider-based plans." The California situation, unless my information is very wrong, is not provider-based, not provider-sponsored health plans. These are big health plans, and they give a lot of capitation and delegation to the groups. So that's one point.

I guess a corollary point is that incentives matter, so diagnostic coding intensity is not just a

creature or maybe an earlier creature of evil health plan executives. Medical groups' doctors do the same thing when it's to their advantage to code higher, and they actually are in a favorable position to do it.

I just wanted to second Marge's comment about favorable mix. I did understand that sentences, with some work, and you did explain later in the discussion. I think that was in the executive summary, that sentence. But I think as it stands there, it is a little puzzling and it probably needs to be, especially in the executive summary, which is what a lot of people will read, it probably does need to be explained more, which you do later, it would probably work better.

Third point, a similar point to Amol, trying to get at consolidation. On page 24, you say the average beneficiary has, quote-unquote, "access to many plans." And the question I had when I read it: Is that the same as access to many organizations offering plans? Because you could have three organizations, or two, offering plans and have 15 plans, but that probably doesn't imply quite as much choice as if you had 15 organizations offering one plan. So I think it's important to clarify that, because,

again, a lot of people will read "access to many plans," and they won't make the distinction between organizations and plans. So I think that's a distinction, in my opinion at least, that throughout needs to be made clear every time it's referred to, basically.

I'll have a little more to say about concentration in Round 2.

And then the last point I have is actually a question about what we just discussed. So in terms of rebates getting bigger, a lot bigger over the years, I just want to see if you -- and you can add to it, I suspect, or correct it -- can list the factors that could lead to larger rebates. So one would be higher benchmarks, higher -- whatever, you know, however you want to define that. Two would be higher coding intensity. But there is a third one, right? I mean, you could say -- it's a little unfair to the plans, I think, to say those might be the only two reasons. If they were actually reducing spending, that could also lead to larger rebates, right?

So is it those three things? Am I missing anything in terms of -- first of all, are those three correct: higher benchmarks, reducing spending, and/or

increasing diagnostic and coding intensity? Are those three correct? And is there anything else?

DR. CHERNEW: It's stars, as Kenny pointed out.

DR. CASALINO: Okay.

DR. JOHNSON: No, that's right. I think that the higher benchmarks could be broken out into a larger share of MA enrollment being in the plans that have a bonus, so stars, there's going to be higher benchmarks because of the higher bonuses for more enrollees. And then among the quartiles, I think it is the 115 quartile is where the largest overpayments are relative to fee-for-service, and there's been some migration of enrollees into that quartile relative to the other quartiles too. So there are reasons why benchmarks are going up but generally those are the three I think we think are --

DR. CASALINO: Would there be any way to quantify, and possibly back of the envelope, but still acceptable way to give us a sense of the relative magnitude of those four factors in creating higher benchmarks, I mean higher benefits, higher rebates?

DR. JOHNSON: Maybe at a later date.

DR. CHERNEW: I would just say, I do want to move

us along but I will say there is a sense that the coding differential grows over time. So I think we don't believe that there's a fixed coding differential, and that's complicated because there's a question of how much room -- at some point you'd think there would be a limit. Joe Newhouse has written on this point and I would never disagree with Joe. Tell him that, David. But I don't think we've gotten close to that point yet, at least if you look at what our data shows. So I think there is the potential for efficiency.

And as an aside for those sitting at home, we believe MA plans can deliver A and B benefits more efficiently than the fee-for-service system. We are pro Medicare Advantage in the belief if there's a question of what they're paid, and I think some of what is changing is an estimate of the coding. How much is inefficiency and stuff is harder to figure out.

DR. CASALINO: I may be a little less pro than you are, Mike, but I do think in fairness, in theory, we know that this isn't the case, but in theory all of the larger rebates could be due to health plans' efficiency in driving cost down in the system, right. So maybe more

explicit attention to what the various factors are, at least naming them, even if we can't get a sense of their relative importance with the fact that they could be driving benefits higher or rebates higher. I think that might help, because that's pretty important, and you kind of have to work to get at it now, I think.

But great chapter. I really enjoyed it as I was reading it.

DR. CHERNEW: I think Scott is next, and if no one has jumped in, last. Yes, in Round 1 anyway.

DR. SARRAN: Thanks for the excellent work. And given how many really important policy questions are raised by this, I think it would be very helpful to parse all the data in here in at least the following ways. I'd like to see them parsed SNF versus non-SNF, and then within SNF by the type of SNF. They're really different businesses, different populations, and they raise and answer some different policy questions.

And as I think you've heard here, I think there are reasons why it would be very helpful to parse by, let's call it the big three or four versus everyone else, for-profits versus non-for-profits, provider-owned versus non-

provider owned.

So my question is how easy is it for you to do that kind of thing? Is all of this in a format where that's pretty quick, or would there be a ton of manual work in order to get at that?

DR. MATHEWS: Scott, let me make a run at that. We can go back to the office and have a discussion about what is or is not feasible in future work. But recall that we need to get this draft chapter out for external review by Monday, so not a lot is going to happen substantively in terms of major new analysis, major stratifications, trying to be able to identify definitively this type of plan versus that type of plan.

But, you know, again, we'll go back, debrief, and figure out what is feasible over the course of our next cycle.

DR. SARRAN: Okay. So then, you know, I totally get, Jim, what you're saying. I think it's important to tee that up for next round of work, again, given the importance of the questions that this raises.

MS. KELLEY: That is the end of Round 1, unless I've missed anyone.

DR. CHERNEW: No. That's what I had too, and I have Stacie kicking off Round 2.

DR. DUSETZINA: Thanks, guys, for a great chapter. I have just one minor suggestion for the chapter as it is, and maybe some of those like looking forward, what we might want in the future comments.

The first is on Figure 2 in the reading materials, that just shows the trend in rebates. I wanted to see the bids and the benchmarks plotted alongside of those because I felt like I could infer what those were from the text. But if you could plot them together it seems like that might be useful information to have on that figure.

I guess for a broader point, when looking at the executive summary, you know, you basically go through and say that people in MA have access to over $2,350 in extra benefits that a fee-for-service enrollee would have to purchase separately. And that just sort of feels like we do a really good job in the chapter of focusing on kind of the component of all the extra things you get but not as much on the what are you trading off there. So it sort of seems like there's no downside to picking MA for

beneficiaries and there's definitely potential downside, and it's the network adequacy question, which I think we don't know enough about. I know we've talked before about how difficult that is to measure, but I think it might be worth adding even a little bit about some of these potential tradeoffs for people where their networks might not support the care that they need access to.

Wayne was just pointed out to me that some large health systems that I'm very familiar with just have left a couple of MA programs. So I think it is important for people in the continuity of their coverage and care.

And I think one thing, I know this is expensive to do, it's a big ask, but you also said we don't know much about how MA beneficiaries are using their supplemental benefits, and I wonder if we should do some targeted surveys of MA beneficiaries around these questions of network adequacy and about supplemental benefits access and use. So do you have dental? Yeah. Have you tried to use it in your area? Can you get access? Does it cover the things you need? I think that might have to come from beneficiaries to really get a sense of how things are going, but could also help us with the work adequacy

question.

But overall a really great chapter. I just think a little bit more on those tradeoffs would be helpful for context.

MS. KELLEY: Greg.

MR. POULSEN: Let me pile and say great report, timely, great information, and I appreciate it very much. What I'm about to say is probably not going to be terribly useful for what you might do between now and Monday. But I think that we need to keep the context of where we might want to go in the longer term with MA. And I may be running out of time to declare myself as about to make a rookie mistake but I'm going to pull it off anyway if I can.

And I think that, you know, at the risk of being de-Keynesian, I think MA plans are the worst of plans and the best of plans. And we see both, and I think that they really do depend on a lot of different things. How to be successful in MA -- and I think I'm going to try and boil down the ones that we talked about, per Larry, from four to two, and it's basically administrative things you can do and it's actually providing care more differently and more

effectively. I mean, those are the two basic areas that we have to work with, and we see examples here of both.

You know, clear back in '82, when TEFRA created managed Medicare, a number of organizations showed its potential, and we saw that through the 1990s. There were organizations that did a remarkable job of taking tough populations and providing them with better health at lower cost, and at high levels of satisfaction. You know, and so they met all three of those.

I think we've seen examples of that continue beyond the '90s and into the current day. Some of the organizations that have members here in this room are part of that group, and I think that's wonderful to look at and we ought to examine those and look what makes them different.

I think you can make a case that the skills that that brings are often based on having the correct incentives at the provider level, where provider decisions are being made. It also makes it an opportunity, a perverse opportunity, to do coding and other things. There's nobody in a better position than the frontline folks to make coding differences, whether they be pushing

the limits a little too far or whether they're just accurate. But it's also true that those are the same folks that can make a difference in the way care is delivered for the benefit of folks.

And it's interesting to me, and I think it may answer some of the questions that came up regarding SNPs, a lot of the organizations look for where is the biggest opportunity to make a difference? Well, it's oftentimes in cases where people are in more serious clinical and often financial situations that go together. And that's where some of the organizations have made the biggest improvement. That's a tremendous societal benefit, and oftentimes a good financial impact as well. And obviously I think we'd like to find ways to encourage that.

I would point out that the vast majority of those that have done really well were, in fact, provider oriented or at least had providers that had financial accountability, with financial accountability, because it motivates them to think clearly about how can we make these people healthier, more focused on their well-being, and how can we deal with some of the social determinants. They are very hard to do in a fee-for-service world.

To the extent that the star ratings have any meaning -- and I'm going to go pre-pandemic, where I think to the extent that you would think that stars have any benefit, I would argue they had a little more benefit before they got widely expanded. But provider-organized or provider-oriented plans were 27 times more likely to be five stars than the rest of the organizations. That's not a small difference. So whether you fully believe in the star rating as being valuable, if it has any value whatsoever if demonstrates having the providers engaged makes a big difference.

However, we also have noted, and the chapter, I think, does a great job of pointing out that there are less virtuous ways to be successful in MA, and we talked about those. We're pointing out that you can consistently do well by maximizing coding. And I guess I would note at that point I agree, absolutely, with the recommendations that were made in 2016 and subsequent, but I wonder if we might want to even look at one thing that goes further than any of those.

And I would note that MA is one of the very, very few insurance programs, private or government, left that

has individual underwriting or something that you might contemplate as individual underwriting. Just about everything else now does things based on some sort of community rating or group history rather than looking at the individuals.

We spend a lot of effort, as a country, trying to look at every single individual that's in an MA plan to figure out she or he is doing, and potentially persuading ourselves that they're not doing as well as they might be doing because we get paid more if we do that. Could we look at what has worked in basically every other aspect of insurance, whether it's small group, large group, individual, through the exchanges, other things. We've basically stepped away from individual underwriting and just looked at history or looked at community rates. And I would suggest that we look at that for MA. I don't see why we shouldn't, and I think it would clean up a whole lot of nasty things that happen right now.

The other thing that I think is a strong case for moving towards pre-payment or some type of payment that's different, towards the providers within the MA plans is looking at another way that organizations can make money

and that's by playing a denials game, which happens a lot. A recent -- let me see if I can grab my data here -- HHS OIG report from last April shows that about a fifth of MA plan denials would've been paid for under fee-for-service Medicare, that they met all the criteria. And so that's another mechanism that certainly does the federal government no good. It does the providers no good. And, in fact, it tends to leave the beneficiaries in a position where they're caught between the two organizations in a way that isn't fair to them.

Finally, in addition to that, I'd note that MA denial rates are about 70 percent higher than commercial denial rates. The same providers that are doing those things, why would that be different? And I think it's because the easiest way to make money in MA is to either inflate coding or reduce the payments to providers.

So, you know, I think to the extent that we can learn something from that, define the way that we pay MA plans differently in a fundamental way, and then encourage, maybe require, MA plans to pay providers in a fundamentally different way that aligns with what we really want to accomplish with the beneficiaries that we're commonly

caring for and have responsibility for. I think that might be a tremendous move forward.

MS. KELLEY: Jonathan.

DR. JAFFERY: Thanks, and I'll try and be brief. This is a great chapter.

You know, one of the things that really jumped out at me, and some of this will build on Greg's comments, but one of the things that really jumped out at me was, you know, we talk a lot about coding intensity, but the newer piece was really this emphasis on just how much of it was from chart review and HRAs, that's two-thirds, and maybe we've talked about it to that degree before. I know it was from a recent report. I can't remember now who it was from. But that struck me as really pronounced, not necessarily surprising, but the degree is really significant.

So it also strikes me that, you know, you've used the word "urgent" a few times in the chapter and today, and we've heard some other comments that speak to some of the urgency. And, you know, there may be avenues to really emphasize that that's a way -- and I know we've recommended it before -- but to move away from even those two things as

being ways that plans can increase their coding intensity.

And Larry mentioned that providers, it's not just plans but providers, especially if they're taking capitation or other delegated risk, do some of these same things. And while that's true, I don't think it's to the same degree, and I don't think it's yet to the same degree in ACOs and other alternative payment models, but it's moving there. And so I think the more we nip that in the bud, probably the better.

And then finally, we've talked about this plenty in the past, but trying to come up with some way to encourage or acquire or even track the degree to which MA delegates risk to providers rather than just passes through to the fee-for-service system is a key point.

So thank you again for the great chapter.

MS. KELLEY: David.

DR. GRABOWSKI: Great. Thanks, and thanks, Luis and Andy. This is a great job and such an important body of work.

I'm a big supporter of all the steps that MedPAC is working on in this space, addressing flaws in coding intensity, the quality system benchmarks, and MA encounter

data completeness. I want to add one other issue, and several Commissioners have already kind of teed this up. But I would assert that special needs plans or SNPs are like regular MA plans only more so. As Cheryl already noted, they're making larger margins than regular MA plans, and they're also growing. From page 20 of the report, in 2022, SNP enrollment grew by 20 percent.

To Greg's earlier point, however, not all the SNPs are created equal, and we have a huge variation in terms of how well they achieve their stated goal, and that's really to integrate care for dually eligible beneficiaries. I'm, of course, referring to the dual eligible or D-SNPs that account for the vast majority of SNP enrollees. But they're not well integrated, either financially or clinically, across the two programs. And this is really a lost opportunity for millions of dually eligible beneficiaries.

It's interesting. In addition to the regular D-SNPs we have what are called highly integrated D-SNPs, HIDE SNPs, and then we have fully integrated D-SNPs, FIDE SSNPs. Only in Medicare would we have sort of the garden variety, highly integrated, and fully integrated, and what we really

want here is the fully integrated flavor, not the lower ones. Yet if you looked at sort of the -- it's basically a pyramid, with the vast majority of beneficiaries being in those regular D-SNPs. And FIDE SNPs are only in a handful of markets, as you both know, and it's not really present across the country.

So I think we really need to take steps to kind of convert what are now D-SNPs into looking much more like FIDE SNPs, truly integrating or working with Medicaid, aligning the plans financially. There is a whole set of steps that we take, and I know MedPAC is supportive of that work. Eric has presented on this in the past. This isn't new, but I think it sometimes gets lost in our broader agenda, Jim, that we're very focused on kind of MA and sort of the big picture.

But I think for our most vulnerable beneficiaries this is really what they need, because I think far too many of them are in sort of fake integrated plans, and they need to be in real integrated plans. Thanks.

MS. KELLEY: Marge.

MS. GINSBURG: Well, I think I'm going to make a suggestion that will probably be rejected based on

everything has to be done by Monday.

[Laughter]

MS. GINSBURG: So my frustration with the cost of MA plans and what this represents for taxpayers is where I am focusing at the moment. Our wording, our criticism of the various things that CMS is doing wrong has increased. We're using stronger words now than I think we did a couple years ago about what's wrong with the system, and I definitely applaud that.

I guess what I'd really love to see in this chapter is a chart, which I actually think we could do by Monday, that shows various recommendations that MedPAC has made for the last -- I don't know -- eight or ten years about what we think needs to be changed about how MA plans are financed and with the goal being to get them back to where the original intention was that fee-for-service would cost more, not less, than MA plans.

And I think a chart that shows year or years, the recommendation that MedPAC has made, any action that CMS or Congress has done, which is probably zip, the financial cost this represents to the country, and I think it's -- my view is it's time to get really specific about putting

their toes to the fire. And I don't know any other way to do it. I think probably most Commissioners would agree with me and have some degree of frustration about how little has actually happened with regard to MedPAC's recommendations.

I don't know how to make it any clearer than a chart that shows exactly what we've been trying to do and how the costs have increased, with an emphasis on what this is costing taxpayers.

So that's my suggestion. I'm sure staff can roll this out by Monday.

[Laughter.]

DR. CHERNEW: Well, I just want to say one thing in response to that because I think it actually is quite important. Ignoring how this plays out in the chapter, although I think it deserves more attention in the chapter, the original intent, I believe, when Medicare Advantage was set up was, as you said, to save money. I increasingly believe that is not how many policymakers see the Medicare Advantage program. And you see that through the 115 percent of fee-for-service portion of it. You see that through the quality bonus program put above the line. You

see that in a number of ways. And I think the questions about what the purpose is of Medicare Advantage have become, in my personal opinion, more muddled.

I think the rationale behind our recommendations have largely been the -- and you guys should jump in, so correct me -- been a version of we believe that we can cut Medicare Advantage in ways that have relatively modest impacts on benefits. And then there's obviously a fiscal reason to cut and make the program better and do a bunch of other things. But I think that that balance of understanding how people view MA, that narrative, I think, of MA has changed. And I think that is what has complicated the -- when we see that chart, rebates going up like this, we tend to react in a particular way. There's others that don't react that way, and so I think that's --

UNIDENTIFIED SPEAKER: To clarify, you mean --

MS. KELLEY: Microphone.

UNIDENTIFIED SPEAKER: But when you say cut Medicare Advantage, you mean payments, not enrollment?

DR. CHERNEW: Yes.

UNIDENTIFIED SPEAKER: Just to be -- we should be clear about that.

DR. CHERNEW: I mean our recommendation, just for those of you that is -- and I think you said this. Our recommendation was at least a 2 percent cut. There's a bunch of other recommendations on the quality program, smoothing out the quartiles, and a bunch of other things. But the MedPAC recommendation which, by the way, we're not going to vote on it again, that's going to remain. This is a status report chapter.

But that being said, those recommendations hold, and they hold for a range of reasons. And I just think that we are increasingly in a complicated world of the way in which people view Medicare Advantage, and we are going to navigate that.

To your main point, which is -- I do think the chapter can be more clear about parts of that, and we'll think about that.

MS. GINSBURG: One other point I wanted to make -- and this is just based on my understanding of how consumers think -- it's really hard to take things away once you start giving it to them and a really, really difficult, and they will -- they will be petitioning Congress like crazy if there's any thought that they're

going to start losing some of their extra benefits. But the more we let this go on without it being significantly challenged, the harder it's going to be ever to turn this around.

MS. KELLEY: Jaewon?

DR. RYU: Yeah. Thanks.

I also really enjoyed this chapter, a lot of similar themes.

I think clearly there are a lot of abuses with the program, and I think the chapter does a great job illustrating that. But I also think we need to be careful because there are plenty of babies in the middle of the bath water as well, and I think a well-designed coding program, just as an example, or diagnosis identification program, whatever you want to call it, it can and it should identify people with certain diseases, get them plugged into care management programs, get them with the right care plan, and maybe even remove and clean up inappropriate or inaccurate diagnoses. And I think there are plenty of those programs out there as well as there is a heck of a lot of abuse out there as well.

I think at a very fundamental level, you can't

manage someone's blood sugar if you don't know they're diabetic, right? And I think that concept, we need to make sure we don't lose sight of that.

It leads me to the March 2016 recommendations, which I really like because, in particular, the one about codes that are only identified through HRAs, I do think that's a great litmus test to weed out which programs and which diagnoses are really having clinical impact and relevance versus which ones are simply captured in this one health risk assessment and dropped forever. So I think reinforcing those recommendations, I'd be fully in support of that.

The other topic I wanted to touch on briefly was the delegated risk model and the discussion around that. I think it was page 57 of the reading materials. I think there too I would try to be a little more tempered only because that model too has a lot of virtues. The alignment of the clinical and financial accountability with the -- closer with the providers, I think that's exactly what we discuss an awful lot in this setting with APMs and so forth. And it allows for care model innovations.

And I think kind of getting back to Larry's

point, there's probably some good data out there as well that would suggest that they are managing inappropriate hospital utilizations and so forth. So I think some mention or acknowledgment of that in that section, I thought would round out that portion of the readings really well.

And then, lastly, I want to come back to the community rating approach that Greg touched on. I think that's exactly right, and I think the timing is almost well lined up for us to really look at that in earnest, maybe explore it as a next phase of the work, because now MA is on the cusp of becoming the majority of beneficiaries and how they're getting covered. So I think there's more than enough critical mass to support an approach like that.

And I think it goes -- ties very nicely to some of our prior discussions around standardizing benefits. So there isn't in that environment clearly the risk adjustment dynamic of gaming benefits to try to game selection. That would go away as well. So, in some ways, I think the bodies of work could intersect pretty well.

MS. KELLEY: Larry?

DR. CASALINO: Yeah. I'm in a position where I

had a couple of brief things to say, and then as people talk, I have more and more things to say. But I can be brief.

Just on Jaewon's points, one point I would say, Jaewon, you mentioned abuses in the program, but I would actually say after several decades of these abuses, abuses is mild. They're not like one-offs that just happened to happen. More like structural problems.

I agree with you that the capitated delegated model has a lot of advantages. I've really -- as a Californian for many years, some people think it's the holy grail really to try to get to that and have it function well.

So, anyway, I thought the chapter was excellent, and the recommendations MedPAC has made to date also with regard to MA, I think, have been excellent.

I have just three quick points. One is on page 23. You point out, appropriately, I think, that the top three health plans, health insurers have 56 percent of Medicare enrollment nationally. And that's great.

I think you might want to go on and put one other calculation in there and kind of highlight it, which is if

you multiply the 0.56 times 0.5, which is about the net percentage of Medicare beneficiaries that are in MA now, that's 28 percent of Medicare beneficiaries in the United States are in three health insurers, MA plans, and in some counties, much, much higher than that as a percentage. So I think that might just be called out that the three health insurers have 28 percent nationally have MA beneficiaries.

I'd like to see that on page 22, actually, where it would fit and perhaps in the executive summary as well.

There are two other points that may or may not have any relevance for between now and Monday, but I think for our work going forward, it may. Insurers have begun quite rapidly buying medical groups around the country. Now Optum, of course, is the biggest example, but several other insurers are buying a lot of groups now as well. And I was struck by the figure, $124 billion in excess payments to Medicare Advantage since 2007 and good chunks of that in the last few years. I mean, one might ask, how many medical groups can you buy with $124 billion? Quite a lot. So that's actually happening. It's not just something going on in my mind, whether we want to mention that or not or think about it in future work, I'll just leave it there.

The last thing I wanted to say is we did mention briefly this morning that administrative burden on physicians and particularly primary care physicians is very high, and that reducing that probably means more to physicians than a couple of percentage point difference in their Medicare payment rate. And we were talking about, well, can Medicare do anything about that?

So I'll just mention three things that Medicare might be able to do something about that, that are applicable to MA. One is the prior authorizations and denials. I didn't know the figure that Greg gave that denials are 70 percent higher in MA than in commercial. That's stunning. This is the kind of thing that actually drives physicians and beneficiaries wild. So it's one thing to look at the fact that different plans use different quality measures and are always changing is also a huge administrative burden on physicians and medical groups and hospitals.

And the same thing with formularies, really, where you're taught in medical school to learn the different classes of drugs and learn what are the most effective drugs at the lowest-cost category, but then when

you're actually dealing with the health insurer formularies in MA, they're always switching around, depending on the deals the health insurers are able to cut with the drug companies or their intermediaries. And it has nothing to do really with any kind of rational learning that physicians could have. So that's another thing. Those are three things, and probably, we could think of more that are relevant to MA and that do greatly increase administrative burden on physicians.

MS. KELLEY: Dana.

DR. GELB SAFRAN: Yeah. Thanks.

So, first topic, just three quick things. So first one, I'll build on the question around one that I was asking about capitation. I'd like to see us temper the language around that, now understanding kind of how much do we actually know and knowing that Monday is our deadline for this work. There's a lot of good analysis, I think. It sounds like you have the data to be able to do to try to understand a little bit more about different payment arrangements between plans and their provider networks and kind of just how is that influencing the results that we're seeing in terms of coding intensity.

But since we don't have time to do that now, I think it's really important to temper the language about what we know and what inferences we're making. And I say that just because it's good science, but I also say it because I think there's a lot of sort of you in the policy circles and even, you know, practice circles that capitation is a really positive thing when counterbalanced with quality measurement to be sure you're not getting -- you know, stinting on care, because it has a lot of virtues. It frees up providers to make decisions about individual patients and the care they need without rules and constraints. It frees them up from the fee-for-service mindset. It addresses cash flow problems, and so I just want us to be really -- and we have a hangover from the 1990s of a fear of capitation. So there's both, and I just think before we put something strong out there that suggests it's really problematic, we need to be really sure of ourselves. So that was one thought.

Second is on the star ratings. Absolutely, they're flawed. A couple of things that I think would be good to at least point to directionally is, number one, I don't think we would say that the measure -- that there's

something wrong with the measures that are in the star program. It's just that they are what we might call little dot measures, right, a lot of process, even sort of structural features of plans and so forth. And consistent with what I think our mindset is around the APM programs, that we really should be focusing these organizations' attention on big dot measures, a few parsimonious, really important outcomes that we want them to achieve. Then they figure out how to get there in all of those little dot processes. They might use those measures, but they wouldn't be being paid for their performance on the little dot, right?

And so one of the things that strikes me is, you know, we've had many conversations around this table about the challenges of functional outcome measurement and talked about the challenges of that in the SNF environment or long-term care in general, where functional improvement is the most important thing. Well, here we are with a Medicare Advantage program actually collecting longitudinal functional outcome data on beneficiaries through the Health of Seniors. I think it's still called that, the HOS survey.

And so it seems a lost opportunity to not be leveraging those functional outcome data already longitudinally tracked as part of the big dot set of results. Also, patient experience measurement is in there, and I think we'd want to make the point needs to stay in there because it is probably one of the most important ways to have that backstop against stinting on care and be sure that the incentives that Greg pointed to around not just coding but underutilization, you know, it's hard to provide care in a really blatantly underutilizing way and not get patients up in arms about it.

So I'd like us to make those comments about the stars program and try to begin to move it more toward big dots and away from little dots.

And then the final thing I was going to say was just real support for the point that Greg made about individual-level underwriting and a time to really think about community underwriting mentality, if not set of policies here. And if for some reason that's not workable in this program, what are the ways that we can further bound the role that coding intensity plays in financial success?

So thanks very much.

MS. KELLEY: Scott.

DR. SARRAN: Yeah. Three very brief comments.

First, regarding HCC scoring, yes, I think we can and should eliminate HCC scores that are generated just by chart reviews or annual assessments, but that doesn't get at the issue of, in a delegated model, the physicians can and increasingly do a job that is well supported by the documentation that justifies higher HCC scores. So, with that in mind, I totally support Greg's directional comments about saying, look, this whole thing is broken. It's a broken way to pay plans, and we really need to look at something different. There's way too much time and energy spent on the part of MA plans, providers and CMS and the whole HCC game. It's just bad. At best, you can say it's bad time spent.

Second, stars. I mean, shame on us all, nationally. I mean, we're paying a boatload of money, and we're not getting what we want from the quality program, and I complete support Dana's comments about a few stronger measures, because the reality is about -- one of the realities about stars was plans chase stars. And they

will. So that the problem isn't that the plans aren't chasing the stars measures in an appropriate way. The problem is we don't have the right measures. So let's fix the measures and get plans to chase the right things.

And the third brief comment in terms of SNPs, I totally reinforced David's comments. I mean, SNPs are all about specialized populations that inherently have specialized value propositions that should be really important to all of us from a public policy perspective. So I think we absolutely need a deeper dive into the measurement around the extent to which we are getting at the triple aim value propositions inherent in each of the types of SNPs.

DR. CHERNEW: Time check. We are now at time. We have several more people. I'm going to let this conversation go, but don't feel the need if anyone is going to say things that others have said. That part is not needed.

Kenny, I think you're next. Is that right?

MR. KAN: Okay. Thanks, Mike. Thanks, Dana.

So three points to convey, tiering, supplemental benefits, and fee-for-service parallel universe, not for

Monday, but for future psychoanalysis.

So Slide 14 of 20, I want to follow on Jaewon's comment. Let us be very, very careful to ensure that risk adjustment policy proposals are not painted with a broad brush, or small plans or small regional non-for-profit plans where I work at will be collateral damage. We will be one of the babies in the bath water, because otherwise the big plans will squeeze out the small guys and lead to much greater consolidation, because the MA market is not as concentrated as the Part D market, since the Big 3 only controlling like 55 percent versus about 80 percent in Part D.

So could such a framework to better recognize this diversity and yet promote competition, it would be a tiered 5.9 percent coding intensity, which would recognize coding disparities between the small guys versus the big guys, whilst you're targeting a 5.9 percent nationally in the aggregate.

I believe that MACPAC has suggested this in the past, and I'd like to see us bring it back in the next cycle.

Second point, supplemental benefits. I want to

follow on what Stacie just said about really analyzing the value prop of those benefits, because the 106 percent fee-for-service metric is influenced by rebates for supplemental benefits. And I just want to emphasize that many MA beneficiaries join MA because they need help with dental, vision, transportation, OTC drug card, food in return as a tradeoff for the network adequacy issue that Stacie highlighted.

So CMS has actually analyzed this in great depth, has encouraged plans to push forth by giving plans flexibility on this. So let us look at analyzing the value prop and the fact that they're able to manage the A and B cost at 83 percent, you know, I think, you know, really attests to the efficiency while providing much needed valuable benefits for MA beneficiaries. I look forward to continuing the dialogue in the next cycle.

And the third point, I believe there are two parallel universes that play here. First, fee-for-service is based on procedure codes, which offer little incentive for providers to quote more diagnosis codes. They're necessary to justify providing a service. It's just not in their DNA. I've spoken to many doctors about this. MA

plans are based on diagnosis codes. So MA plans have financial incentives to capture diagnosis codes accurately, both to reflect the care costs, the higher care costs in the premium, and more importantly, to manage care, to build a longitudinal care profile to help them manage costs, and that's why they're able to provide A and B costs at 83 percent.

So, since MA is expected to exceed the 51 percent threshold this year, you know, and will likely increase more given support that the program has on both sides of Congress, could MedPAC analyze the visibility of recommending that we change fee-for-service to a diagnosis-based system in a future cycle?

Thank you.

MS. KELLEY: Amol?

DR. NAVATHE: Thanks, Dana.

Luis and Andy, fantastic work, as usual. Obviously, a super, super important topic here.

So I'm going to try, at Mike's urging, to be briefer than longer and try to make five points relatively briefly, as fast as I can.

So, first, I think it's pretty clear that the MA

program is offering a lot of value. I mean, people are voting with their feet in terms of enrollment. It's also -- because of the way it's financed and the flexibilities that Kenny and others have highlighted; I think it's an engine of innovation that actually spills over to other aspects of health care as well. So I think we could do better to acknowledge some of those pieces where MA is actually stimulating some benefits that are even spilling over in other areas.

Second point, I definitely simultaneously subscribe to that, to the idea that there's a tremendous opportunity for efficiencies, broadly speaking, within the MA program. I think there's also an equity effect, if you will, in a sense, perhaps not the traditional sense of the word, but in the chapter and other Commissioners have highlighted that there's this $2,050 difference, if you will, in the benefits that fee-for-service benes are getting. And given the network adequacy and other reasons, there are reasons that some beneficiaries have an interest to be in fee-for-service or it's better for them to be in fee-for-service, and because of this parity issue, if you will, we're effectively penalizing them. And so I think we

should be mindful, and I think that's probably one of the strongest reasons to think about why there should be some parity between how we finance MA versus fee-for-service.

A third point, I think you've highlighted in the chapter. I think it's worth noting that in the initial statute that established MA program, that the initial payment rates were 95 percent of fee-for-service. So there was a thought, at least in the origination, that this program should generate efficiencies for the federal government and the taxpayer.

Fourth point, I think the supplemental benefits point is obviously super important because it clearly does offer value, as Kenny pointed out, and I think it's a driver for many beneficiaries to join the program.

At the same time, there's a definite lack of data, and I think there's also incentives in the way the supplemental benefits are financed and how they're actually delivered to provide benefits through mechanisms like cost sharing, like supplemental benefits that aren't premium reductions and such that allow MA plans to benefit from them. And so I think there's a lot more to do there, and I think what I would say simply is that I strongly support

the work that we've been doing on standardized benefits as a way to try to address that going forward.

Fifth point I want to say is I also support the efforts to try to improve competition, and I think some of this touches on stars. Some of this touches on other program -- broad MA program operations and rules around how consolidation functions, because I think it is important that we recognize.

I was very struck in the reading materials around the concentration of MA program, and I think if we truly believe that competition is beneficial, which I think the whole idea of having a private market for Medicare in some sense is that it is coming from that thesis, then I think we should ensure and do our best to provide guidance around how we can make that market more competitive.

Thanks.

MS. KELLEY: Robert.

DR. CHERRY: Yes. Thank you. It's good to know that we have just until Monday.

[Laughter.]

DR. CHERRY: One important point -- and maybe I might be just a little bit too sensitive about this, but,

you know, we have a couple of sentences that talk about coding intensity leading to either excess payments or inflated payments. You know, the implication of that is that there may be billing improprieties, and I could very overreading that, but that's sort of the way I take it. And if I'm taking it that way, others may be as well. We may want to soften the language a little bit.

One suggestion, because I do like Mike's suggestion about, you know, coding differentials, we could say something like, you know, there are coding differentials that lead to payments that are unfavorable to target. In this way, "coding differentials" could mean a wide variety of things, not necessarily billing improprieties.

Regarding the delegated model, a couple of comments. I wonder if it's related to what I just mentioned about coding intensity. In the delegated model to various physician groups, for example, they don't see it as coding intensity. They see it as coding and documentation improvement, whether it's training and education, within the context of billing regulations to be able to document and code and bill appropriately. And for

them it's not necessarily payment excess; it's revenue capture. So there's a different kind of perspective that I just wanted to mention.

But with that revenue capture, it does allow them to reinvest in the program, to allow for them to grow their MA programs and provide supplemental services like dental, hearing, and vision as well.

The other thing, just to mention what Jaewon had commented on, is that, you know, those coding and documentation efforts also translates into accurate data which are used by those delegated models for performance improvement activities and also measuring, you know, quality.

The other thing regarding the delegated models is that often MA is actually viewed as part of a population health program, and so I'm a little concerned about, you know, removing the high-risk assessments just to reduce costs, because those high-risk assessments may actually be important for risk adjustment methodologies, for identifying high-risk populations, targeted performance improvement activities, and improving the overall quality of care since, again, a lot of delegated models do view

this as a population health initiative.

So I don't exactly understand what the downstream effects are of actually removing that, including, you know, revenue capture that could lead potentially to other supplemental benefits for the benefit of the beneficiary as well.

So, personally, you know, I would pull that recommendation, but, you know, that's up to others as well, just simply because I don't understand the downstream effects of that.

And then, finally, just sort of related to this coding intensity term, there's a disconnect between incomplete data yet we're saying there's coding intensity. So if there's coding intensity, then we should have data on dental services, vision, you know, as well as hearing, because somebody must be seeing the patient, documenting, coding for it, generating revenue as a result of that. I can understand how there's no visibility around gym memberships, but some of the other services around supplemental benefits must be there. And, you know, as far as MedPAC, we may be limited in terms of doing any type of tracer methodology, because it's been suggested in the

past, but perhaps a recommendation to CMS that, you know, limited samples of selected MA plans, just to understand how the data flows from the chart to billing codes, how the MA plans capture those billing codes, and how that's pushed out or not pushed out so that we can capture that on the back end I think would be critically important. MedPAC staff may not have the ability to look at primary source data like electronic medical records, for example.

So those are, you know, several of my comments related to all this stuff. Thank you. But, otherwise, you know, really great work with the document.

MS. KELLEY: Cheryl?

DR. CHERNEW: I think Cheryl is last.

MS. KELLEY: Yes.

DR. DAMBERG: Okay, the pressure's on. I have to be quick.

So in terms of the coding intensity -- I'm looking at Slide 17 -- I definitely support the first two in terms of removing the health risk assessment and the two years of MA and fee-for-service diagnostic data. But I was kind of surprised that we are not including eliminating the chart review, which I would support.

Two, regarding supplemental benefits, I wholeheartedly support and am glad there's language in there about obtaining data on the use of supplemental benefits. That may take time to emerge, so building on Stacie's comment, I think there are things that MedPAC could be doing in terms of interviews with beneficiaries to find out more about those benefits, how they're being used. I don't know if there's some type of secret shopper kind of work that could be done here, but I'd support that kind of work.

I'm going to pile onto Marge's passion and what she said about just kind of reminding people what we're all about in MA and what we're trying to achieve, because I think, you know, this beast or this animal or whatever you want to call it, has morphed. And the question is: Is it what we want it to be? And how do we remind people what we want it to be?

And so, again, building on some of David's comments around SNPs, you know, I think it's really important, especially given the higher margins in that space, and that's where the growth opportunity is, is to really understand what's going on in that space and whether

that's, you know, delivering better value to that subset of beneficiaries. I think we really don't know what's going on in that space.

I really liked Greg's comment, especially about denials and thinking about ways to, you know, reduce administrative hassles in the system as it kind of dovetails into our conversations about workforce.

DR. CHERNEW: Okay. I was going to summarize. I am not going to because of where we are time-wise. There will be a chapter that will be sent out. There will be very, very short turnaround. There will be some changes to the language. There will be some changes not to the language -- some things that are not changed in the language. But all of this is actually quite useful as we go forward in how we think about this.

So I think with that, let's take, just as we do this to our staff, let's just take a two-minute break, maybe three, and just come back right away, and we're going to jump into another topic that I think is going to generate a ton of interest, which is behavioral health.

[Recess.]

DR. CHERNEW: All right. We're back. I think

one of the topics that has gotten increasing attention across the board in the country, including in the Medicare program, is issues of behavioral health. It goes without saying that we have a lot of challenges in the behavioral health space in the country, and that extends to Medicare. So I'm going to turn it over to Betty to discuss what was a congressional request on outpatient behavioral health services. Betty.

DR. FOUT: Thank you. Good afternoon. In this presentation, as part of a congressional request, we are going to discuss Medicare clinician and outpatient behavioral health services, and we would like to thank Ledia Tabor for her valuable contributions, first of all.

As a reminder, a PDF of these slides is available from the webinar's control panel on the right side of your screen.

In January 2022, the Chairman of the Committee on Ways and Means requested that the Commission conduct an analysis of behavioral health services in the Medicare program. The request has three components. First is to update the Commission's prior work on trends and issues in inpatient psychiatric care for beneficiaries. Second is to

describe the utilization of outpatient behavioral health services, including tele-behavioral health services, and the characteristics of beneficiaries using them. And third, to the extent possible, is to describe the use of behavioral health services by beneficiaries enrolled in Medicare Advantage.

Late last September, we presented on inpatient psychiatric care under Medicare and received feedback from Commissioners. In this presentation, we address the second and third components related to clinician and outpatient provision of behavioral health services. We anticipate that these analyses and the previously presented materials will result in an informational chapter in the June 2023 report to Congress.

Medicare covers a range of behavioral health services. These are discussed more fully in your paper.

Last September, we presented on psychiatric hospitalizations, which are covered under Medicare Part A. Today, we discuss clinician and other outpatient behavioral health services covered under Medicare Part B.

To identify Part B behavioral health services and the beneficiaries who received those services, we selected

records from the fee-for-service claims data based on meeting at least one of three criteria: the presence of behavioral health conditions determined from diagnosis codes on the claim, receipt of behavioral health services such as psychotherapy or partial hospitalization, and provision of services in certain behavioral health-related locations such as community mental health centers or psychiatric treatment facilities. We include Part B behavioral health services provided by hospital outpatient departments and other facilities, as listed on this slide.

In 2021, 4.9 million beneficiaries received Part B behavioral health services. They represented 16 percent of the fee-for-service population. This percentage has been consistently 16 percent over the last few years.

Total spending on these services in 2021 was $4.8 billion. This includes both in-person and tele-behavioral health services. Spending per beneficiary was $981 and has also been stable until recently. It rose by 11 percent between 2020 and 2021, which likely reflects increases in payment rates for E&M visits that went into effect in January 2021.

Medicare beneficiaries receiving Part B

behavioral health services were amongst the most vulnerable and costly. In these charts, the top, blue bars represent Medicare fee-for-service beneficiaries who received any Part B behavioral health services in the year. The bottom, pink bars represent all other Medicare fee-for-service beneficiaries.

The top bars on the chart on the left show that beneficiaries receiving behavioral health services were much more likely to be low income compared to other beneficiaries. They were also more likely to be disabled, as shown in the bottom bars. On the right, we show that per capita Medicare Part A and B spending for those receiving behavioral health services were two and half times higher than for all other beneficiaries. Per capita Medicare Part D prescription drug spending for these beneficiaries was nearly twice as much as for other fee-for-service beneficiaries.

Beneficiaries receiving behavioral health services also were more likely to be female, younger, and have higher risk scores compared to other fee-for-service beneficiaries.

In 2021, Part B behavioral health spending for

the treatment of depression was higher than for any other behavioral health condition. Over $1.4 billion was spent on the treatment for depression, as shown in the top bar of this figure. This represented 31 percent of all Part B behavioral health spending. Treatment for anxiety and schizophrenia composed the next largest shares at 15 and 14 percent, and spending for substance use disorders was $540 million dollars or 12 percent of behavioral health spending.

On this slide, we report on the types of Part B behavioral health services provided to Medicare fee-for-service beneficiaries. To avoid double counting the volume of services, we include only behavioral health services paid under the physician fee schedule and exclude other outpatient payments on this slide.

As shown in this table, psychotherapy and E&M visits for treating behavioral health conditions accounted for the majority of spending on behavioral health services, over 70 percent when combined. Beneficiaries receiving psychotherapy tended to use more of it. As shown in the last column of this table, psychotherapy volume was 11.9 compared to 4.2 for E&M visits for behavioral health

conditions. Other behavioral health services include psychiatric evaluations, partial hospitalizations, and behavioral health integration services. Your paper contains more detail on the use of these other services.

Per the congressional request, we examined utilization of behavioral health services by Medicare Advantage enrollees. We had previously concluded that the accuracy of the encounter data was not yet sufficient for comparing MA and fee-for-service utilization, and that limitation continues to this day. However, while we cannot with certainty compare the volume of behavioral health services between MA and fee-for-service, we believe we are able to determine whether MA enrollees received some behavioral health services.

This figure shows the percent of beneficiaries using each type of behavioral health service after applying a similar strategy as used for our fee-for-service analysis. The bars represent the percent of fee-for-service and MA beneficiaries using each service and the leftmost bars show that 17 percent of MA enrollees received behavioral health services, which is very similar to 16 percent among fee-for-service beneficiaries. The

percentages were also similar between MA and fee-for-service beneficiaries across the various types of services shown in the figure.

We switch now to substance use disorders among fee-for-service beneficiaries. We had reported on an earlier slide that over half a billion dollars were spent on the treatment of substance use disorders under Medicare Part B. This figure shows that, conditional on the fee-for-service population, the number of beneficiaries treated for alcohol use, the top blue line, and other substance use disorders, the bottom white line, has declined while treatment of opioid use disorders, the middle red middle line, has grown, most notably since 2019.

This growth may even be understated since studies have reported that older adults are at higher risk for undiagnosed and untreated substance use disorders. The studies find that older adults are less likely to be assessed and treated compared to younger adults due to greater difficulty in screening related to cognitive impairment and misattribution of symptoms to the aging process, among other reasons.

To address the growth in opioid use disorders, as

of January 1, 2020, Medicare Part B began covering a bundle of services to treat opioid use disorders. This bundle includes provision of medication-assisted treatment, counseling, and therapy. Thus far, use of opioid treatment programs is low, around 40 thousand beneficiaries, but take-up has increased by 27 percent in 2021, compared to the year before. Spending on OTP services was $252 million in 2021.

During the presentation on inpatient psychiatric facilities in September, Commissioners expressed interest in learning more about the continuum of behavioral health services, both prior to and following a psychiatric hospitalization. We expect that beneficiaries needing psychiatric hospital-level care would have received other medical services prior to the stay and would require substantial follow-up after the stay.

We identified psychiatric hospitalizations that began and ended 2018. We searched the Medicare claims for health care services that occurred in several time frames before and after the IPF stay. We identified emergency department visits that did not result in a direct inpatient admission, acute care inpatient hospitalizations, visits by

behavioral health practitioners, and partial hospitalizations.

On this slide, we show the utilization of these services in the 7 and 30 days before the IPF stay. The figures in your paper includes additional services and time frames. The blue bars represent the percent of IPF stays with a particular service in the 7 days prior to IPF admission and the pink bars represent the same percentage for 30 days prior.

We found relatively high rates of ED visits and acute care inpatient hospitalizations prior to the IPF admission. ED visits occurred for 45 percent of IPF stays in the 30 days prior to IPF admission. We found lower rates of visits with behavioral health practitioners and partial hospitalizations prior to IPF admission.

This figure shows the use of services in the 30 days following the IPF stay. Again, the figures in your paper includes additional services and time frames.

We found that visits with behavioral health practitioners occurred in the month following the IPF discharge for only 30 percent of stays. A partial hospitalization followed the IPF stay 9 percent of the

time. Emergency department visits occurred following the IPF discharge for a quarter of stays.

This relatively high rates of emergency department use and acute care inpatient hospitalizations and the relatively low rates of visits with behavioral health clinicians suggest that many of these patients may not be receiving effective, well-coordinated behavioral health care.

We now turn to the clinicians who are providing behavioral health care.

This figure shows the volume of Part B behavioral health services provided to Medicare fee-for-service beneficiaries stratified by the most common clinician specialties.

We observed shifts in the clinicians who provided these services. The top blue line of this figure shows that psychiatrists provided the most volume in all years, but their volume has declined over time. Over the same period, there was an increase in the volume of behavioral health services provided by nurse practitioners and physician assistants, as shown in the bottom white line.

Tele-behavioral health grew rapidly in 2020 and

continued to grow in 2021. The share of Part B behavioral health services spent on tele-behavioral health grew from 1 percent in 2019 to 28 percent in 2021. In contrast, overall telehealth declined in 2021, though remained higher than pre-pandemic levels, as will be discussed in a presentation following this one.

Tele-behavioral health tended to be used in the treatment of depression, anxiety, trauma, and bipolar disorders and was less commonly used for schizophrenia and substance use disorders.

We now discuss the beneficiaries who use tele-behavioral health care.

Sixty-three percent of beneficiaries who received behavioral health services in 2021 received only in-person behavioral health care. Twenty-two percent received both in-person and tele-behavioral health care, and 15 percent received only tele-behavioral health care. We are referring here to behavioral health services only. Any of these beneficiaries may have received in-person or virtual non-behavioral health care during the year.

Beneficiaries receiving any tele-behavioral health tended to be female, younger, low-income, live in a

metropolitan area, and have a lower risk score compared to those receiving in-person behavioral health care. They also tended to spend less on Medicare Part A and B services, but they spent more on Part D prescription drugs.

Beneficiaries who used only tele-behavioral health had the lowest risk scores and the lowest Medicare Part A and B per capita spending.

Similar to the findings on beneficiaries, there was substantial growth in the share of behavioral health clinicians providing telehealth to Medicare fee-for-service beneficiaries. In this figure, the percent of clinicians providing in-person only care is indicated by the blue part of the bars, the percent providing both in-person and telehealth is indicated by the red, and the percent providing only telehealth is indicated by the green.

The vast majority of the clinicians provided only in-person care in 2019. In 2020, high percentages of clinicians delivered some telehealth services, which continued into 2021. But as shown in the top green sections of the bars, there was notable growth in the percentage of clinicians delivering only telehealth services in 2021. These clinicians did not provide any in-

person services during the year.

It will be important to monitor the trends in the share of behavioral health clinicians who provide telehealth-only services as another aspect of assessing access to care.

As next steps, this paper will be combined with the analysis on psychiatric hospitals that was presented in late September 2022. We anticipate reviewing the combined chapter during a spring presentation.

For discussion today, we would like Commissioners to comment on whether any clarifications or further investigations are needed for this particular paper, and whether there is any additional guidance for us to consider in putting together the June 2023 chapter.

I'll now turn it back to Mike.

DR. CHERNEW: Great, Betty. That was terrific. This is a really important topic.

Dana, we will go through the queue, and if I have this right Lynn is the first one in it. Lynn.

MS. BARR: I hit the buzzer. All right. Thank you for a terrific report. I think this investigation into behavioral health is really, really helpful and very eye-

opening.

I have a couple of clarifying questions, or a little more information I'd like to see. We were looking at rural versus urban utilization of these services. There has always been concern about the access issues in rural communities to that type of care and the privacy issues. So if you go to see a behavioral health or psychologist or something in a rural community, by 1:00 everybody knows, you know. So there is no privacy when you're in a really small town.

And so I'm wondering if we could look a little bit at some of the access issues. One of the things I'm concerned about is when we look at rural versus urban utilization of these services, they look like they're about right, you know, compared to the populations. But then you look at opioid deaths, so specifically around substance use disorders, and you look at opioid deaths in rural communities versus urban communities, and there are huge differences. I mean, the opioid pandemic hit rural areas very hard. So I think you'll see more disparities if you put that in the context of the incidence and deaths. So if we could take a look at that, that might be a little bit

more alarming than is seen in the data right there.

The other question I had was about the role of these commercial organizations in telehealth particularly for behavioral and mental health, and I believe I just read an article in the last week about -- and you may know this, the one I'm talking about -- about an organization that basically was overprescribing drugs. So I'm curious, you know, you've got these 13 percent of visits which are only telehealth. I'm guessing those are those companies, you know, to some extent. So I'm just wondering about this cottage industry that's happening out there and what is the impact of them, and how does all that fit together. And specifically as we look at the face-to-face role, which, when that does come -- so now you have to see that provider face to face at least once before initiating therapy, how is all that going to play out? And I'll reserve further comments for Round 2. Thank you.

MS. KELLEY: Jonathan.

DR. JAFFERY: Thanks, and thanks, Betty. I can't emphasize enough how important this topic is, and it's a great chapter. There's just a wealth of information that we haven't really thought too much about before.

Just briefly, and Lynn, you just mentioned this thing about those being the big companies. It would be good to know that stuff, but I think there are quite a number of mental health providers that have chosen to be fully online, so we may be surprised.

Can you go to Slide 10 for my Round 1 question? You know, I don't think it's much of a surprise probably to any of us that we see opioid use disorders go up, but I was surprised to see alcohol use disorders go down. I think we know that there's been, that Medicare age, older population has tracked the general population in terms of increased drinking, and we saw a lot of that in COVID.

So it just makes me question what's happening. Is there something you think in the data or something else we're not capturing? It seems very counterintuitive to me that that would go down. It's not a zero-sum game with opioids. Do you have any thoughts about that?

DR. FOUT: These are claims that we're looking at and the diagnosis on the claim, so I presume it's possible. What I'm presuming is that if you have both the opioid use disorder and alcohol disorder you might not show up twice.

DR. JAFFERY: Gotcha, and that may be. That may

be something because, yeah, I think it's true that most people who abuse opioids have been abusing alcohol too. That makes sense. Thanks.

MS. KELLEY: Scott.

DR. SARRAN: Yeah, excellent work. In the category of things I think we'd like to see at some point in time, as a clinician, thinking simplistically, I parse the broad population of beneficiaries receiving behavioral services into the following categories that might be a useful taxonomy. One is depression and anxiety. The second is schizophrenia, schizoaffective and bipolar disease. Some lump those and call it "serious mental illness." The third is substance use disorder. And fourth would be dual diagnosis, meaning any of the others plus substance use.

I think if we're reasonably easily able to parse those out, looking at the data of the services received, et cetera, and particularly looking at some of the things that point at opportunities for improvement, such as the care received or not received before and after an indexed hospitalization, may be very informative.

MS. KELLEY: Larry?

DR. CASALINO: Was that me, Dana?

MS. KELLEY: Yes.

DR. CASALINO: Okay. Two quick points. One is I think the rate of 30-day rehospitalization for, I guess, any reason after an inpatient hospitalization for a psychiatric or behavioral health reason was 18 percent. Is that right? I think the data shows 18 percent rehospitalization rate.

DR. RILEY: 25 [off microphone].

DR. CASALINO: Was it 25?

DR. RILEY: [Nodding affirmatively.]

DR. CASALINO: Okay. Maybe just to give, I think, some context, whatever the number is, it might be useful -- you know, what's the rehospitalization rate in Medicare now after admission for any cause or -- I think it's still pretty high, right? So some baseline would be helpful to show if this is a lot higher or if it's a lot lower.

The second point is, you know, access via counting, like did you have at least one behavioral health service, may not mean that much, because in general I think one behavioral health visit isn't likely to be very useful

to people. And so I'd be interested in knowing, you know, how many visits after -- for people who had a visit, how many more did they have? And what I have in mind really is -- when I was in practice, it was often hard to get people to see a behavioral health specialist, I found. Some people wanted to, but a lot didn't. And it made a difference if I could say, "I'm going to send you to Joan Smith. I've known her for years. She's really good." A lot of people are particularly horrified at the idea of seeing a psychiatrist. "You can trust her. She'll get back to me," blah, blah, blah. And that increased the likelihood that they would actually go. As opposed to in those days -- and I'm not sure what it's like now -- the Medicare Advantage plans would by and large contract with these behavioral health companies and the best I could tell a patient was, "Call 1-800" so-and-so "and you'll get somebody." I couldn't say, "You're going to see Joan Smith, and she's really good," and so on and so forth.

That seemed to me not very desirable, although there's a lot of problems now with access in fee-for-service Medicare as well, I realize.

So some information on the extent to which

Medicare -- how Medicare Advantage provides behavioral health, and there are potential advantages to contracting with companies that specialize in that. So I'm being very general, but I think more information on that, if there's any data on how well it works, what the effects are and utilization and so on. I think we're missing a lot potentially if we don't have any information at all about Medicare Advantage and contracting out behavioral health care to these companies.

MS. KELLEY: Cheryl -- oh, yes, Lynn, I'm sorry, go ahead.

MS. BARR: Just to your point about the services they're counting, I was a little concerned about SBIRT being counted, and I'm not sure how widely used SBIRT is today. But it's something that's easy to bill for, and I worry that it's like, oh, I had a physical, and you mentioned something, and, you know, so like a one-time SBIRT claim does not necessarily mean this patient has a significant issue. And I am a little concerned about how using SBIRT might confound your data.

Thank you.

MS. KELLEY: Cheryl.

DR. DAMBERG: Thank you. This is a really interesting chapter, and thanks for all the hard work putting it all together.

I have two questions. In terms of the high opt-out rate, do we understand why that's happening? Is it because they can get paid more elsewhere? They can go private pay? I don't know how much we actually know about that space. Is it because Medicare's payment rates are too low? I don't know. So I think if there were something that could be added to help provide some context, that would be helpful.

MS. KELLEY: I'll jump in here. I think we could definitely add some context on that. This has historically been the specialty that has the highest opt-out rate among providers. It's not new. And I think actually psychiatrists are much less likely to participate in any insurance plan than other providers. So we can certainly add more context to the paper if that would be helpful.

DR. JAFFERY: So my wife's a therapist, and so one thing is exactly -- they tend not to -- often will not accept insurance. My wife's practice actually does. But another big part of it is -- there's a couple. One is the

documentation, and I think a lot of therapists feel that using insurance forces them to put a specific diagnosis, and they often don't want to do that for a variety of reasons. And so I think that's a big driver that doesn't probably exist for the rest of us clinicians.

DR. DAMBERG: Yeah, that's helpful. But I do think if we can add some more context there, that would be great.

The other question that I had -- I'm looking at the shift of, say, more psychiatrists shifting to only providing telehealth -- is: Do we know anything about those providers? And I'm thinking are these more likely to be physicians who were in like solo practice previously, not part of health systems? And so, you know, during the pandemic they closed down their offices, moved home, and they're just doing it from their house. You know, what is it that we could learn to try to --

DR. FOUT: We could definitely look into more of who those clinicians are.

DR. DAMBERG: Yeah, because I think the PECOS data could help there.

MS. KELLEY: Greg.

MR. POULSEN: Thanks. My question is sort of at least focused on Slide 14, and as we look at that information, I wondered to what extent we have looked at organizations that have a big focus on mental health integration where primary care docs, internists, and family practitioners are doing bigger and bigger chunks of work that historically would have been done by focused mental health professionals. It may be difficult to get to for some of the same reasons that Jonathan talked about. A lot of times the diagnosis isn't made clear, although they're, in fact, attempting to treat and oftentimes with oversight from psychiatry.

Jaewon's organization is doing that. Mine is; others are. And I don't know quite how to capture that, but it seems like it's something that ought to be mentioned since more and more folks are doing that.

So I guess the question is: Have we got a way to -- do we have any insight into that? And do we have a way to include that kind of dynamic that I think is increasing?

DR. FOUT: I think we could look into that. I see what you're saying.

MR. POULSEN: Thank you. That would be great.

And I meant to begin by saying this is a terrific chapter. I think it's great, and it's much needed.

MS. KELLEY: That's all I have for Round 1, unless I've missed someone.

DR. CHERNEW: That's what I had, too, and so for Round 2 I think we're going to start it off with Stacie.

DR. CASALINO: May I make a very quick point? I might have missed this, but I'm not sure it's in the chapter. There's a lot -- these are probably huge underestimates of not just the degree of behavioral health problems but amount of behavioral health care that's provided. A lot of physician office visits are essentially that, but the physician often won't code a psychiatric code, be it depression -- or they may code fatigue instead of depression and so on. I don't know if there's any research that tries to quantify any of that, but it might at least be worth mentioning, both an underestimate of the amount of services given and probably a huge underestimate of the amount of services given by primary care physicians, you know, for what it's worth. It may be very good; it may not be good at all.

So, yeah, I don't know if there's a way to get at

that, but it's a pretty big deal that it at least should be mentioned, I think.

DR. NAVATHE: So, Larry, to that point, not specifically the Medicare population, but my group awhile ago and others have done some work using natural image processing and such on the notes, and you can actually see there's a large discrepancy between descriptions of depressive symptoms and even noting a diagnosis of depression and anxiety or something versus what actually gets coded on the claim. So I think there is that disparity. I don't know what it is in Medicare specifically, but it definitely exists and it's sizable.

MS. KELLEY: So I have Stacie for the first Round 2 question.

DR. DUSETZINA: Thank you. Betty, great report. I will say as a caveat I wrote an actual dissertation on mental health services using claims, so I apologize in advance.

[Laughter.]

DR. DUSETZINA: It will be easy, I promise. So I also wanted to just say, like Cheryl, I also thought it would be nice to add some context about behavioral health

providers like leaving all health insurance types not just Medicare, so that it's really clear this is not just underpaying for services. So I totally agree. I want to just plus one on that.

I think one of the things I was wondering about is a lot of the analysis focuses on just A and B, and so much moves -- so much of how we treat behavioral health mental health services is through the drug side. I wondered if things would look different if you had a set of analysis with A, B, and D. So like Slide 10 that Jon brought up about the alcohol use disorder and that looking like it was a little bit different, if you incorporated medications used for each of those things as part of capturing that, it might look kind of more as we would expect if people are just substituting that from other types of services. Maybe not, but, you know, it just seems that that's kind of how we shifted to deal with mental health workforce shortages and access issues as medications.

And then the only other small -- oh, two small points. One is for the prescription drug piece, I really appreciated that piece. I did wonder if it was possible to

tease out how much brand versus generic spending, because there's so many generics in this space, but it does seem like there have been a few brands that have entered that are really expensive, and that might just be nice to kind of quantify.

The final one was a colleague was -- I've worked on some work on the medication-assisted treatments. The terminology has now moved there to medications for opioid use disorder to get away from the concept that the medications are assisting something, that instead the MOUD should be kind of the terminology, if that's an okay update. But excellent, excellent work.

MS. KELLEY: Lynn.

MS. BARR: Thank you. I was curious about a couple of things. One of them is, as we're looking at depression being, you know, the biggest piece of this, how has that changed since we've done depression screening as a quality measure that's a common measure? And so I'm wondering, is this just being -- because we're now doing PHQ -- what is it?

MULTIPLE COMMISSIONERS: 9s.

MS. BARR: -- 9s, on every patient that walks in

the door, you know, is that then causing an increase and that could inform maybe future policy. So it's almost actually a Round 1 thing.

My Round 2 comment is -- and I alluded to this a little bit -- I'm very concerned about the face-to-face rule and how that affects rural areas that do not have access. And so if there's a way to get at that at all in the data or to figure out -- because I believe that there's a greater need for these services in rural than in urban areas just based on, you know, what's happened in terms of depths of despair. Yet I don't see parity in treatment, you know, with that. So I'm worried that the face-to-face rules just make it even harder for access and that we might end up with a recommendation that would say that the face-to-face rule for behavioral health really doesn't make sense, and we need to think differently about it.

Thank you.

MS. KELLEY: David.

DR. GRABOWSKI: First, great chapter. Thanks, Betty, for this work. For the Commission, I'm really pleased we're focusing on this issue. This is super important work.

Like our last session, I have just an additional brief comment related to the coverage and care of dually eligible beneficiaries. From the data Betty presented, low-income Medicare beneficiaries who are largely duals are much more likely to have behavioral health needs. I really like the text you had on pages 9 and 10 where you detail what Medicaid covers separate from what Medicare is currently covering for these individuals.

However, I would like us to go even a step further, and I believe the chapter would be stronger with some additional information on where the gaps in coverage for individual, these two sets of coverages. Yes, they cover different services, but they don't really coordinate very well for individuals with behavioral health needs. There are some programs out there, one in Massachusetts. I won't get into the specifics of it, but I do think there are some opportunities to try to bridge that care. But I think it's safe to say also that some serious gaps exist for most of our kind of neediest beneficiaries.

So it would be nice to document those gaps. I don't know if that happens in a text box or as part of the existing discussion. And as part of that discussion, you

could also think about some of those policies and how they integrate services and also how those policies are working and often unfortunately not working for duals with behavioral health needs, especially around enrollment and access to service, spending, and outcomes to care.

Again, great work, but I think we could dig a little deeper and really kind of the -- where a lot of the beneficiaries with behavioral health needs sit and where I think there are some serious gaps.

Thanks.

MS. KELLEY: Dana?

DR. GELB SAFRAN: Yeah, thanks. Adding my appreciation for this really important work. I'm glad we're doing it. And I'll just make three comments.

One, the findings that you share at the beginning around higher spending for beneficiaries with versus without behavioral health conditions is, you know, very familiar from other insurance sectors and I think a really rich place to pursue. I can share that, you know, when I was in my role at BlueCross Mass, we surfaced this about a decade ago, and yet I think it's still really not very well understood what the mechanisms are, and, specifically, you

know, how much of the higher utilization that we're seeing is because of patients with behavioral health conditions who are presenting with somatic symptoms that just get referred on for another visit with a specialist and then another test and so forth as opposed to the behavioral health conditions themselves potentially exacerbating the likelihood of onset for chronic conditions or the worsening of those conditions.

So all of that just really needs to be understood, and I think with the data that we have, we're in a great position to really try to understand what's going on there and contribute importantly, and it has such important policy implications and implications for practice and for patients' well-being. So I'd really encourage a deep dive there.

Two other comments. One, the data on lack of follow-up, both lack of any -- you know, only 30 percent having any kind of mental health visit after a hospital stay and the high rates of emergency room use is, you know, distressing but not surprising. I think that, too, has been seen in every other sector.

One thing just to be aware of -- and I don't know

if this is true of Medicare rules, but I know that a lot of commercial insurers who hold providers or plans accountable for follow-up on behavioral health after a hospital stay will count it as met -- and I think the HEDIS rules do this, too, but I'm not certain so verify this -- will count it as met if after discharge but before leaving the facility somebody meets with the patient, which, you know, just isn't real follow-up but it's just an important thing to know as you're looking into this. But it just underscores the importance of getting to better, more robust, real quality measures for this aspect of care.

That leads to the final comment, which is, you know, on tele-behavioral health, I think it's likely here to stay, at least in the, you know, foreseeable future if not in perpetuity. And we really have much more that we need to understand about quality differentials that may or may not exist. And also access, right? Is it helping with access as much as think and hope? And that would be a great thing. But are we trading off quality for access? And just really understanding that I think is a very important part of the agenda as we start to get into this space.

Those are my comments, and thanks again for starting us down this really important path. Great work.

MS. KELLEY: Jonathan?

DR. JAFFERY: Thanks. And, again, thanks. I said before, this is such a great chapter on such an important topic like others have said. I do hope that, even beyond June, this is really just the start of the work in this space.

A couple comments. I just wanted to emphasize what Scott had mentioned in Round 1 around the different categories. I think that is a thought, a good way to think about it. That is a lot of how we sort of naturally categorize it, with the one caveat being that -- and this would be interesting to see -- that people with -- individuals with dual diagnosis are probably a much bigger piece of the substance use disorder pie than people with just the substance use disorders are -- is relatively small.

I did have another thing, a second point. I had another thought about the group of behavioral health providers that are all telehealth, and there may be one other thing that contributes to that different than other

clinicians is that the nature of their work is that they're spending an hour face-to-face with somebody, often reluctant to wear masks because it makes it a little more difficult to have that therapeutic intervention, which may be very different than those of us who would go into an E&M visits for 15 minutes and where you could wear a mask and have it not really limit the encounter in the same way. So I think that might add to some reluctance too that want to go to that environment and so, therefore, stick to virtual.

And the last thing I wanted to mention was, you talk about -- in the chapter about the low take-up of behavioral health integration services, despite the evidence of the benefits of it in integrating primary care and behavioral health care and including in ACOs, which is very disappointing. I guess I'd like to -- I'd love to see -- and this builds on actually Dana's comments about cost. There might be some more that could be said here about what that evidence is and really kind of drive home that there's so many benefits to that, that particularly outside the fee-for-service system where it's financially maybe not that sustainable, it really doesn't have any downside. It's -- the outcomes are better. It can lower costs.

That's been shown for a long time. It's a huge provider satisfier.

And the other thing, Larry, you'd mentioned stigma that also could help with -- it helps with stigma because you're not referring somebody to some other place. They're staying within their primary care space, and it's not in -- which maybe works in a rural place too, where you -- where it's very visible. So I'd love to see some more emphasis on that and really sort of driving home the point of just how useful that model is, because that's not new.

Thank you.

MS. BARR: So what we saw with a lot of our providers is they just build CCM for BHI. So the two programs are so similar in terms of -- they're just very similar in terms of billing requirements, and most of these patients have chronic conditions. And so, if they could bill CCM on a patient instead of BHI, they would. So that may be confounding the data some because, again, stigma.

MS. KELLEY: Scott.

DR. SARRAN: Yeah. Thanks again for the excellent work.

I think when I look at Slides 12 and 13, in

particular, I think those are great flashlights that are shining on big opportunities for improvement in terms of early engagement -- early and sustained engagement of people with behavioral health and substance use conditions.

This is a space where there's just such a huge gap, particularly in the fee-for-service system between what beneficiaries' needs are and the way the health care system is configured to meet those needs.

It's also an area where MA should shine compared to fee-for-service. There's just very little way you can make fee-for-service a near-perfect system for people with behavioral health conditions, but you can do that in MA. The outcomes that we all want -- quality of life, functional status, avoidance of hospitalizations being perhaps the big obvious three -- each of those has an antecedent key process measure or two that's been well proven and treat depression, sustained adherence with long-term antipsychotics, sustained engagement with substance use treatments, et cetera. It's been proven what the process measure needs to do.

And I would at least like to see us perhaps marry some of this work to some of the MA work around what we

hold plans accountable for because, again, this is a space where MA should just completely beat the fee-for-service system in outcome and process measures. And, again, not to reiterate too much our previous conversation, we're paying enough to get what's important and what we want for our beneficiaries. So we'll see if we can sync those up.

MS. KELLEY: Robert?

DR. CHERRY: Yes. Thank you. Great work. I could tell you, behavioral health, it's not only an important topic in my day job, but it also keeps me up at night because it's a necessary service for the community but also has its unique challenges as well as a specialty.

Just a couple comments related to the decline in physician services and the fact that there are a number of physicians that opt out of Medicare. I think, anecdotally, several of us have communicated that there's probably a strong private-pay model that's driving this. It would be great to validate it, although I would acknowledge it's probably difficult to really assess the total extent of private pay in this particular specialty.

However, it's probably easier to assess who those people are that are opting out, because if we can

understand that a little bit better, we may be able to target interventions a bit better to at least reduce the tide of people that may be going into private pay.

It's also nice that nurse practitioners are taking up some of the gap, although, if I were to worry about things, I would worry that they may also take on private practice opportunities as well. So I think it's something to monitor along with the physicians as well.

And then in terms of Part D -- and I hesitate to bring this up since Stacie had such a deep expertise in all of this. But, you know, one of the reasons why there may be an increase in Part D patients and their leveraging of telehealth services could also be the acuity issue too. And there's probably a difference between administrative risk scores and clinical risk scores, and there's a lack of clinical risk scores within the specialty of behavioral health. And I have a feeling that there's probably high acuity that's driving and leveraging telehealth services because it's easier to monitor them, more frequently that way, and that they may have a higher need for prescription services as a result.

So it would be nice at some point in time to

develop a clinical model to really kind of get a little more sophisticated in understanding these patients a little bit better.

Otherwise great work, and I'm looking forward to the final report.

MS. KELLEY: Kenny?

MR. KAN: Yes. Betty, this is great work, very rich data. I really enjoyed reading the chapter.

Just for pages 6, 10, 12, and 13, if the data exists, would it be possible to show how MA differs from a fee-for-service?

I'm especially also very intrigued by how access plays into that. I suspect that a physician may be less inclined to accept MA than fee-for-service. So I'd like to see the data, you know, pass that out.

Thank you.

MS. KELLEY: Larry?

DR. CASALINO: It doesn't need to be emphasized, but this really is an important topic. And, again, for context, this might be put in. One of the important things is -- I haven't seen data recently, but my memory is something like it's been estimated that 30 percent of

visits to primary care physicians have a behavioral health problem is either the real fundamental source of it or an important source of the visit.

I don't know what's been published on that, really, but as I mentioned, often those visits will not -- there will be no behavioral health diagnosis on those visits.

So any kind of even references to the literature or any kind of mention of that would be a problem, because if you just -- I think the chapter is wonderful, but if you read it, it actually looks like, well, there's really quite a bit of use of behavioral health and probably quite a bit of provision of behavioral health, but probably it's really way underused, right? And, again, a test to that would be if you've had one visit, how many more do you have? Because it's hard for me to admit. It would be really a super visit if one visit would take care of your behavioral health problem.

But I think that -- and other things that could be looked at in terms of how good is the access really and how satisfied are patients with it, I don't know. There must be questions about this in the current beneficiary

survey, but I actually don't know if there are -- or similarly in the MedPAC survey, if there are any questions. Maybe there could be, because this really is about as important as anything, I think, and a few questions about access to behavioral health services and satisfaction with them or experience with them would be useful.

And then in the focus groups that MedPAC has, some questions for the physicians about an MA and not an MA, what kind of access can you get? If you need a psychiatrist, can you get one and so on and so forth? I think it would be incredibly illuminating, because I do think if you talk to the average primary care physician now, they'll actually -- maybe not in some places that have integrated care, for example, but I think most of them feel almost hopeless about it really. They know that their patients need behavioral health services, but they don't feel like they can really get them for them for whatever reasons, insurance, workforce needs, networks, workforce scarcity.

MS. KELLEY: That's all I have for Round 2 except for Betty, and I'll go ahead and read her comment. Betty says regarding Slide 12, utilization, 7 and 30 days before

the IPF stay, the ED visit with no hospitalization versus the visit with behavioral health practitioners and the suggestion that perhaps the ED visit could be prevented, this is very important. The impact on the ED providers, staff, and on the patients in the ED has a huge ripple effect, because the ED is not always well prepared to easily deal with behavioral health patients. So any Medicare tools that could help address this would have an impact far beyond the individual patient.

Anyone else have a Round 2 comment that I missed?

Oh, sorry, Amol. Okay.

DR. NAVATHE: This is hopefully very quick.

So, on Slide 6 -- and I apologize if this was mentioned and I happened to miss it. So, when we're showing the difference here between the total Medicare per capita spending in those that -- beneficiaries that use behavioral health services and presumably therefore have a behavioral health condition versus those that don't, I think one thing that would be helpful here is, in fact, if we could shade in a sub-color within the blue that reflects the spending on the behavioral health services itself. I think, in part, to make it clear to the reader that

preponderance of the difference is not being driven by behavioral health spending itself, but in fact, it's being driven by other nonbehavioral health spending.

MS. BARR: On this point, a lot of that spending is being skewed by the fact there are duals, predominantly duals. So is there a way to also kind of normalize the data? Because I don't know if they are duals because of their behavioral health issues or the other way around. But it does sort of confound the data a little bit, because it's not really compared against -- it's drawing out a whole large portion of the population.

DR. CHERNEW: Betty, did you want to -- you moved like you were going to say something.

DR. FOUT: Oh. No, those were good suggestions. I wrote it down.

DR. CHERNEW: All right.

So what's nice about this conversation is there's really widespread agreement on a number of basic points, how important it is. One of the points where I think there's widespread agreement, which is more discouraging, is how challenging the data work is, and that includes overall issues with the data. That includes stuff that

we're probably going to have a challenge getting at with the coding problems, for example. I think the MA comparison-type work, I think is particularly important. I think the opt-out questions about practitioners will feed into our workforce set of activities.

I think that's all very important.

I am not sure if we will have to regroup to see how far we can go down this space. I feel like there's a lot of people that have spent time frustrated with some of these particular data issues. I'm not sure we're going to do natural language processing, a set of activities, but I do believe that this is a remarkably important area and one that is really challenging. And I believe strongly that when there are beneficiaries that are in what I think CMS would call "accountable relationships," that it is important that they care for the beneficiaries' behavioral as well as their physical health issues. And to the extent that we can find ways to promote that, we certainly will.

But I will close with the broader point of agreement, which is, Betty, this was outstanding work, and people are very appreciative of it. So thank you very much.

Any comments? Scott.

DR. SARRAN: Just one quick add-on question or add-on comment is we were discussing in the earlier section on MA, the dual SNPs. Those are the MA plans that absolutely should stand out as stellar in their performance. So that's something I think we're going to keep in mind as we think about outcomes we measure and hold people accountable. Fully integrated dual programs should absolutely be hitting it out of the park in terms of excellent outcomes compared to everyone else.

DR. CHERNEW: Okay. We're going to take -- let's take a five-minute break, and we will be back to talk about a topic which has some overlap with behavioral health but certainly is much broader than that and one I think of great interest and honestly one that I think Congress will be grappling with over the coming years.

We have made -- not recommendations. We have discussed policy options that involve time limiting sort of some of these coverages for telehealth services. We saw some of that, as was mentioned earlier, in the omnibus bill through 2024 now. But I think this is an area where we will be devoting considerable time to telehealth. So I

look forward to our return to discuss it.

Anyway, we'll be back in a minute.

[Recess.]

DR. CHERNEW: All right. Ledia, you are up. Welcome back, everybody, for our last session of what I think has been a very productive day. Ariel and Ledia are going to talk to us about telehealth. So Ledia, go ahead.

MS. TABOR: Good afternoon. 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 Corinna Cline for her work on this paper and presentation. Today, we will discuss Medicare telehealth policy for the second time this meeting cycle with a focus on telehealth use and beneficiary and clinician experiences.

First, we will review the requirements of our mandated report on telehealth. Then we'll briefly review Medicare's temporary expansions of coverage for telehealth services during the PHE, the Commission's policy option for covering telehealth after the PHE that was in our March 2021 report, and changes to telehealth policy since the start of the PHE.

Next, Ariel will present an update on Medicare's claims analysis of telehealth spending and use. Then I'll summarize findings from our beneficiary and clinician focus groups, and provide some updates on telehealth and program integrity work.

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

In the Consolidated Appropriations Act, 2022, the Congress mandated that MedPAC submit a report by June 2023, which should include four elements. First, the utilization of telehealth services, and second, Medicare program expenditures on telehealth, both of which pieces we will review today.

Third, Medicare payment policy for telehealth services and alternative approaches to such payment policy, including for FQHCs and RHCs, which we discussed at the Commission meeting in late September last year. Fourth, the implications of expanded Medicare coverage of telehealth services on beneficiary access to care and quality, which we plan to discuss at this April's meeting.

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

systems. However, coverage of telehealth was limited by statute under the physician fee schedule because as we will discuss later in the presentation, there are concerns about its impact on spending and program integrity. Under the fee schedule, Medicare paid for a limited set of telehealth services provided to beneficiaries in rural areas in certain settings, such as physicians' offices and hospitals, with some exceptions.

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

To allow beneficiaries to maintain access to care and help limit community spread of COVID-19 during the public health emergency, Medicare temporarily expanded coverage of telehealth under the fee schedule.

This table lists the key policy changes that apply during the temporary coverage, which are described in your chapter, so I will not go into detail now. In summary, telehealth has been substantially expanded during the PHE, including Medicare paying for telehealth services received in patients' homes.

In our March 2021 report, we described a policy

option for covering telehealth after the PHE. Under this option, Medicare would continue certain telehealth expansions for a limited duration, such as one to two years, after the PHE ends.

These expansions would include:

1. Paying for specified telehealth services provided to all beneficiaries regardless of their location;

2. Covering additional telehealth services if there is potential for clinical benefit; and

3. Covering certain telehealth services when they are provided through an audio-only interaction, if there is potential for clinical benefit.

Continuing these expansions for a limited period of time would allow policymakers to gather more evidence about the impact of telehealth, when combined with in-person care, on access, quality, and cost. This evidence should inform any permanent changes to Medicare's telehealth policies.

Our policy option also calls for returning to some of Medicare's prior telehealth policies, along with establishing some additional safeguards.

First, Medicare should go back to paying the fee

schedule's facility rate for telehealth services. Second, providers should not be allowed to reduce or waive beneficiary cost sharing for telehealth services. Further, there should be additional safeguards to protect Medicare and beneficiaries from unnecessary spending and potential fraud related to telehealth. Some of these safeguards that the Commission has discussed in the past are listed on the slide.

Since the PHE began, Congress and CMS have made other changes to telehealth policies. At the end of 2022, Congress extended the Medicare telehealth flexibilities for two years until December 31, 2024.

Another change is that Medicare permanently began covering tele-behavioral health services beneficiaries receive at home. After 2024, an in-person visit must be provided within six months prior to the initial telehealth service. For subsequent mental telehealth services, there is an annual in-person visit requirement; however, the policy does not apply if the practitioner and patient agree that the benefits of an in-person service are outweighed by the risks and burdens.

Beginning in January 2023, CMS is requiring a

claims-modifier for audio-only services, which will allow policymakers and researchers to study the impact of many audio-only telehealth services. The proposal of an audio-only modifier is consistent with the Commission's March 2022 recommendation to the Secretary.

And now Ariel will discuss the updated claims analysis.

MR. WINTER: We used claims data from fee-for-service Medicare to examine volume and spending on telehealth services before and during the PHE. This chart shows fee-for-service Medicare spending on telehealth during 2020 and 2021, by quarter. The blue sections of the bars represent telehealth provided by clinicians and paid under the physician fee schedule, and the pink sections represent telehealth provided by federally qualified health centers, rural health clinics, critical access hospitals, and other providers.

During the early months of the PHE, after coverage of telehealth was expanded, Medicare spending for these services grew dramatically, peaking at about $1.9 billion in the second quarter of 2020.

As the number of in-person services began to

rebound after the 2nd quarter, telehealth spending declined to about $1.3 billion in the third and fourth quarters of 2020. Telehealth spending declined again during the second quarter of 2021 to about $1 billion, and totaled about $800 million in the fourth quarter of 2021.

Annual telehealth spending declined from $4.8 billion in 2020 to $4.1 billion in 2021, which is still far higher than spending in 2019, which was $130 million. Eighty-seven percent of telehealth spending in 2020 and 2021 was for clinician services, and the remaining 13 percent was spent on other providers.

The analyses described in the remaining slides focus only on telehealth services paid under the physician fee schedule, because the fee schedule accounted for a large majority of total Medicare spending for telehealth services.

This slide shows the number of unique fee-for-service Medicare beneficiaries who received a telehealth service paid under the physician fee schedule in each quarter of 2020 and 2021. The chart looks similar to the previous slide.

The number of beneficiaries receiving a

telehealth service accelerated rapidly in early 2020, climbing to 9.8 million in the second quarter, before falling to 6.3 million in the next quarter. By the fourth quarter of 2021, the number had leveled off at 3.5 million beneficiaries.

Overall, 14 million unique beneficiaries received at least one telehealth service during all of 2020, which declined to 10 million beneficiaries during all of 2021.

This chart shows the distribution of physician fee schedule telehealth spending by type of service. Evaluation and management office and outpatient services accounted for the majority of telehealth spending in both years, although the share declined from 71 percent in 2020 to 67 percent in 2021.

The share of telehealth spending on E&M behavioral health services, such as psychiatric evaluation, rose from 17 percent in 2020 to 22 percent in 2021, which highlights the growing significance of tele-behavioral health services. Betty's earlier presentation on outpatient behavioral health services provided a more comprehensive description of tele-behavioral health.

In this slide, we drill down into the billing

patterns of E&M office and outpatient visits.

When provided by telehealth, 95 percent of these visits were for established patients while 5 percent were for new patients. Visits for established patients are divided into five code levels, which are determined by the medical complexity of the visit or the amount of time a clinician spends on the visit. Higher levels indicate greater medical complexity or longer visits.

This chart shows that the distribution of code levels was about the same for in-person visits and telehealth visits in 2021. For example, 50 percent of in-person office and outpatient visits were Level 4, which is comparable to the 48 percent of telehealth visits that were Level 4. Level 4 visits typically involve between 30 and 39 minutes of clinician time, as shown on the right side of the chart.

We found these results surprising, because we've heard from clinician focus groups that telehealth visits are generally shorter than in-person visits, and we will return to this issue later in the presentation.

This slide looks at the use of telehealth services by type of clinician.

Almost 1.3 million clinicians billed for at least one physician fee schedule service, of any type, in 2021. Of these, over 500,000 billed for at least one telehealth service. Specialist physicians, the first row of the table, made up 37 percent of all clinicians who provided telehealth services, followed by advanced practice registered nurses and physician assistants, who accounted for 24 percent, and primary care physicians, who made up 22 percent.

The last column shows average spending per clinician on telehealth services. Clinical psychologists had the highest average spending, over $14,000 per clinician, followed by licensed clinical social workers, at just over $8,000 per clinician. These specialties mainly provide mental health services, and their high average spending on telehealth indicates the important role of telehealth in treating mental health conditions.

The statutory mandate for this report requires us to analyze the provision of telehealth services by clinicians to beneficiaries who are located in a different state. During the PHE, all 50 states and Washington, D.C., enacted temporary licensure waivers that allowed clinicians

to provide telehealth services to out-of-state patients. Although most state licensure waivers have expired, 15 states still have such waivers, and some states have permanently allowed out-of-state clinicians to practice telehealth in their state.

Using fee-for-service Medicare claims data, we found that the share of telehealth services that were provided to beneficiaries in a different state than the clinician was small: 5 percent in 2020 and 6 percent in 2021. However, the share of telehealth services provided to out-of-state beneficiaries varied by type of service. In 2021, for example, 21.5 percent of E&M visits provided to patients in emergency departments were delivered to out-of-state beneficiaries, compared with only 4.7 percent of care management and care coordination services. In addition, the share of telehealth services provided by out-of-state clinicians varied widely by state.

Here are some other key findings from our analysis, and there are more details about them in your paper.

When we examined telehealth spending by body system, we found that mental, behavioral and

neurodevelopmental disorders accounted for 34 percent of spending for telehealth in 2021, up from 25 percent in 2020.

We also analyzed geographic variations in the use of telehealth. We found that the number of telehealth services per beneficiary varied by geographic region, but changes in use of telehealth in 2020 and 2021 were similar across regions. For example, the number of telehealth services peaked in all regions in the second quarter of 2020 and declined in the next quarter.

We also examined the use of telehealth for different cohorts of beneficiaries. Certain groups of beneficiaries received more telehealth services per beneficiary than others in 2021: those who were under age 65, who were disabled, had end-stage renal disease, had lower incomes, or lived in urban areas. These findings are consistent with trends that we see in overall health care use.

I'll now turn it over to Ledia.

MS. TABOR: MedPAC's annual focus groups with beneficiaries and clinicians provide additional insight about experiences with telehealth. Because the focus

groups were conducted in the summer of 2022, they allow us to track more recent experiences and identify emerging trends.

Many beneficiaries reported having telehealth visits over the past year mainly with clinicians with whom they have an existing relationship. They were generally satisfied with these visits, citing advantages such as convenience and no travel time.

Consistent with our analysis of Medicare claims, many clinicians in our focus groups reported that they continued to provide telehealth after rapidly expanding it early in the pandemic. Some clinicians appreciated the convenience and flexibility it allows in terms of doing visits in their home, visit length and location, such as doing the visit in their home, as well as improved access for patients. Others preferred in-person visits due to perceived better quality of care or to provide procedures and testing.

In our focus groups, clinicians reported that generally telehealth visits took less time compared to in-person visits. Some explained the shorter visits because there is no physical exam.

Also, most clinicians believed telehealth cost less than in-person visits.

Many beneficiaries and clinicians would like to continue the option of telehealth visits after the PHE ends.

Now switching topics to telehealth and program integrity. Historically, policymakers have been cautious about covering telehealth services because little is known about the effect of telehealth on quality of care and patient outcomes, also, because telehealth services are considered more susceptible to overuse and fraud. However, telehealth offers benefits to patients, including convenience and not having to leave home if they feel ill.

In considering a permanent expansion of telehealth, a key issue is how to achieve the benefits of telehealth while limiting the risks to beneficiaries and the program.

The HHS Office of Inspector General reviewed Medicare telehealth claims data from the first year of the pandemic using several program integrity measures with very high thresholds, such as billing telehealth services at the highest, most expensive level every time. Their study

identified about 1,700 providers whose billing for telehealth posed a high risk to Medicare. This represents about 0.2 percent of all providers that billed telehealth and about $128 million in payments.

The OIG recommended that CMS improve program integrity for these services by strengthening monitoring and targeted oversight of telehealth services, improving the transparency of "incident to" services when clinical staff primarily deliver a telehealth service, and other actions.

Congress recently required the Secretary to conduct a study on Medicare program integrity related to telehealth services. The Secretary is required to use medical records to analyze information on the duration of telehealth services furnished, and to the extent feasible the impact of telehealth services on future utilization of services.

Our analysis of claims data supports the need for more review on the duration of telehealth services. As shown earlier on Slide 12, the distribution of the levels of office visits was about the same for in-person and telehealth visits. However, in our focus groups most

clinicians said that telehealth visits take less time, so we could expect there to be a higher percentage of lower-level telehealth visits compared to in-person visits.

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

I'll conclude with a reminder that this material and mandated report will be a chapter in our June 2023 report to the Congress. For your discussion, we would like your comments on the materials.

Now, I'll turn it back over to Mike.

DR. CHERNEW: Great. This is one of the, I think, most complicated areas that we're going to face because it's so, in my view, ill-suited for fee-for-service but so valuable to so many people in so many ways, and quite honestly, people like it, as they should. This will be material that will show up in June, but it won't be the last time we're going to be grappling with all of these other various issues. So I really appreciate the work that you have done.

We will go through the queue, and if I have this

correct, the queue is going to start with Larry. Larry.

DR. CASALINO: Just one Round 1 question.

Could you -- and I really do mean this is a Round 1. I don't think I'll probably address it in Round 2, and I think we have talked about this a little bit before. But I think -- and by the way, I really like the paper, as we always say and as is always true.

I think the paper could do a better job of explaining the rationale for recommending payment at the facility fee payment rate rather than, for example, the professional services component. It seems to me when you're providing a telehealth service, there is no facility really to speak of. But your professional time is what you're providing.

So I definitely am a proponent of paying less for telehealth visits than for in-person visits. But if I were just naively coming to this without having seen the chapter, I would say, well, of course, okay, we just pay them at professional services rate and leave out the facility payment.

So I think the paper could do a better job of

explaining the rationale, but maybe you could explain it a bit here.

MR. WINTER: Yeah. So we're talking about the professional fee paid to the physician under the physician fee schedule on.

DR. CASALINO: Yeah.

MR. WINTER: But if there -- there's a difference, the rate is -- usually varies if it's provided in an office where the physician incurs the practice expense, practice expenses for the service, or if it's provided in a facility like a hospital where the hospital incurs the practice cost of the service. So, in both cases, the physician is getting paid under the fee schedule. In both cases, they're getting paid the exact same work RVUs, and the PLI is very similar. But the difference is that when it's done in a hospital, the physician does not get the -- gets a lower practice expense, doesn't get the same practice expense it would get -- the physician would get if it were provided in an office.

So maybe there's a labeling issue. We can say this is a professional fee, but it's set at a -- set at the

facility. It's set at the level that would be paid if the service were provided in a facility instead of an office. Would that help?

DR. CASALINO: Yeah. I think I actually didn't understand then, even after the last session we had on this. Maybe I'm the only one who didn't, but still somebody else might not if I didn't.

So the suggestion, then, is to pay wherever the physician is providing the service. The recommendation is to pay what the rate would be to a -- for professional service offered in a facility, in a hospital facility. So the professional service rate in a hospital facility is -- for any service rate is lower or for in-person is lower than the professional service payment rate for if you're doing it in a non-hospital office, right? And so is this recommendation to pay for all telehealth visits at that professional services rate as if paid in the hospital? Is that --

MR. WINTER: As if the service were provided in a hospital --

DR. CASALINO: Okay. It's not --

MR. WINTER: -- or other facility.

DR. CASALINO: -- to pay what a facility fee part of the service provided in a hospital is. Okay. Yeah, that wasn't --

MR. WINTER: And this was the policy before the PHE, just to be clear.

MS. TABOR: And just to double clarify it, it is the lower rate. The facility fee is lower than the non-facility fee.

DR. CASALINO: Right. But it isn't really a -- but it's not the -- it's not the facility fee that's being paid. It's the professional rate in a facility. Is that right?

MR. WINTER: Correct. It's not -- we're not talking about a payment made to a hospital or a SNF or dialysis center. We're talking about the payment to the clinician.

DR. CHERNEW: This is the ideal Round 1 question, by the way, because you can see there's a lot that needs clarifying. So -- right, exactly. So the key point is -- let me see if I -- let me see if I can summarize, and if not, that will just show you one. If the service is provided in a physician's office, right, the recommendation

is to pay the facility rate, which is the lower payment than it would have been if you would have just showed up there in person, right?

MS. BARR: Professional, the professional fee rate. It is the professional fee.

DR. CHERNEW: Yeah. But that -- but there is no -- but if it's -- but if it's done in an office, there is no facility fee. If it's done in the office, there's a --

MS. BARR: [Speaking off microphone.]

DR. CHERNEW: No.

DR. NAVATHE: No, no. That you paid the physician.

DR. CHERNEW: Okay. Let me just go -- let me -- let me -- I'm going to go through again and then we will reclarify this.

If the service is delivered in a physician's office, you get paid the physician fee schedule amount that you would have gotten if that service had been delivered in a hospital outpatient department, and that is all you get paid if it's delivered there.

And the rationale is that the cost of delivering it is lower. That was the original view, right?

MR. WINTER: And, Mike, just to be clear, you're talking about a telehealth service here?

DR. CHERNEW: I'm talking about telehealth service. Right, I'm talking about teleservice. If a telehealth service is delivered in an HOPD, it gets paid at the what the HOPD rate would be. That's the same rate. That doesn't change anymore. And then the question is, would the facility -- would there be a facility fee in addition to that, or would there not be?

MR. WINTER: Just to be clear, when you said it would be paid at what the HOPD rate is, do you mean the physician fee schedule rate service is provided --

DR. CHERNEW: If the service is provided in an HOPD, yes.

MR. WINTER: Okay. That's correct.

And if the patient -- if the patient were located in an HOPD and the clinician were located somewhere else, let's say their office or their home, the hospital could bill for an originating site fee, because they're hosting the patient. They're providing the technology to enable the telehealth service, which is about -- it's about $27. So they have the option of doing that if the patient is

located in the hospital.

DR. CHERNEW: Right. That is different than the facility fee would have been if the patient would have gone to the hospital and gone in the actual service.

DR. CASALINO: Let me give it a true. This is where a blackboard would be.

DR. CHERNEW: We have time. There is no Round 2. Keep going. In fact, there's no other Round 1. It's just this.

[Laughter.]

DR. CASALINO: A blackboard would be really useful here. We could probably settle this in a minute.

But it's interesting to see how much -- that I'm not the only one who is seriously confused. So let's leave out the -- if a patient is in the hospital, the hospital can charge a fee, because that can happen, but it's not really what we're talking about.

So, for in-person services, right now, right, if you're provided as a physician, you get a professional fee for it, and let's just say that's $70, right? If you provide the same service in a hospital facility, you might only get the professional component. It might only be $50

instead of $70, but there might be a hospital component that's $40. So it really comes to -- $50 and $40 is $90 instead of the $70 that Medicare would pay to someone providing service in the physician office. That's correct for in-person physician.

MR. WINTER: Yes.

DR. CASALINO: So is the recommendation, then, if you provide a telehealth service to pay a professional fee, but it's the professional fee as if the service was provided in the hospital, not as if it was provided in a physician office -- so it's the lower fee, and the rationale for that -- yeah. And the rationale for that is the hospital -- the physician service fee paid in a hospital setting is just for the physician service. Whereas, the fee paid to a physician in an office acknowledges that they have a -- that they're -- that they have a similar office expense. But, in a hospital, that's taken care of. So okay.

MR. WINTER: Yes.

DR. CASALINO: So the recommendation, pay at the rate that a physician would be paid if they were delivering this service in a -- an in-person service in a hospital,

and that's the lower rate.

MR. WINTER: Yes.

DR. CASALINO: But it's not the facility rate that the hospital gets paid.

MR. WINTER: Correct.

DR. CASALINO: So maybe that could be made really explicit, even with it --

[Laughter.]

MS. KELLEY: If I could just --

DR. CASALINO: If this section is not that easy to say in words, but a little diagram or a little --

MR. WINTER: Yeah. We get a table explaining this in our 2021 chapter in March, and we can bring --

DR. CASALINO: Okay. It didn't stick with me.

DR. CHERNEW: There will be a link to this session, just a little video.

MR. WINTER: We can bring that table back.

MS. KELLEY: Just to clarify, the practice expense RVUs are officially called a facility and a non-facility practice expense, and that's where -- that's why we're using the word "facility" here. I understand why you're getting confused, it’s confusing, but that's why we

keep falling back on that language. It is the term that CMS uses. But we can be more clear in the paper, we can explain it.

DR. CHERNEW: Again, the example is the price is $50, no matter where you are, in Larry's -- using Larry's numbers.

Okay. Do you have other clarifying questions?

DR. CASALINO: I could come up with something.

[Laughter.]

DR. CHERNEW: That was my -- okay. So we're going to keep moving through the clarifying question queue, but for those of you paying attention, that's how you ask a clarifying question.

MS. KELLEY: Cheryl.

DR. DAMBERG: Yeah. So one of the things I was trying to understand -- and I don't know whether you have data -- do we know how many physicians that have been billing Medicare, say in 2019, who have not pivoted to telehealth at all and kind of what defines them, and did some of those people exit the market?

MR. WINTER: So the first question I heard was, how many clinicians have not provided a telehealth service

in 2021?

DR. DAMBERG: Right.

MR. WINTER: So it's about 800,000, roughly, a little less than that, 750, something like that.

And what was the second question?

DR. DAMBERG: So do we know whether the ones that didn't pivot to doing telehealth exited the market?

MR. WINTER: We can look into that, because we did the analysis for the upcoming March report -- the upcoming March chapter on physician update that looked at exits and entries for a physician. So we can cross those two results and see what we get.

I imagine, given that exits were very small, we're not going to find a lot of exits in either group, those that did telehealth and those that didn't.

DR. DAMBERG: Okay.

MS. TABOR: I will say we -- in thinking about the focus groups with clinicians, the clinicians that participated in the groups that were not offering telehealth any longer --

DR. DAMBERG: Yeah.

MS. TABOR: -- a lot of them were proceduralists,

where telehealth, you know, may make sense for others in their practice but not for them.

DR. DAMBERG: Yeah. Okay. Thanks.

And then I guess the question that I had, so clinicians described the ability to see a higher volume of patients. So is there some way you can measure that to see does this create better access for Medicare beneficiaries if there's more throughput potentially?

MR. WINTER: I didn't hear the first part of the question. You're talking about -- you mentioned -- you're talking about clinicians who were doing telehealth?

DR. DAMBERG: Yeah. So the clinicians' report, you know, when you interviewed them or did your focus group that, you know, they could see more patients. You know, they could get through a visit them more quickly. So does that mean they're seeing more people per day, and so maybe it expands access in certain circumstances? I don't know.

MS. TABOR: It's an interesting question. We can think about it.

MS. KELLEY: Kenny.

MR. KAN: Yes. Ledia and Ariel, this is great work, very rich data.

I'm really curious. In the slide deck for pages 11, 12, and 13, how the findings could vary between urban versus rural, because I was trying to think through the access. Was this the social distancing that happened during the pandemic? I'd be really, really intrigued.

And then on page 15 --

MR. WINTER: Let me stop you there. I'm sorry.

MR. KAN: Yeah.

MR. WINTER: So slides 11, 12, and 13, you'd like to see that just for --

MR. KAN: Urban versus rural.

MR. WINTER: -- urban versus rural.

MR. KAN: Right.

MR. WINTER: Okay. So the clinician, certainly 11 and 12, doable. Thirteen might be a little bit harder because we're talking about the clinician. So we could try to look at the clinician's location, like their business address, and see if they're rural versus urban. Would that be helpful?

MR. KAN: Yes.

MR. WINTER: Okay.

MR. KAN: And then on page 15, when you said that

folks in urban areas, beneficiaries in urban area would use telehealth more, I'm trying to think through, is that one of a matter of convenience or may have something to do -- I was trying to compare urban with this rural again. Is this really a convenience thing, or is it really a technology, you know, acumen thing?

MR. WINTER: It's hard to say. It could be a matter of technology. I think there's some evidence that -- more than some evidence. There's evidence that in rural areas, there's less availability of broadband technology. So that could be an issue in rural areas.

In terms of convenience, if convenience were the issue, you'd expect rural areas to have higher use of telehealth because they have longer distances to drive.

And another factor is that, generally speaking, beneficiaries in urban areas have higher use of services than beneficiaries in -- than beneficiaries in rural areas. So that could be a factor as well, that overall they have higher use in urban areas, and therefore that could explain why they have higher use of telehealth as well.

MR. KAN: Thank you.

MS. KELLEY: Dana.

DR. GELB SAFRAN: Thanks. Thanks for this great work.

Two clarifying questions. One, do I remember right that telehealth refers to an interaction that is either phone only or video? It's remote, and so it could be either the mode of telephone or the mode of video. Is that correct?

MR. WINTER: So during the PHE -- before the PHE, it had to be audio and video. During the PHE, CMS said there are certain codes, certain services where you can provide it by audio only.

DR. GELB SAFRAN: Yeah.

MR. WINTER: Other codes still have to be audio and video. So it does vary by code, and it's limited to the duration of the PHE and then -- or limited until the end of 2024.

DR. GELB SAFRAN: Yep. And so have you -- in the analyses that you're sharing with us, have you looked and then just decided to collapse at the distinction between visits over time that were phone only versus phone and -- you know, audio and video?

MR. WINTER: The reason we didn't present

separate information about that in this presentation is that we don't have data for -- so there are 86 codes that can be provided audio only, right?

DR. GELB SAFRAN: Yeah.

MR. WINTER: Only six, for only six of them, can we identify in claims data that they were provided audio only. The other ones, they could have been audio only or audio and video, and there's no modifier as of -- until this year, there was no modifier to tell us to distinguish between the two modes.

DR. GELB SAFRAN: Got it.

MR. WINTER: As of this year, as of January 1st, CMS is requiring providers to include a modifier in the claim if this service was provided audio only, and that was pursuant to our recommendation from last March.

DR. GELB SAFRAN: Great.

MR. WINTER: So, just for those, for the six audio-only codes where we know there were audio only, those are E&M codes. Just to give you a sense of the amount we're talking about, they accounted for a $765 million in spending in 2020, which was about almost 20 percent of all telehealth spending.

DR. GELB SAFRAN: Okay.

MR. WINTER: And that declined to about $560 million in 2021, which was about 15 percent of all telehealth spending. So it's a fair chunk of the --

DR. GELB SAFRAN: Yeah.

MR. WINTER: -- the business, but it's declining. Its share is declining.

DR. GELB SAFRAN: Yep.

MR. WINTER: And that's in the paper.

DR. GELB SAFRAN: Thanks. Yeah. Great. Okay. Thank you.

And then the other thing, I was curious just from understanding any biases in the sample. Can you just say a little bit more about the focus groups, like how many, how many participants in each, how we recruited them, just a little on the methods?

MS. TABOR: Sure. So we selected three different major urban cities in three different parts of the country, and we recruit Medicare beneficiaries. We had groups of Medicare-only beneficiaries. We had groups of duals. We tried to recruit a variety of beneficiary characteristics that meet the population that we're in. So that's -- we do

look at race, ethnicity, income, and age and sex to try to get a kind of diverse group.

And we hold -- there's usually about 10 participants in each group, in each city. I believe for beneficiaries, we had four groups, and then for clinicians, it was three. It's one group of primary care physicians, one group of specialists, and one group of APRNs.

DR. GELB SAFRAN: Thanks.

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

MS. BARR: I do.

So I do think it's a little unfortunate that you've excluded RHCs and FQHCs from the analysis. So that could be a Round 2 question, but I think it's important to understand like the ratio of payment that somebody would get in order to determine whether or not we've created disparities in care, particularly for underserved communities.

And so my experience was -- and I believe there was publications around this -- that the uptake of these services in rural communities was much lower than urban communities, and if it's audio only, everybody's got a

phone. So I don't think that's it.

And what I was told was they couldn't afford to do it, because the way rural health clinics get paid is they get paid based on the number of Medicare patients they give services to as a percentage, and these would be excluded from that cost report. And so any patients that they gave telehealth services are excluded from their cost report, which brings down their total payment significantly.

Also, I believe that the payment that they were going to get and was why I'd like to create some ratios, in a provider-based rural health clinic, that payment might be $50 versus $300. Whereas, for a physician office, it might be $50 versus $100. And so the penalty was so high for rural physicians that they felt they couldn't do this, and I feel like we need to get at that information if that is true, because that would be an important recommendation. If you're going to discount the services -- and we should, right? I mean, the costs are the same. You have to accommodate for these special payment models people have and cost reporting, et cetera. That's very important for us to consider, and there should be a fair ratio that says

we're going to pay you 80 percent of the fee schedule, we're going to pay you -- you know, whatever you would have gotten, we'll give you 50 percent, 70 percent, 80 percent to have some equity across the populations.

So I think I got some Round 2 in there, and I apologize for that.

DR. CHERNEW: The thing is you're number one in Round 2, and you were the last one in Round 1. So it turns out we're going to transition to Round 2. Lynn?

[Laughter.]

MS. BARR: Thank you. Thank you. Thank you for your grace there.

So I just -- I feel like we really need to understand this because I believe that we're creating a health equity crisis in the way that we're paying telehealth.

Thank you.

That's one and two.

DR. CHERNEW: One and two? Wow. Okay. That, I think, then brings us to the second Round 2 person, which I think is Robert.

DR. CHERRY: Thank you. Great report. I think

it's an interesting and challenging topic. There are clear benefits to this, you know, in terms of continuity of care, both on the provider side as well as on the patient side, you know, having flexibility and convenience. So it's very positive.

I think one of the concerns we have, of course, is fraud and abuse, and in your report, you mention that the OIG has identified 0.2 percent of providers that might be subject to that. While it sounds like a small number, we know that those small numbers can generate a lot of dollars at the end of the day, so it's no small task.

When I put my clinical hat on, though, there's a lot of challenges, and I mentioned it before, if you're trying to create sort of a one-size-fits-all type of model, because in a new patient in dermatology -- and I mentioned this before -- an initial visit by telehealth may be entirely appropriate, but not true for psychiatry where in-person is actually necessary. Same for someone that's been referred to primary care for hypertension, you know, you're going to want to have an in-person visit, but a subsequent visit could be through telehealth.

At the same time, with that subsequent visit for

hypertension, low-income patients are vulnerable because they may not have a home blood pressure cuff; they may not even have a home scale to even weigh themselves. And, therefore, should there be offsets for that to help cover those costs, at least for low-income patients so they can take advantage of telehealth services.

The other complexity is sort of, you know, those that present with ILI or influenza-like illness, you know, so telehealth can be an appropriate service when you're trying to decide whether or not patients should have a COVID test, an RSV test, a flu test, entirely appropriate. But it also brings up some complexity related to the earlier R1 discussion, which is that that type of service can occur across multiple settings. It can occur in a hospital outpatient department, a private office, but also not mentioned, this can also occur in a private telehealth company. It could also occur in a retail pharmacy. I'm not quite sure what the model is when you start going in sort of atypical environments like that.

So I'm not going to reopen that R1 question, but maybe some clarification on that as you kind of think through this for the next round of discussions in the next

couple of months.

The other thing as well, you know, we want to try to keep it as simple as possible, despite the complexity. One way of sort of looking at these things, because there is a lot of clinical complexity and difficult to wrap your mind around it, is that the patient themselves can be actually the best voice and judge of whether or not there's value for telehealth. And I think developing, you know, a survey instrument similar to HCAHPS and CG CAHPS that's specific for telehealth, that can be monitored and leveraged in terms of whether or not people that are providing telehealth services are actually accommodating the patients and providing that value can be helpful over the long term of making sure that, you know, we're delivering the best quality of care to the beneficiaries. So I'd just mention that.

Otherwise, I'm looking forward to other rich discussions on this topic.

MS. KELLEY: Larry.

DR. CASALINO: I had just a couple, I think, fairly quick things. Like Robert, I wanted to say something about fraud and abuse. My first reaction to the

fact that OIG found that one-fifth of 1 percent of clinicians who are billing telehealth services looked pretty evidently like fraud and abuse. So, well, let's not make regulations that mess up, you know, things for 99.98 percent because there just a few who easy to identify and do something with.

But then I thought some more about there really is a risk, I think a real risk, that quite a lot of physicians will bill just a bit more than is appropriate for telehealth visits. And, you know, your table that shows the time that almost half of telehealth visits were coded as 30 to 39 minutes, I find that extraordinarily hard to believe, honestly. That's -- and almost the same number for in-person visits. Even that I find hard to believe. But for telehealth I really doubt that it happens very often that a physician sits there and chats for 35 minutes, you know, 30 to 39 minutes on the phone with a patient, and that that's half that they do that.

So that's not the kind of fraud and abuse we're talking about for this two-tenth of 1 percent, but it could be much more expensive to Medicare even if there's only a little bit of it. So it would be great -- probably someone

else will do this if -- maybe it has been done. But MedPAC I think could do it, look at a sample of physicians, and just count up their in-person minutes and their telehealth minutes, and see if that's something that plausibly can be done in a reasonable work day. I think that would be a real contribution because I find that table -- or that figure stunning.

Another point, this hasn't come up yet, but I personally agree that cost sharing shouldn't be waived. I think that is a good barrier against fraud and abuse, really, especially against unnecessary visits and maybe to some extent against unnecessarily highly coded visits.

And then I think the last thing I have to say -- and I've said it before, and I was really glad that you guys did put it in the previous paper, and there's a little bit of reference to it in this one. The congressional request did say you may include analysis by provider type, among other things, and one provider type could be physician specialty, but it also could be, you know, a teladoc company versus bricks-and-mortar provider of care that also does telehealth. And, you know, I'll just reiterate again -- I said it before. I do it quickly. I

think companies that are telehealth-only can provide an important service, but it is a form of cherrypicking in a variety of ways and can be provided I think at much lower cost than Geisinger would be able to provide telehealth services because Geisinger also has to support bricks-and-mortar. It's really important for the country that bricks-and-mortar facilities don't get hollowed out, and particularly this could hurt primary care. So there could be a lot of cherrypicking away from primary care, and when someone actually needs to see a primary care physician in a bricks-and-mortar family or another physician, they may not be there.

So MedPAC has a principle of not paying more for a service, not paying a lot more for a service than the cost of delivering the service, and I think that principle would suggest that teladoc companies be paid less.

So I know we've recommended that CMS -- and this paper does it -- that CMS collects the cost of providing services for different provider types, meaning, for example, teladoc versus bricks-and-mortar. I think that's great. And I would also emphasize that you mention in the paper the OIG recommends that a way be found to identify

services that are provided by teladoc companies. I think this is an issue we should stay on and try to even provide more input on. I don't think there's been that much services in Medicare to individual beneficiaries from teladoc companies to date, but I'm not sure that that situation will stay. And as Marge was saying earlier, once you have something in place, it's hard to take it away. So if we start off paying teladocs the same as bricks-and-mortar, I think it could lead to really serious problems pretty quickly.

MS. GINSBURG: If I can just jump in a second, everything you said, I agree.

[Laughter.]

DR. CHERNEW: So one of the things I think -- in a moment I think we're going to go to Stacie if I have this right, but before we go to Stacie, let me just say one of the challenges with backward-looking analysis, particularly on program integrity activities, is because nothing has been put permanently in place, there hasn't been a strong incentive to ramp up with business models. So I don't mean to channel Bruce Pyenson, but I think Bruce's concern was always once you get to the point where you say, okay, this

is how it's going to be and it's going to be this way long term, what you've seen in the past, which actually I think really -- you know, we can quibble around the details, but I don't think it's really been that shocking. I think on balance we would have said that during the pandemic and even now, telehealth is probably a net benefit in a bunch of ways. We might quibble with the coding on some of the services, but, you know, for the most part it hasn't been, to use Bruce Pyenson language, he used to say some version of program integrity on steroids, or some version of steroids.

But, anyway, but going forward, you don't know what that would be, and that's why you have to be really careful about how you do that, and I think that's something we've been worried about, because what you've seen in the past might not indicate what you see in the future, which is what you said.

DR. CASALINO: And Teladoc executives have actually said we're not really getting into Medicare, providing services for individual Medicare beneficiaries at all or in a big way, because we don't know what Medicare's going to do with it.

DR. CHERNEW: As an aside, again, in all programs there's the people that are trying to be good actors and other people not so much. I'm actually less worried about Teladoc than about opening this up to a whole range of other things that you might imagine that might not be completely established as Teladoc. But that's a broader separate issue that we won't go into now, so we'll go to -- I think Stacie's next.

DR. DUSETZINA: That's right. Thank you for a great report. I really enjoyed reading it. I also felt pretty optimistic seeing some of the leveling off, you know, that we're kind of rebounding back out of the COVID space and maybe getting to like a new normal for telehealth services.

I guess I would say that, again, as an apology, I trained as an epidemiologist. I always want to stratify everything. I'm sorry. But in the report, you do a really good job of talking about showing how much higher telehealth was among people who were disabled, with ESRD, et cetera, and then some of the additional materials that were provided were kind of grouped together, and it just made me really want to see that stratified by disabled

versus aged beneficiaries.

So, for example, Table 3 with the clinical categories, it was really dominated by behavioral health diagnoses, and then there was like this huge other things category. And I wondered, you know, if that was separated out by those two groups, would we see slightly different patterns where maybe a little bit more of a signal for older adults? And are they really going and doing telehealth to get medication management for chronic conditions? Something like that.

And the same thought kind of goes to Table 5 on the specialist piece, because I kind of wondered, you know, who's making up those specialists? Is it really behavioral health care specialists? Is it psychiatrists? Or is it something completely different? And I wonder if you were able to stratify in that way just by those two broad categories, if we have like a little bit more insight into what's going on.

And then the last thought was -- and this is probably naive, but Slide 12, where you show the intensity of services, it just -- you know, I like the thing about how much time is being spent on the phone or in these

visits? It doesn't seem realistic. I wonder if there should be like a limit like you can't be more than a 3 if you're on a phone call, like otherwise you should be in an office. Like cap it at a certain level and maybe reduce some of those incentives for too much overuse of telehealth, like the right amount of use.

Great chapter, really enjoyed it. Thank you both.

DR. DAMBERG: Thanks. I'm struggling a little bit sort of looked out on the horizon and thinking about how to measure quality of care and whether this has value and trying to think through all of the care coordination issues. And I don't know whether there's some way to start laying groundwork for -- and, you know, this is not fully baked, but do we care whether telehealth is delivered say within a system of care that people are using versus they're using care outside the system and some of that information and coordination is not coming back to the system where they routinely get their care?

So I think it would be helpful to start thinking about what does continuity look like, how would we define it, and -- because I think that is something that maybe

could fall apart in the context of telehealth if people start just doing scattershot using all these different providers and there's no one kind of managing that care.

UNIDENTIFIED SPEAKER: You mean like for everybody [off microphone] today?

[Laughter.]

DR. CHERNEW: But there's complicated issues around, for example, attribution and alternative payment models and network stuff and MA and all kinds of --

DR. DAMBERG: Yeah, I don't mean to say this is easy, but I think it --

DR. CHERNEW: No, I agree completely. I think there's -- particularly if people -- the concern was that people get marketed to -- there's obviously this notion that you're going to reach out to some beneficiaries, but someone could reach out to a beneficiary and offer services in ways -- it gets quite complicated. So I think this is -- I'm going to just reiterate what I said at the beginning of this. This report will appear in the June -- this chapter will appear in the June report, but this will not be the last time we spend with this. I think having a Medicare program that has not been designed for the

technology changes that we're seeing is problematic. And I think, you know, not only -- we've been talking about these like they're just different types of visits, but there's all other kinds of services that are -- remote patient monitoring, there's a whole range of asynchronous services and stuff going on. This, I think, is actually going to be a real challenge to how care is delivered and the real experience of clinicians that are delivering that care.

I think you were last so -- no, you weren't, so David is now --

DR. GRABOWSKI: Sorry. Just picking up on that, Mike, all the sort of factors you just listed also make it really hard to study, and obviously in April we're going to see some data about the impact of expanded telehealth coverage on access and quality. And I was wondering if maybe, if they were willing -- this is probably a really bad Round 1 question, Larry, but, like, could you sort of give us like what kinds of outcomes you're going to be able to study and kind of something about study design that we could at least begin to sort of think about that? Because it's really hard to interpret this expansion and all the changes that we saw without thinking about what's the

context here for access and quality.

Thanks.

MS. TABOR: I'll be able to say more in April, but we are testing out the idea -- it's a proof of concept -- of can you measure -- think about measure telehealth quality using population-based measures, so comparing areas that had a higher intensity of telehealth use and did their outcomes improve. And it really is a proof of concept, and I'm looking forward to telling you all about it in April. But it is this kind of high-level approach we're taking.

DR. CHERNEW: So I will say, and, again, I think -- actually I won't say this -- maybe I will because this relates to this. There's been some work, I know, from Ateev and some others where they're looking at -- there's been wide variation in system adoption. So the extent to which you can assign patients to systems that went all in on telehealth and systems that didn't, you can say something, of course, the systems that went all in were different than the systems that didn't. So I think this is a complicated area.

Greg, you get the last word.

MR. POULSEN: This will be the shortest Round 2

that I have ever made or probably ever will make, and it is the point that you made at first, I think should be emphasized probably in writing, and that is, telehealth works superbly in a prepaid or capitated environment. It's very problematic in a fee-for-service environment.

DR. CHERNEW: That has been a concern of mine.

Okay. I have spoken enough that I think I have summarized. Again, Ledia and Ariel, this is really terrific work and understand that I think we understand how hard this is for a range of reasons, both because of the heterogeneity of the service, the balancing of what is clearly good about it, what's clearly worrisome about policy around it; our desire to use these new tools to promote access to care, which is obviously important; our desire to avoid them messing up the system in terms of overuse, hollowing out the bricks-and-mortars, which is something I've written about in other contexts. So, again, I'll say thank you.

For those at home, please reach out to us on the website. You can give us comments at Medpac.gov/meeting, or you can submit them directly to meetingcomments@medpac.gov. We do want to hear your

comments on this. I have to believe -- I'd like to believe that there's a lot of people in the audience that know a lot about behavioral health, a lot about MA, a lot about telehealth, and we would like to hear your comments about this discussion. In all of those areas we will be doing a lot more work. So, again, thank you all. We are going to show up here tomorrow at 9 o'clock. We are going to have a day about drugs. So that will be tomorrow.

Anyway, thank you all. We'll see you then.

[Whereupon, at 5:10 p.m., the meeting was recessed, to reconvene at 9:00 a.m. on Friday, January 13, 2023.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Friday, January 13, 2023
9:00 a.m.

COMMISSIONERS PRESENT:

MICHAEL CHERNEW, PhD, Chair
AMOL S. NAVATHE, MD, PhD, Vice Chair
LYNN BARR, MPH
LAWRENCE P. CASALINO, MD, PhD
ROBERT CHERRY, MD, MS, FACS, FACHE
CHERYL DAMBERG, PhD, MPH
STACIE B. DUSETZINA, PhD
MARJORIE E. GINSBURG, BSN, MPH
DAVID GRABOWSKI, PhD
JONATHAN B. JAFFERY, MD, MS, MMM, FACP
KENNY KAN, CPA, CFA, MAAA
GREGORY POULSON, MBA
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AGENDA PAGE

P R O C E E D I N G S

[9:00 a.m.]

DR. CHERNEW: Good morning, and welcome to our Friday session of our January meeting. We have two great sessions today on prescription drugs.

First, I want to welcome Betty who made it through the air traffic conundrum to join us. So thank you. I'll acknowledge Larry's wonderful bowling, just for those joining at home.

[Laughter.]

DR. CHERNEW: And Lynn is working on your trophy. Amol wants a second-place trophy. He's still bitter, but we will get to consensus.

DR. NAVATHE: Thanks, Larry.

DR. CHERNEW: That's totally my mistake. We don't have time to talk about bowling.

All right. So we are actually going to talk about Part D drugs. For those of you that are following MedPAC for more than a cycle, you realize that it -- I think it was before I was Chair, there was some spectacular Part D drug work that was done, much of which is reflected in some of the new Part D rules, and now we have, as we

typically would have, a status report activity on Part D.

So I'm going to turn it over to Tara to start to discuss that status report.

MS. O'NEILL HAYES: Thank you. Good morning.

Shinobu, Rachel, and I are here to present the annual status report on Part D, Medicare's outpatient drug benefit. This material will be a chapter in the Commission's upcoming March report. As a reminder to the audience, a PDF of these slides is available at the right-hand slide of your screen.

Today we will start with a snapshot of the Part D program and discuss ongoing trends under the current structure of the Part D benefit, including program costs, drug prices, and beneficiary experiences.

Next, we will walk through the Part D-related provisions of the Inflation Reduction Act, which was passed in August of last year and contained many drug pricing and coverage policies.

Then we will discuss how those provisions may change the drug pricing landscape and the Part D program in particular.

Part D provides Medicare beneficiaries with

access to prescription drug coverage by using private plans that compete to deliver pharmacy benefits. Plan sponsors and their PBMs take part in multiple negotiations, first with pharmacies to set up networks and agree on payment rates for prescriptions and post-sale fees and also with manufacturers of brand-name drugs over formulary placement and post-sale rebates.

Medicare subsidizes about 75 percent of premiums for basic benefits for all enrollees plus additional subsidies for low-income enrollees. The program was intended to have plan sponsors bear financial risk for enrollee spending, so sponsors would have incentive to manage benefits through formularies and tiered cost sharing.

Medicare does, however, limit plan risk by providing reinsurance, risk adjustment, and risk corridors to limit plan losses and profits.

Until recently, the Secretary was prohibited from interfering in these negotiations, which we will discuss what has changed when we get to the section on the Inflation Reduction Act.

In 2022, Part D's enrollment reached nearly 50

million, and more than half of all enrollees were in Medicare Advantage drug plans, referred to as MA-PDs, rather than stand-alone prescription drug plans, or PDPs. This is a dramatic shift from the start of the program.

This movement is also true for the 27 percent of LIS enrollees, who used to be predominantly in fee-for-service but have increasingly moved into MA-PDs as plan sponsors offer more generous coverage and introduce targeted special needs plans, or SNPs.

For 2023, plan sponsors are offering more of each type of plan with the greatest growth among SNPs.

In 2022, the weighted average monthly Part D premium, averaged across basic and enhanced plans from both PDPs and MA-PDs, was unchanged from 2021 at $26. Average Part D premiums have bounced around $30 per month since about 2010, though the overall average hides a lot of variation.

Note that MA-PDs can use some of their Part C rebates to reduce Part D premiums. So, in 2022, MA-PD enrollees paid an average Part D premium of less than $15 per month after Part C rebates of $47 were applied to their Part D premium. Meanwhile, PDP enrollees paid an average

of $40 per month. Total Medicare spending on Part D in 2021 was $95.9 billion.

While enrollment and plan offerings continue to grow, the Part D market has become more concentrated and the organizations more vertically integrated, with concentration being particularly high among PDPs.

Many of the largest plan sponsors are vertically integrated with PBMs and pharmacies. In Part D, the market for PBM services is even more concentrated than that for plan sponsors because larger PBMs provide services to smaller sponsors on a contract basis.

Vertical integration has advantages and disadvantages. Owning a PBM can help a plan sponsor make sure the PBM is looking at tradeoffs between medical and pharmacy spending. Integration also gives sponsors access to large amounts of prescription claims and cost data that can be useful for, say, monitoring adherence and potentially coordinating care.

However, there is concern that vertical integration and market concentration may contribute to anticompetitive behavior. For example, a health plan that also owns pharmacies and a PBM could attempt to restrict

pharmacy network participation or raise prices of PBM services for competing contracted health plans.

Integration also makes it difficult to assess the profitability of plans because there's little visibility into the transfer prices between upstream and downstream companies.

In 2021, capitated payments as a share of Medicare's payments to plans continued to decline, totaling $7.8 billion, a decrease from 2017 of 14.5 percent per year on average. Cost-based reinsurance totaled $52.4 billion, an increase of nearly 9 percent per year on average since 2017.

Reinsurance costs are driven by enrollees with spending high enough to reach the annual out-of-pocket threshold. That $52.4 billion in reinsurance costs covered expenses for 4.1 million people, or about 8 percent of all Part D enrollees. Of those 4.1 million individuals, roughly 464,000 used drugs with very high prices, where a single prescription was sufficient to meet the out-of-pocket threshold.

The shift toward cost-based payments, which accounted for 87 percent of Medicare's basic benefit

payments in 2021, continues in 2023 with the direct subsidy averaging less than $2 per member per month and reinsurance averaging $94 per member per month.

Today the structure of Part D's benefit has plan sponsors bearing relatively little financial risk in certain phases of the benefit. Part D now has 2 standard benefits, one for enrollees without low-income subsidies, on the left, and another for those with the LIS, on the right).

Focus, if you will, on the darker blue parts on the right-hand side of each graphic. Those are the portions where plan sponsors bear financial risk for enrollee benefits. You can see in both cases; plans do not bear much risk in the coverage gap or in the catastrophic phase where Medicare pays 80 percent of costs.

There are other problems with this benefit structure, but relatively low plan liability for benefits undermines plans' incentives to manage spending. At the same time, plan sponsors and their PBMs collect rebates from drug manufacturers that can be larger than their benefit liability.

MS. SUZUKI: Insurance risk provides an incentive

for plan sponsors to offer attractive benefits while managing costs through formularies and other tools. However, plan's share of insurance risk has decreased dramatically since the start of the program. We saw this trend continue for the most recent six-year period between 2015 and 2021, shown in blue.

In 2021, plans were at risk for 26 percent of Part D spending, net of all rebates and discounts, including coverage gap discounts paid by manufacturers. That is down from 34 percent in 2015. Plans' share of risk varied across plan types, ranging from 12 percent for SNPs to 33 percent for other MA-PDs.

Medicare's risk rose during this period, shown in green. In 2021, Medicare was at risk for 61 percent of net Part D spending. That includes both payments for reinsurance and the low-income, cost-sharing subsidy. That is up from 52 percent in 2015. The increase in Medicare's share of risk was largest for SNPs, followed by other MA-PDs.

In 2020, the Commission made recommendations to restructure the Part D benefits. To address distortions in plan incentives created by rebates and discounts that

increase Medicare costs, the Commission recommended the elimination of the coverage-gap discount and increasing plan liability in the coverage gap and the catastrophic phase of the benefit for all beneficiaries, including those who receive the low-income subsidy.

To address high prices and high-cost sharing, which we will touch on next, we recommended creating a new manufacturer discount in the catastrophic phase and capping beneficiary out-of-pocket costs to provide complete insurance protection once they reach the catastrophic phase of the benefit. The restructure also reduced plans' reliance on cost-based reinsurance by increasing the capitated direct subsidy payments to improve incentives to manage the benefit.

Now switching gears to discuss beneficiary experiences. One thing we have found year after year is that the majority of beneficiaries are satisfied with the drug benefit. According to the 2020 Medicare Current Beneficiary Survey, which is the latest year available, about 80 percent of Part D enrollees reported overall satisfaction with the program. Beneficiaries tended to be more satisfied with the amount paid for drugs, drug

coverage, and pharmacy participation, while they tended to be less satisfied with the ability to understand the program and the information they received. At the same time, less than three-fourths were confident their coverage met their needs.

Although it has long been believed that premiums are paramount among the factors beneficiaries consider when choosing their plan, in 2020 somewhat higher share of beneficiaries reported considering cost sharing for their medications than premiums.

Beneficiaries' concern about high-cost sharing is often related to prices at the pharmacy. In 2021, the growth in average prices, measured at the point-of-sale, accelerated, growing by 4.2 percent compared with roughly 2.5 percent in the previous two years. Prices of single-source drugs and biologics continued to drive the trend, with prices now averaging four times those observed at the start of the program.

In 2021, prices of these expensive brand drugs averaged nearly 40 times that of average generic prices. That's up from less than six times in the early years of the program. Because generic drugs account for 90 percent

of all prescriptions, decreases in generic prices have helped moderate overall price growth. However, the rate of decrease in generic prices has slowed in recent years, and as a result, the price index accounting for generic substitution saw an uptick in 2021, rising by 3.5 percent, compared with 1 to 2 percent growth in 2019 and 2020.

In addition, generics' share of prescriptions has plateaued at about 90 percent since 2017. Because a significant portion of brand spending is made up of biologics, further opportunities for generic substitution is likely to be limited. That means any meaningful savings would have to come from successful launch and adoption of biosimilars that would help spur price competition.

Despite relative high satisfaction with Part D costs, coinsurance on high-priced products may make them unaffordable for some beneficiaries. In the focus groups convened for the Commission, physicians and beneficiaries were acutely aware of high drug costs and reported having frequent discussions about ways to lower costs.

In the MCBS survey, 25 percent of Part D beneficiaries reported problems with affordability.

Changes made by the Inflation Reduction Act of

2022, which we will discuss next, will cap beneficiary out-of-pocket costs and will improve access for all beneficiaries.

The recently passed Inflation Reduction Act contains many provisions that affect Part D. Manufacturers of prescriptions dispensed since last October will be required to pay a rebate if the price of their product sold through the program rises faster than inflation.

Beginning this year, cost sharing insulin products will be capped at $35 per month, and there will be no cost sharing for all adult-recommended vaccines.

Beginning in 2024, cost sharing in the catastrophic phase will be eliminated, and the subsidy rates will adjust to limit the increase in the average premium. Those who currently qualify only for a partial LIS subsidy will be eligible for the more generous, full LIS subsidies.

Beginning in 2025, Part D's benefit structure will have a new design, including a hard cap on enrollees' out-of-pocket spending.

Finally, one of the most widely reported and notable changes affecting Part D is the new authority given

to the Secretary of Health and Human Services to negotiate the price of some outpatient drugs.

By September 1st of this year, the Secretary will select the first 10 drugs to be negotiated, and the negotiated maximum fair prices will be announced by September 1st of 2024. The negotiated prices will be effective beginning in 2026, with additional drugs being selected for negotiation each year.

Now focusing on the redesign of benefit. The redesigned benefit will apply a uniform structure to both LIS and non-LIS enrollees.

In 2025, the IRA changes will provide beneficiaries with a $2,000 annual out-of-pocket cap, eliminate the coverage gap, and increasing plan liability, shown in blue.

Under the new benefit, plans would be at risk for 65 percent of spending during the initial coverage phase and 60 percent in the catastrophic phase. Medicare's reinsurance would be reduced from 80 percent to 20 percent.

There will be a new manufacturer discount, shown in green, 10 percent in the initial coverage phase and 20 percent in the catastrophic phase.

The IRA changes to the Part D benefit share many similarities with the Commission's 2020 recommendations. The new design would rely less on cost-based payments and restore plans' incentive to manage the benefit. Higher plan liability would provide better formulary incentives and would ensure that plans no longer benefit financially from preferring high-priced drugs with rebates.

However, other IRA changes are likely to alter the drug pricing landscape. For example, the inflation rebate is expected to result in higher launch prices but potentially slower price growth for some products.

The effects on prices would likely depend on factors such as the extent of therapeutic competition and Medicare's market share.

For your discussion, we are interested in your feedback regarding the mailing materials and would be happy to answer any questions you have.

In April, we will be presenting on the findings from our analysis of the DIR data. This is a continuation of the work we presented to you last fall.

With that, we'll turn it back to Mike.

DR. CHERNEW: Thank you, Shinobu. That was

really wonderful, and I think this just illustrates the power of all the work that's gone on here in the past. So I think that's terrific.

I'm going to pause for a second while I look around for the Round 1 queue people.

That was a very clear presentation. I think we're going to jump to Round 2.

Stacie, I think you're going to be the lead-off on Round 2.

DR. DUSETZINA: Surprising everyone.

Thanks for such an excellent chapter. I always love reading this chapter, and I especially loved reading it this time.

I just have a couple of minor comments to make or things to think about either for the chapter or for as we're moving forward. So I'll kind of go in order when they came to me in the chapter.

One is, early on, we talk about the incentives for plan sponsors to manage the benefit, and I think it might be worth in that section talking a little bit about the specialty drug spending and the concentration in the protected classes. And, you know, unfortunately, plans

don't really have any new tools. It seems to manage the spending there. So I think we might want to add a little bit of nuance around the fact that that's how we talk about when the benefit gets redesigned that plans could do better, but it's like with no new tools in their toolkits for doing so.

Another thing, just a broader point -- and this is a little bit looking forward to the benefit redesign, but I thought it would be well worth mentioning the smoothing mechanism that's being proposed for handling out-of-pocket costs. I think we're well positioned to give people a good overview of what that means in reality and some of the potential operational challenges, because my read of it is basically that we're asking plans to create almost like a financing system for drug fills.

And another thing that just strikes me, so for those who maybe haven't lived and breathed the Inflation Reduction Act taxed on this issue, the idea is that when somebody comes in and they fill a really expensive drug, that they could ask to have their costs smoothed out for the remainder of the year. So, if you fill the drug in January, you smooth that up to $2,000 by month, but that

creates like a financing type of mechanism that plans don't really have in place right now and I think is something where the law suggests it would rely a lot on pharmacists to inform people that they could enroll into these options. And though people could enroll in any given month, you imagine you go to the pharmacy, you say, "It's too expensive for me," and then they say, "Well, you're not in a smoothing mechanism. So go back. Enroll in it next month, and then come back to the pharmacy." So I worry that that instills potential for health disparities where maybe, depending on who you are, your pharmacist might not volunteer that information to you.

So I think it's something that we'll want to be thinking about, and this would be a nice opportunity to just bring up a little bit on the details to tell people that's coming.

And then just kind of selfishly, as we get closer to that, I think it would be great to know more from plan sponsors about what their thoughts are on the operationalization of this work and how do they ensure they collect on those payments and how is it working for beneficiaries, because it sounds overly complicated to me,

to be honest.

A couple of very minor things. One was the employer group waiver plans that were presented in page 16 of the report. I was just curious if it was possible to break those down by MA-PD versus -- like, you know, basically get a little more color there. And part of what I was wondering too is will they really start to go away more than they have before with the Inflation reduction Act, because I guess my gut reaction is that employers offer those because they don't want that unlimited out-of-pocket cost for people. But now that the Part D benefit will be much more generous, maybe they more kind of more rapidly disappear. But that's just a guess.

I also wanted to say thank you for highlighting the issue of the market segmentation that we had discussed in that other chapter, just of plans going away and kind of capturing beneficiaries and raising premiums on them. I think it's important to highlight and for us to continue to look at.

Okay. The last point is more of something that just struck me as reading the chapter on the generic drugs and also listening to the presentation this morning and

kind of where we've maxed out our benefits on generic drugs. But there's been a recent, small amount of literature on things like these places where you can get drugs at low cost, like Cost Plus Drugs. I know you mentioned some of these in the chapter, and I think it's curious, because if you compare point-of-sale prices that are being paid by the plans, the Part D plans, in a lot of cases, they're much higher than those prices that are being obtained when people pay cash.

And it makes me wonder, like, how much better could these plans be doing at negotiating for generic drug prices, because we think that those prices are -- that they're not getting additional rebates. We think that's the real price, but it seems like we're leaving a lot of money on the table or plans aren't getting the best deal that they could be getting. I know this is like a really kind of nascent space, at least from the literature, but it seems intriguing to me given the price differentials.

But, as always, love this chapter and great job, all of you.

MS. KELLEY: Dana?

DR. GELB SAFRAN: Yeah, thanks. This is

tremendously exciting to see this year, and my comment is more of a question. It might have been a Round 1 or it might actually be a question for Stacie. I'm just curious -- you know, I'm still struck by the contrast between Slide 7 and Slide 14 in terms of the plan liability, and I know that was a big part of what we were intending through our recommendation would happen, even if the legislation doesn't exactly mirror our recommendation.

What I'm curious about is with all of what's happening with the introduction of very high-priced drugs that are biologics, how do we think that this will affect kind of initial pricing or what's happening in that market?

MS. SUZUKI: I think there's a lot of discussion around what various provisions may have on pricing, and I think we sort of have a big picture. It's probably going to depend on Medicare's market share for the product in the therapeutic competition, because their ability to price is very dependent on that. There are other provisions like inflation cap, inflation rebate, and some drugs would be affected by negotiations as well. And I think there are different ways in which each product could be affected. For example, some biologics could be exempt from the

negotiation, and if they were expected -- if a biosimilar was expecting to enter the market and that could affect what the pricing would be for the biosimilar products versus if the reference product was not one of the potential selected drugs.

I think there's a lot of uncertainty with respect to pricing generally. I think some of the consensus we heard is the inflation rebate would probably result in higher launch prices, anticipating that they would have to pay for any increase beyond the CPIU.

DR. GELB SAFRAN: Interesting. Thank you so much.

MS. KELLEY: Robert?

DR. CHERRY: Yes, thank you. Great report, very crisp and clean. Thank you.

I just have one question, sort of an R1/R2 type of question. It's on page 31 to 32 in our pre-read materials. There was an interesting statement about pharmacy discount cards where -- I guess the way they're constructed; it makes it difficult for both the provider and a health plan to understand what the patient is taking in their totality and help to coordinate care and also

track their quality measures as well.

I don't pretend that I know how these pharmacy data systems communicate or don't communicate with each other, but it does seem like it's potentially low-hanging fruit from a policy perspective. Maybe it's a potential recommendation so that, you know, care is better coordinated.

MS. KELLEY: Jaewon?

DR. RYU: Yeah, I just had a quick question. There's a couple mentions around MA-PD versus the PDP dynamic, and I think there has been migration towards MA-PD away from PDP. But I thought it would be interesting if there is this information, but if the chapter could at least spend a little bit of time on just the clinical implications of that. Like do you see in measures of effective disease management, do we see that that gets done somehow better in the MA-PD environment versus the PDP? It sounds like some of that migration is consumer choice around will there more likely be in enhanced coverage plans versus the basic. But it stands to reason that if there's a clinical and pharmacy sort of interplay with the benefits, in theory you'd think there should be a better

clinical integrated outcome with that. I don't know if that's true. I don't know if there's information to get at that. But that might be an interesting component of that migration to touch on.

MS. KELLEY: Cheryl?

DR. DAMBERG: Thanks. Really nice chapter.

One of the things that -- so full disclosure, I do work for Medicare, running the disenrollment survey, and the primary reason why people disenroll from Part D plans, PDPs, is due to financial reasons. And we've done some focus groups with consumers, and, you know, we repeatedly heard from disabled individuals a lot of problems, you know, being able to afford drugs, and, you know, particularly issues with co-payments because they have frequent visits to the doctor and those costs add up over the course of a year. And it would be helpful -- I know you've done breakouts in some of these tables in terms of LIS versus not, but I think it would also be helpful to break it out by disabled versus not.

MS. KELLEY: David?

DR. GRABOWSKI: Thanks. Great work as always. This chapter is -- I think "crisp" is the great word Robert

used.

I was really struck by what the beneficiaries reported around high and lower satisfaction, and especially the program being easy to understand, which I think we all can appreciate the information provided. And then the one I wanted to sort of touch on was the confidence around the coverage meets their needs. It strikes me that MedPAC could think a little bit about the Plan Finder tool and how beneficiaries are matching to their plans. Our team has done some work on that, and I think, you know, with some simple remedies, you could get a much better matching function. I think there's ways of kind of improving the choice function there such that individuals aren't matching to coverage that doesn't meet their needs.

So I think that's an area we've touched on in the past, and I know we've thought a lot about this in other sectors. Are beneficiaries choosing the right SNP or the right hospital? But maybe -- I think we could pay more attention to that here. Thanks.

DR. CHERNEW: So let me jump in for a second on that point. Actually, David was, I think, in some ways a little gentle to the literature. I think there's pretty

good evidence that people don't make very good choices of Part D plans for a whole range of reasons. And there's a lot of tools to try and help them. My general view is we need more than tools to get people to make the right choices. I think there's reasonable evidence that there's a lot of money left on the table. And I think -- so because of the changes to the benefit design, it's going to take us a while, I think, to get on top of where we are now, but I think one thing that is potentially going to happen, now that the plans are more responsible for a higher share of the drug spend, they'll be using tools in those areas to do things, and it may be more consequential for beneficiaries in a range of ways. And so we're going to have to, I think, watch that.

I think there was a general view that Part D exemplified the point that bidding works, because premiums are very stable in Part D. But, of course, a lot of what was going on is drug spending wasn't held that stable; it was just the part that Part D was covering was quite stable. And so I think there's going to be a lot of stuff to monitor when this weird interim -- I don't know if you all feel this. I feel like we're in this weird interim

space where we've identified some problems, we've put in some solutions, and I think we're going to have to keep monitoring to see what happens.

I think the choice matters not only because I think there's reasonable evidence that choice isn't that great, but I think poor choices might become more consequential going forward.

I keep looking at the queue.

The other thing that I think is going to be particularly important as one goes through this -- and this is more of a personal area -- is to make sure that there are not barriers to really important medications that people face as the benefit designs change. This would fit under my rubric of value-based insurances. You've seen some of this in the insulin rule. Insulin is the poster child for a very important medication and is the poster child for markets that weren't working very well. I think rebates in insulin were 80 percent or something, and people were paying co-pays off of the gross, not the net, and a bunch of things like that. But that's by no means the only area where some of those problems arose.

So I think making sure that people have access to

the really important medications -- and there are many -- to make sure they can manage their diseases, chronic or otherwise, I think is important as the benefit designs go forward. But, you know, I'm not sure what to say here in this chapter, because we're in sort of middle space, I think, of where we are to see what happens.

I guess I'll commend a few things. This focus on vertical integration is really important. I think the MA-PD discussion, the point that Jaewon raised, is also a particularly important one, how they behave differently. And I do think there's actually some evidence that MA-PD plans do a better job in certain aspects of managing some of these things.

In any case, I think there's a lot of stuff here that is really important, and I think we'll continue to expand it as we see how the market sort of settles down.

I guess the last thing that's going to take a while to be clear, and it is clear, the big debate, of course, is what's this going to do to the drug development space and a whole bunch of things like that. I think we're just going to have to wait and see.

So from where we sit -- I know this debate will

be raging prospectively; hopefully it'll be raging retrospectively. In any case, I think, Marge, you had a comment.

MS. GINSBURG: Yeah, I think I want to respond to yours and also to David's comment about consumers making the right choices. In all my time on MedPAC, I don't think I have ever recommended or suggested that we do some research on how the SHIP counselors are assisting their clients in this. And I do say this with some experience because when I started as a SHIP counselor five years ago, we weren't taught Plan Finder back then, if it even existed, and we never did any kind of analysis for our clients. Now that is step one for virtually every client we get. Either we assess whether they have the ability to do Plan Finder themselves, and we send them instructions, or we do it. And 80 percent of the time I'm doing Plan Finder for clients, and I think it makes a big difference.

So I guess what I'm suggesting or at least posing on this issue about beneficiaries making the best choice for themselves is what are their options for -- what kind of assistance is out there to help them get this done? And if the committee feels like it's warranted to even make a

suggestion in the chapter that people be well aware of the program of SHIP counseling, and that they are prepared -- and I'm assuming this is true in every state, not just California, but there are people there who are prepared and skilled to help them make the best choice, and yet they're not trying to sell them anything, as you all know.

So, anyway, interesting idea. Have we ever done any research among the SHIP programs about the extent to which they are using Plan Finder to help their clients? Anyway, I'll leave it at that. But I'm very excited about this as a possible mechanism to really increase consumers' ability to get the plans that best meet their needs.

DR. DAMBERG: This is following on Marge's comment. The other space here is the role of agents and brokers, and so I think as you think about doing exploration, the question is how are they helping them navigate the space, because they are used a lot by beneficiaries.

DR. CHERNEW: I think there's issues of inertia and other related changes as people's needs change and stuff happens.

Stacie wanted to --

DR. DUSETZINA: I want to go into Round 3.

DR. CHERNEW: Yes, we are now in Round 3, and we can move on. We have Part B next, and that's going to be -- you know, we're going to be moving to policy options, so we have a lot more to discuss. But, in any case, go on, Stacie.

DR. DUSETZINA: So I just wanted to maybe reflect a little bit on Dana's question about the prices, and I think Shinobu's response was excellent and spot-on with my thinking. I think that it ties into those comments that Mike had just made about innovation, and a lot of times when we're talking about that, we were talking about drug price negotiation and things like that that have this relationship with innovation incentives.

But in the Part D space, you know, what we're basically saying is we are going to max out what beneficiaries have to pay at $2,000 in the next couple of years, there will not be price sensitivity, and we still have protected classes. A lot of new drugs that we're going to see coming into the market are cancer drugs. They're on the protected classes. They are predominantly used to treat Medicare beneficiaries, and we've already

seen their prices going up dramatically, even when patients are exposed to cost sharing.

So I think that there is probably going to be some price increases and excessive price increases in the protected class space, especially because there aren't really tools to manage that for those new launches and because it won't affect whether beneficiaries take them. In fact, I think there will be a massive behavioral response from beneficiaries who are prescribed expensive drugs. And, you know, I think that was kind of highlighted with how many people had hit the catastrophic phase with one fill. You know, about half a million people. And that's a lot of people, but that also assumes that they all were able to pay potentially $3,000 or more out-of-pocket to do that on that first fill.

So I think -- and then maybe talking back on that innovation piece, like this is a dramatic expansion of the generosity of the Medicare benefit. This is a lot more sales for a lot of companies who have people they know who, when they hit the coverage gap today, they're going to stop taking their meds or take less of them.

So, you know, I think this provides a lot of

incentive for companies who, you know, have drugs that will treat Medicare beneficiaries because their benefits are going to be so much more generous. And I feel like often in the discussion of all the changes coming, like people miss that whole, well, you may sell a lot more drugs, you might -- some of you might make a little bit.

DR. CHERNEW: So the first point -- I'm going to parse that for a sec. The first point is the acknowledgment of the connection between profitability and innovation. The second point is the acknowledgment that in this particular space, in fact, the incentive to innovate may be going up quite a lot as we remove some of the dampening effect, and I think we're doing that to protect -- and I think it was really tragic when individuals had no out-of-pocket max and they had important medications that they would have to pay out-of-pocket, your cancer medications. I think there's always this tension what to do.

I think what we're going to see, to tie this again to Jaewon's point, is there will have to be supply-side approaches, which might be easier for Part D plans -- for Medicare Advantage plans to do than Part D plans,

because I think they can better engage the providers and types of supply risk. But there's a lot -- there's a lot unknown for how this will play out, and I think it will be interesting to see if innovation flows to the protected classes. And I think there's some evidence of that type of thing, broadly speaking, going on. Stacie, you could speak to that. But I think it is important to both acknowledge the connection between the incentives and innovation and to recognize that not everything we've done will discourage innovation.

And I think we should also say we don't want a blank check world, right? We can't allow that connection to prevent us from trying to have a more efficient functioning market.

DR. DUSETZINA: [Off microphone.]

DR. CHERNEW: That's what I was going to say, Stacie. I think my chair-dom has just been usurped. This is fine, actually. It's been nice being here.

[Laughter.]

DR. CHERNEW: In any case, it is -- we will transition, I think, to the Part B topic, but I think for Shinobu, Tara, and Rachel, you should take really a lot of

compliments on how the chapter was done. It's very thorough. And, again, I think it is in some ways nice to move to a phase now where the recommendations you made in 2020 have had their influence on the policy process, and we will now have to take -- you know, people have talked a lot about the Inflation Reduction Act, but really a lot of its impact is years down the road in a range of ways, so I think we're going to be in this sort of transition of checking the status for a while. But I do think there may be specific places where we may re-engage to make sure that people have access to important drugs, that they make better plan choices, that we understand the MA-PD connections, that we understand the vertical integration implications for what's going on here. So I do think there's a lot of other areas where we can engage while we wait to see how the current policy changes play out. But I think that's just terrific work.

So, with that, we will take a ten-minute break, and we will come back at roughly 9:50-ish, and we will jump into Medicare Part B. And for those of you watching at home, we are working towards a set of recommendations on Part B for our June report, which will be voted on in

April, which means you will have draft recommendations in March. And we're going to be looking at some policy options in about ten minutes. So we'll be back soon.

[Recess.]

DR. CHERNEW: Hello, everybody.

We are going to continue our work on prescription drugs. I gather by the light that Nancy is going to start. We are going to focus now on Part B, and this work is intended to take us towards some recommendations that hopefully we will be voting on in April. So we will go through the policy options now, and that brings us to Nancy.

MS. RAY: Good morning. The audience can download a PDF of these slides on the right-hand side of the screen.

An important driver of Medicare Part B drug spending is the price Medicare pays for drugs. Manufacturers set their own prices for new drugs, and historically have set high prices whether or not there is evidence that the drug is more effective than the standard of care. High prices and limited price competition among existing sole-source drugs is also a concern.

Today's session is a continuation of the Commission's work on improving payment for Part B drugs. In June 2017, we made a number of recommendations, including using a type of reference pricing policy to spur competition between biosimilars and their originator biologic. In our June 2019 report, we discussed extending this policy to improve price competition for drugs with therapeutic alternatives. And beginning in October of 2021, we added to our agenda addressing the payment of costly drugs with uncertain clinical benefit and improving financial incentives under the Part B drug payment method.

During today's session we will continue our September 2022 discussion of the three policies listed on the slide. The first two policies address manufacturers' pricing behavior for new drugs with uncertain clinical benefit and existing drugs with therapeutic alternatives. And the last policy addresses concerns about the 6 percent add-on and providers' financial incentives.

While the Inflation Reduction Act contains changes to Part B drug payment, it has not negated the policy package that we will be discussing today.

The Chair's goal for the January 2023 meeting is

to get Commissioners' feedback on the package of policies, anticipating a chapter with recommendations in our June 2023 report. I am going to move through things at a high level, but more details are in your paper, which we are happy to discuss on Q&A.

The Medicare program and beneficiaries spent $42 billion on Part B drugs in 2021. Spending is growing rapidly, about 9 percent per year on average over the last decade. The largest driver of spending growth has been the rise in the average price Medicare Part B paid for drugs, which reflects post-launch price growth, launch of higher-priced products, and shifts in the mix of drugs.

Although there are many Part B covered drugs, spending is concentrated. The top 20 drugs accounted for more than 50 percent of spending and are used for treatment of cancer, eye disorders, and inflammatory conditions.

Most Part B drugs are paid at a rate of 106 percent average sales price, ASP. We will talk more about the 6 percent add-on later in this presentation.

ASP reflects the average price realized by the drug manufacturer for sales to most purchasers, net of most rebates, discounts, and price concessions. ASP is an

average. An individual provider's purchase price for a drug may differ from ASP.

Exceptions to ASP+6 payment rate are listed on the slide.

When a provider furnishes a Part B drug, the provider also receives a separate payment for drug administration services under the physician fee schedule or outpatient prospective payment system.

Medicare has few tools to influence prices of Part B drugs. Statutory and regulatory language require that Medicare pay for a drug's FDA labeled indication.

The way Medicare codes Part B drugs affects price competition which in turn affects spending. Products assigned to the same billing code -- a brand and its generics -- spur price competition. By contrast, assigning products to their own code -- single-source drugs, originator biologics, and biosimilars -- does not spur competition, with the manufacturer effectively determining Medicare's payment rate for the product. And Medicare's payment policies generally do not consider whether a new product results in a better clinical outcome than its alternatives.

The policy options that we will be discussing aim to improve payment for drugs with uncertain clinical benefit, spur price competition among drugs with similar health effects that treat a given condition, improve financial incentives under the Part B drug payment system, and maintain incentives for innovation

This policy option focuses on the payment of new accelerated approval drugs. At time of their approval, for some accelerated approval drugs, there is uncertainty about their impact on beneficiaries' outcomes. Although the FDA requires manufacturers to complete confirmatory trials showing clinical benefit, some trials are never completed or are completed after many years.

In addition, some accelerated approval products are launching at high prices with uncertain clinical benefit.

This policy would give the Secretary the authority to cap the payment of a new accelerated approval drugs until the manufacturer completes the confirmatory trials. This policy aims to make Medicare a more prudent purchaser of health care services, while ensuring access to high-quality care for beneficiaries and to spur

manufacturers to complete their confirmatory trials in a timely fashion.

Here are key design issues for Medicare to consider when implementing this policy. If the Commission developed a draft recommendation, these design issues could be discussed in the text accompanying the recommendation.

The first issue concerns which accelerated approval drugs would be capped. Based on your September 2022 discussion, Medicare could use discretion and target products that have little evidence on the clinical benefit for Medicare beneficiaries; are launched by manufacturers at a price that is judged to be excessive relative to their expected clinical benefit; and are expected to have a large budget impact for the Medicare program beneficiaries and taxpayers. This approach aims to balance the tradeoffs between incentives for innovation and affordability and access for beneficiaries and taxpayers.

Moving to how to set the cap could be set. While your paper lists several ways to set it, some Commissioners supported an approach that would be based on the clinical benefit and cost of the new drug relative to the standard of care.

Another key issue is when Medicare would apply the cap. Based on your September 2022 discussion, Commissioners supported an approach under which the Secretary could be given the flexibility to determine whether implementing the cap from a product's launch is warranted versus implementing a cap over time, for example, to address instances when manufacturers do not complete confirmatory trials in a timely manner. A flexible approach would allow Medicare to act based on each new product's specific circumstances.

MS. NEUMAN: We now turn to an option that addresses concerns about pricing for drugs with similar health effects.

Because Part B pays each single source product based on its own ASP, it does not promote price competition among therapeutically similar products.

In 2017, the Commission recommended a combined billing code policy for biosimilars and originator biologics, which is a type of reference pricing that would pay these products the same average rate to spur price competition.

Building on that recommendation, this policy

would extend reference pricing beyond biosimilars by applying a single ASP-based payment rate to drugs and biologics with similar health effects. Doing so would spur price competition.

So here is how a reference pricing policy for Part B products with similar health effects could work. Each product in a reference group, that is, a group of single-source products with similar health effects, would remain in its own billing code. Medicare would set a payment rate for the reference group.

While your paper discusses several methods that could be considered for setting the reference price, basing it on the volume-weighted ASPs of all products in the reference group would be similar to how payment is set for brand and generic drugs, and would give providers more time to adjust to the new payment rate.

Another key design element of reference pricing is identifying and defining reference groups. To do this, CMS could consider a number of factors. Reference groups could be organized to include drugs that have similar indications and work in similar ways. Medicare could also consider the ease of implementing reference pricing for

particular groups and first focus on those where it is the most straightforward. In defining reference groups, it will be important that there be a clear and transparent process that provides opportunities for public comment from beneficiaries, clinical experts, and others. CMS could also seek a technology assessment from clinical experts, for example from academic or research institutions.

It will also be important to provide pricing information to clinicians and beneficiaries so they can make informed decisions. And your paper has more details on design and implementation issues, and we'd be happy to discuss anything on question.

Now moving to the third policy that focuses on improving provider incentives under the ASP payment system.

Medicare pays providers a percentage add-on for Part B drugs. In most cases, the rate is ASP+6 percent, or if ASP data are lacking, Medicare pays a percentage of wholesale acquisition cost, or WAC.

While clinical factors play a central role in prescribing decisions, there is concern that the percentage add-on may create incentives for providers to select higher priced drugs when a lower priced drug is available to treat

a particular patient's condition.

To address concerns about the percentage add-on, the policy we are considering would give the Secretary the authority to reduce add-on payments for Part B drugs paid based on average sales price to improve financial incentives, and eliminate the add-on payments for Part B drugs paid based on wholesale acquisition cost.

The description of policy option is general, but as we've discussed before the design of how one would reduce the add-on is important. Recall, we've discussed a three-part approach to modifying the add-on. That approach is shown on this slide. It's the ASP add-on is equal to the lessor of 6 percent, or 3 percent + $24, or $220 per drug per day.

You'll notice the numbers are slightly different than September, and that's because we moved from using 2019 data to 2021 data to develop the model. Also note these numbers are illustrative. Policymakers might consider other percentages or dollar amounts.

Walking through the three pieces of the formula, the add-on remains unchanged -- that is 6 percent -- for lower priced drugs. For higher priced drugs, the

percentage add-on is reduced to 3 percent + $24. And for the most expensive drugs, the add-on is capped at $220 per drug per day.

In terms of the effects of this approach it would reduce add-ons for drugs with ASP per administration of greater than $800. The differences in add-on payments across differently priced drugs would be reduced, particularly among the most expensive drugs, improving financial incentives. And reduced add-on payments would also result in savings for taxpayers and beneficiaries.

So this brings us to the end of the presentation. We are happy to answer any questions and look forward to your discussion. And as mentioned at the outset, based on your feedback, it's the Chair's goal to develop draft recommendations that we could come back to you with in the spring.

DR. CHERNEW: Great. Thank you so much. I think we're going to jump into Round 2 -- Round 1, Round 1 -- and I think we're going to start with Larry and go from there.

DR. CASALINO: I have a little bit unusual and perhaps superfluous Round 1 comment. But I just want to say that, you know, the written materials and the

presentations that the staff gives are always really excellent, but today's are even beyond that, simply superb. These are among the most complicated topics, if not the most complicated, that we try to deal with, and the presentations, both presentations today were just so clear.

And just to finish up I want to say obviously the staff does a wonderful job, but the fact that the presentations and the written materials are uniformly of such high quality, that can't be an accident, no matter how good the staff is. And Jim, really, I think you and Dana, you really have to take a huge amount of credit for that. I mean, this is the beginning of my fourth year on the Commission --

[Applause.]

DR. CHERNEW: That's not a Round 1 question, by the way, but I suppose we'll allow it.

DR. CASALINO: Okay.

DR. MATHEWS: It's not superfluous either. Thank you.

DR. CHERNEW: Oh. That was a Round 1 question.

Okay. I think Amol.

DR. NAVATHE: So I have a couple of questions,

and I think some of them may be truly clarifying. So I just wanted to clarify, we're not really -- I think it's probably highly implied but I just wanted to be sure. So when we're talking about, in the accelerated approval option when we're talking about capping for some period of time until a confirmatory trial, for example, is completed, the notion here is that that price would be capped for that time period and any prescribing essentially is paid at that capped level.

Once that confirmatory trial is confirmed, is completed, there is no back paying that would happen. It's not that that only applies during that period but then if confirmed there would be a true-up in a retrospective fashion.

DR. CHERNEW: I think the answer is we are not contemplating a recommendation --

MS. RAY: That's right.

DR. CHERNEW: -- where you would get paid -- if the price was 10, capped at 10, and then it gets confirmed and the price goes up to 20, you don't get that gap back.

DR. NAVATHE: Correct. Okay.

DR. CHERNEW: That was, I think, what you were

asking. Amol was in the policy option now. I have to say that.

MS. RAY: That's correct.

DR. NAVATHE: I just wanted to clarify.

MS. RAY: That's correct.

DR. NAVATHE: Okay. I just wanted to clarify that. Okay.

The next question I have is probably not a great Round 1 question but I'm going to ask it anyway. So when we're talking about identifying which accelerated approval drugs would receive the payment cap, we go through a bunch of different criteria, and some of them are quite discreet, such as approved based on surrogate outcomes, and then we have four total criteria, at least in the paper. And the other ones are, to use a very technical term, squishier, right. So there's little evidence of clinical benefit. There's prices that are excessive relative to that expected clinical benefit and are expected to have a large budget impact.

And what I was curious about here is that obviously we are, in part, depending on the Secretary has having flexibility around that. But how would we think

about putting some sort of more objective criteria or at least quantitative parameters around that?

MS. RAY: Yeah.

[Laughter.]

MS. RAY: I mean, off the top of my head, my initial response is I think that might be a little bit challenging. I think, on the first parameter -- so all accelerated approval drugs are based on surrogate outcomes. I guess the issue here is what is the level of evidence for Medicare beneficiaries. And that, again, strictly off the top of my head, I'm not sure how -- I would have to do a little bit more thinking about that to get any more specific than that. I mean, certainly the Secretary could compare the level of evidence for Medicare beneficiaries for the drug in question to other drugs in its class, if it's not a first-in-class agent, for example. But we would have to do a little bit more thinking about that.

In terms of its price, there I think we're a little bit firmer evidence in the sense that you could compare the net clinical benefit of the product to the standard of care, and, you know, if it's twice as much as what is suggested in a typical cost-effective analysis

finding, then that might be something to look at.

And then the last parameter was the total spending impact on Medicare, which is again based on the price.

So I think the pricing is less squishy, to use that term, than the clinical evidence available, based on the accelerated approval trial.

DR. CHERNEW: Okay. Can I just jump in to maybe help clarify how we're thinking about this, which is useful to say? The framing of the language is largely to give the Secretary authority to do things but not to demand that they do something. And the reason for that is I think there's a wide range of examples of drugs that make it through the accelerated approval pathway, where I think we would agree and acknowledge the importance of a pathway. I would say COVID vaccines is a clear example, and I think we would agree that the magnitude of the challenge, the evidence was that that was a drug that needed to go through the process and get access to people, and frankly, we had to have a system that would encourage that type of development of the drug in the first place. I think we have to acknowledge that connection.

On the other hand, I will take the Aduhelm example. We have a comment letter that we wrote on that. I think we felt there that the evidence was not as strong in that particular case and we were actually supportive in our comment letter, broadly speaking, of what CMS did, and more importantly, that they had the authority to do that.

And so we are not in a position to claim the evidence or how the evidence would come, and I think there will be continued tension about the extent to which CMS makes a determination separately from what FDA says. And again, the Medicare beneficiary specificity matters. I think there are some other things that might matter in that discussion.

So because of that it becomes very challenging. We have phrased these recommendations in ways that talk about giving the Secretary that authority. In the specific case of CED, coverage-to-evidence development, which we have talked about here in some detail, particularly last cycle -- there was a lot of coverage-to-evidence development discussion -- there already is the authority to impose coverage-to-evidence development, which they did do in the case of Aduhelm, and which we were supportive of.

So we don't have a specific recommendation about expanded authority for coverage-to-evidence development, but as we think about these criteria, we are trying to give flexibility while acknowledging the importance of the accelerated approval pathway.

That was probably a longer answer than a clarifying one. So we won't say use a randomized trial. It's going to have to be a case-by-case basis, which I think we acknowledge.

DR. NAVATHE: Great. Thanks.

I had one last question, which is shifting gears to the ASP work, and there's a line in the paper which basically -- and it's on page 47, and it says that the Commission's position in 2016 remains a standing recommendation. And I was curious if you could clarify what specifically we're referencing there, given the Supreme Court decision that's reverting the payments back to ASP+6 percent for the 340B hospitals.

MS. NEUMAN: So the paper is talking about how we previously did not include 340B drugs in our ASP add-on analysis because they were paid ASP minus 22 ½. Now with the Supreme Court changed, they are now paid ASP+6, and so

the question is whether they should now be in our add-on analysis.

And what we've written in the paper is that we've continued to exclude them from our analysis of the ASP add-on because the Commission has the 2016 recommendation for changing payment on 340B, and there's a textbox that discusses that recommendation, which would take -- that recommendation would take the ASP payment below anything that has an add-on. So that's why we continue to exclude it.

DR. NAVATHE: I see. But that would require -- so that recommendation obviously would require statutory change, given the Supreme Court decision, correct?

MS. NEUMAN: It would, yes.

DR. NAVATHE: Okay. That's the one I wanted to clarify. Thank you.

MS. KELLEY: Kenny?

MR. KAN: Yes. I just want to follow on to what Larry just said. This work here is beyond outstanding, and I'm wildly enthusiastic about the work here and the chapter here.

So I think Mike sort of answered my question, and

I actually agree with him. We should give the Secretary the flexibility, because I think we are really -- there are really a lot of uncertainty about the drugs. This could potentially impact whether it's COVID vaccines or Aduhelm. What if it's just like tweaking some molecules? And then the drug comes out like $50,000, and, oh, maybe it increases potentially by two days. I don't know. I mean, I think those are the -- those are the things that we have to think through and giving Secretary the flexibility, which might clarify. I am actually very supportive of that.

I also want to -- I am very, very enthusiastic about Policy Option 3. I think it will definitely -- where having a cap -- a $50,000 drug, if you have a 6 percent ASP add-on, I think, you know, optics-wise, it could impact how the drugs could be dispensed. So I think having an add-on will actually, I believe, help the health care ecosystem and lead to a flat fee.

Thank you.

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

DR. GELB SAFRAN: Thank you.

Just adding my appreciation for this great work. Thank you.

And my question has to do with your point when you were presenting the Policy Option 3 and the add-on, that by switching to 2021 data, I think you said, from 2019, the numbers have changed. I'll confess, I don't remember what the numbers were, the last round, but that caught my ear and just in terms of stability over time in the policy and what the implications would be.

So I wondered if you could just comment a little bit on sort of what kinds of changes are we looking at and what do you think the implications are for the policy and the stability of what those add-ons would look like over time.

MS. NEUMAN: Sure. So I think back in September, it was plus $21 instead of plus $24, and the cap was $175 instead of $220. I think that the reason that you see that change is because between 2019 and 2020, spending went up. And so the model that we used to set these amounts took that into account.

If someone were to adopt this policy, a policy choice that they would make is whatever year of data they

used -- let's say they used 2021 -- a question would be going forward, is that, say, $24 -- is that just going to be updated by CPI or something like that, or are you going to update it with the trend in drug prices? And that's a policy choice that would need to be made.

In our modeling, we didn't make that choice. We thought we should use the most recent data to show you what it looks like now, and then policymakers would have to decide going forward.

DR. GELB SAFRAN: This will be a Round 2, but I'll just say it here and not put my name back in.

That's really important, what you just said, and I think that's worth including in the chapter, just as, you know, this will become a policy choice. I think that's a really valuable point.

Thanks so much.

MS. KELLEY: Greg?

MR. POULSEN: Thank you.

My key points were actually already addressed, most importantly by Larry.

But I guess on policy 3 -- and I was just looking through to make sure I hadn't missed something in the

chapter -- I think for people reading it, it would be useful to make clear why we are looking at, as part of the ASP add-on, the 6 percent and the 3 percent plus 24 and the 220 as opposed to an administration fee, sort of irrespective. And at least to me, that's still a little foggy in my mind why we would do that, and if there's a compelling reason, I think, at least I would like to see narrative that registers in my head where I'm less experienced in this than maybe some of the folks around the room.

So I guess the question that I have, is there a brief answer that we can give as to why this should ever be a percentage as opposed to an administration fee that's associated with the cost of providing that care?

MS. NEUMAN: So the percentage add-on can, especially for drugs that are high volume and low priced, offer a bit of protection for the provider if their purchase price is a little bit above or below that. And so what we've tried to do is include some percentage add-on for the lesser expensive drugs but to ramp it down the more expensive the drugs become.

The other thing to note is that there is a

sequester that is in effect, and so if you were to pay no add-on at all, you would be paying less than ASP. So the percentage add-on also evens that out a bit.

DR. MATHEWS: Can I jump in here, Kim?

So, Greg, one thing I want to make sure comes across clearly, I think this is in the draft material, but if it didn't punch through, we can highlight this.

The add-on that we are talking about is separate from any drug administration fee. So, under the physician fee schedule and under the OPPS, there are separate payments made to the provider for the cost of administering the drug to the payment, and what we are talking about is the add-on to the ASP of the drug itself.

And what I'm about to say is not written down in any piece of legislation or policy. So take this with a huge grain of salt, but the 6 percent add-on, arguably, was to reflect the fact that not all providers are able to purchase a drug at or below the average sales price. So, for low-volume providers, there needed to be a little bit of a cushion to ensure that they were not underwater with respect to the Medicare payment rate, and what we are talking about in this policy option is changing that add-

on. And we are not touching the otherwise applicable administration fees that remain under the physician fee schedule and the OPPS.

Does that help?

MR. POULSEN: Yeah, that helps a lot.

And I did read this, and I read it quickly twice. But because of my lack of focus in this area, generally, that didn't come through, and I think it would be useful if we were to have what you just said in there.

And then I think it does make sense, both why we would want it to be changed in a downward direction but also why it deserves to exist at all.

Thanks.

MS. KELLEY: Lynn?

MS. BARR: I'm going to risk a really stupid question here. So, when a drug is a Part B drug, like Humira, right -- I believe Humira is a Part B drug, right?

UNIDENTIFIED SPEAKER: [Speaking off microphone.]

MS. BARR: What?

UNIDENTIFIED SPEAKER: Mostly Part B.

MS. BARR: Because it's self-injectable. So my question is exactly that. When a drug goes from a Part B

drug to a self-injected drug, right, what's the dynamic there, and where is the -- yeah, because I believe that it would go from Part B to Part D, right?

And so I'm curious about are we creating any incentives or disincentives for manufacturers to not develop injectable drugs, or is there any sort of interplay in here that -- are we in any way either pushing people to make more injectable, you know, self-injectable drugs, or pushing them away from making self-injectable drugs? It seems like a stupid question, but I just I just wanted to understand it.

[Pause.]

MS. BARR: I can tell by the looks on their faces, it's a very stupid question.

[Laughter.]

DR. CHERNEW: No, not at all. It's a --

DR. DUSETZINA: No, I had thought on this, but it was a broader point.

So I've been thinking a little bit about this but kind of in the context of more on the accelerated approval space, and this goes back a little bit to the Inflation Reduction Act and a lot of chatter going on right now about

how that has been set up in a way that incentivizes more infused drug development, because there's a longer time before potential negotiation. And Scott just sent me an article that really flags this, highlights this issue.

And, you know, I think that this maybe counterbalances it a little bit, because there have not been any options for Medicare Part B to do anything about pricing or in the fee-for-service, no utilization management. And then going also back to the Part D space we just talked about, there's now, like, better coverage for small molecules.

So I think, in some ways, those policy changes maybe also kind of cancel each other out a little bit, where right now the industry is talking a lot about how the new law is going to dramatically decrease their interest in the small molecule market. But I actually think that, in some ways, when I think about how this might be operationalized, I think it maybe would give people pause.

I guess in the background too, though, I think that people are -- drug development is happening based on the way that the drug is best delivered, and convenience to the patient, chronic disease management, like, you still

want to go for small molecules. I don't necessarily think that the decision is quite as straightforward as "Well, I just decided to give you an infused drug instead of an oral drug."

DR. CHERNEW: Let me give you a another take on that answer, and hopefully -- I do think the incentives across the board are important, incentives for developing the drugs in the first place, incentives for where they go into B or D in a range of ways.

I think the separation between B and D is sometimes problematic for a bunch of reasons. It's both confusing to people; there's different benefits. We've worried about that in vaccine policy in previous chapters.

I think the way that I would read these types of recommendations are not to negate any of that complexity but to understand that -- or I think the view of the policy option to move to recommendations is the first-order problem is some of these other issues that we're trying to solve, and that the second-order issues, to the extent that they become problematic, we would have to think about what to do about them.

And that might be a bigger, different way to go

at, but we shouldn't -- this is a personal comment now. So there's a Round 2 and maybe a Round 3. But my personal view is we shouldn't hold up trying to fix some of these things that are associated, for example, with ASP+6 because we're not sure about some of the, maybe, second-order incentive effects.

That's not to negate the importance of the incentive effects, and I want to be really clear about that. I worry a lot about incentive effects, but I think first order, there's other big problems that I think we're trying to address here that are, maybe just in my mind, more first order than how they're going to manage whether something's in Part B or Part D. And, at some other point, we might think about how the increasing use of new drugs in the medical benefit is a separate problem that may require separate attention.

MS. BARR: Thank you.

DR. GRABOWSKI: I think Larry had a Round 1.

MS. KELLEY: He took himself out of the queue. So I think we're to Round 2 now, unless anyone else has a Round 1 question.

DR. CHERNEW: The nice thing about this is I

think we're going to start with Stacie.

MS. KELLEY: Yes.

DR. DUSETZINA: I think I can keep it under an hour.

[Laughter.]

DR. CHERNEW: We may have some time, so don't cut anything out.

DR. DUSETZINA: I know. I know. Charts and graphs.

So, first of all, I just would like to say I love this work. I love this chapter, and I'm incredibly supportive of all three of the policy options presented broadly. So I want to maybe talk about some of the places where I had strong preferences when you gave us sets of options and where I think, going back to a Round 1 question, we can be a little bit more concrete and where I think we are still probably going to need to stay a little bit squishy.

So I'll start with the accelerated approval of drugs and the idea of price caps for policy 1. So I think, for me, very strongly, I would support the idea of price caps in situations where CMS has looked at the evidence

that is presented and says that it's not clear enough for Medicare beneficiaries, and they determine if coverage with evidence development is necessary. Under that situation, I feel like there's strong argument to price-cap at the time of launch.

For drugs that have the more squishy characteristics, so maybe their benefits are unclear for Medicare beneficiaries, but it doesn't rise to the level of CED, which I think is important to note, CED, even though we've seen it used with a Aduhelm recently, is very, very rarely used in the drug space. So I would like to suggest that the Secretary have some flexibility there to be able to decide if a price cap is necessary at the time of launch.

But I think it has to be based on both a preponderance of really concern about the data, of benefit, especially in the Medicare beneficiaries, and the potential size of the population affected, so how many beneficiaries might be exposed to a drug where we aren't really sure that it's working for them.

And I think kind of by definition, that gets a little bit into the space of budget impact, because if we

have a large number of beneficiaries, the spending is going to obviously be higher there. So I think that would be a place where I'd say discretion for the secretary to have that tool, if necessary, but maybe not as, like, automatic.

Now, I also think there are really good opportunities to have an automatic price cap in situations where studies have gone past their FDA-required deadlines. So, for all of these drugs, they have agreements with FDA in place to complete confirmatory trials, to confirm the clinical benefits, and there are timelines associated with that, based on the drug and how long it would take to reach those endpoints. So it's possible to determine if studies are late, and I think in those cases, we would want an incentive for companies to complete those studies and get that evidence as quickly as possible. So we should price-cap when they start failing to meet their deadlines.

And then I think we could be clearer in the text. There are examples where studies have failed to confirm benefit, but the drugs have remained on the market. We should be clear that Medicare should not pay for drugs once they have failed confirmatory studies, regardless of whether they're still in the market.

Now, the nuance here is that a lot of drugs under accelerated approval have multiple indications. So I think this creates a little bit of complexity or thinking that is necessary around this issue of should this be drug indication-level policy or should it be more broad.

Now, I think we don't really do indication-based pricing in the U.S., so this makes it hard, but I think in a lot of ways, this would be something we'd have to kind of think through.

Slight preference in my mind for drug and indication pairing, but you could imagine that if a company had a drug that it wasn't a beneficial drug, it had failed as confirmatory study, but they weren't willing to take it off the market, and it was still being used in this way, if you said, like, we're not paying for any of your indications, it would be much more likely to have that indication withdrawn by the sponsor.

Okay. I'm going to pause there and then -- oh. Now, you've got the other sets of questions, like how would we come up with this price, and you gave us Table 1 with a set of options of what you'd need to think about for coming up with the price.

In my mind, the only reasonable way to set the price is based on net clinical benefit. I strongly believe the other two options would actually create a disadvantage in the situation where there's a really good drug, because I do think we want to acknowledge that we have some examples of drugs that we think have not really met the bar or are of questionable benefit. But we also have a lot of cancer drugs and a lot of beneficial drugs that go through this pathway.

Net clinical benefit gives an opportunity to pay well for drugs that actually do have a lot of benefit for people and for which we're just waiting because it takes a long time to reach clinical benefit outcomes. The example that kind of comes to my mind often is for breast cancer. Thankfully, five-year survival is actually a fairly normal occurrence, and so it takes a long time to get to overall survival benefits. But we still want those new drugs and treatment options for patients. So try to think about it in that realm of what's best for really paying well when the drug really works well, even if we don't have that full clinical information.

Okay. For Policy Option 2 -- so this is shifting

over to the average sales price and the blended payments for Part B drugs -- I love this concept. I think it's great. I like where we've gotten with it. I think in the chapter there, we could be a little bit clearer how much precedence there is for this. You know, like private plans are already doing things like utilization management to steer people to the lowest cost option. We're talking about a way for us to operationalize this in a fee-for-service program, but in general, I think that there's a lot of groundwork that has already been laid that really normalizes it, because I think one read of the chapter could be that we don't really know how to come up with head-to-head competitors. And it's, like, no, we do. So maybe we can mention things like P&T committees for formulary design or thinking about -- plans are really doing this already, and we're just talking about doing this in a payment way.

I strongly support method 1 for the average sales price, the blending of the prices, the weighted average of the individual drug codes. I think it seems easier to implement and probably less legally contentious than any of the least costly alternative options, and I think the other

thing that, again, I kept trying to think, well, what about when there's a new entrant that's really better and it gets blended in? So this gives a chance for like if there's really a shift in what people are using because there's a better option. Then that can increase the payment as well as decrease the payment in a way that I think is still supporting, like, bringing better drugs into the market.

I do think that we could really emphasize the low-hanging fruit. You did a great job of talking about the drugs that are approved through this kind of different FDA pathway that are kind of like between generics and brands, the line extensions. Those are really good examples of places where this could be used with very low risk.

The other is biosimilars, and I think that that just didn't come through as strongly to me that, you know, like we should really make sure that that's clear, that that's a very low-hanging fruit where we'd expect the indications and use to be similar between the reference product and those products.

Okay. Then the last comment, I fully support Policy Option 3. I think that the way that that has been

set up is beautifully done. It still kind of allows for choice, protects from not, you know, going underwater if you don't purchase as much drugs, and removes some of those incentives to price higher. I feel like we've had previous discussions about that and everybody was -- seemed pretty good consensus around that point. So I hope we'll spend more time kind of hashing out the first policy option today.

Okay. Very last one, and this is more kind of contextually or thinking about some of the innovation-related issues. On page 48 of the report, there's, you know, kind of a comment on innovation, but I actually think it would be important to separate out this a little bit more so that we can be clear that, you know, for the policy option that talks about blending the codes, this is really not like a very risky business when it comes to innovation. We do this already. We have inside-class competition. To me what that really feels like is that this is a place where we have a ton of experience and is relatively lower risk.

On the accelerated approval side, I think it is important to really recognize that we still want there to

be strong incentives for drug development, and, again, you know, that pathway is really dominated by cancer products in the last decade. So we want companies to be developing these drugs and to be, you know, incentivized to do so. What we're just hoping to do is provide a little bit more opportunities to respond in cases where we feel like it's unclear that these drugs are really going to help Medicare beneficiaries and that they are going to place an oversized burden on taxpayers and beneficiaries in the program.

Okay. That was well within an hour --

[Laughter.]

DR. DUSETZINA: -- so I'm going to stop there for now.

DR. CHERNEW: So let me just -- I want to just make sure I follow one point that's important as we go around, and, again, this matters as we develop this. There's this question about the timing of when the Secretary would set a cap, and the tension that you just talked about was we really do want to make sure there's incentive to develop the drugs that would go through accelerated approval. So it is not like there's a drug that magically appears and then the question is what

happens. And so I think what I heard you saying is -- and, again, you can correct me if it's not what you said. This is why I'm making this point. Although we would like the Secretary to have some discretion in what I will call "egregious cases" prior to the confirmatory trials, the sense I get is you would want that to be used very judiciously because -- two things. One is the evidence by definition is not going to be -- there will be some evidence, but it's not going to be very easy to do net -- you know, it's easy to say we should use net clinical benefit, but when you don't have really strong evidence, you have some intermediate endpoint, you have to figure out what the right value would be on that net clinical benefit and all those things. It makes application of a price cap hard in that pre-confirmatory trial period.

So in the price cap post-confirmatory trial period, we're trying to solve a somewhat different problem, which is we want the confirmatory trials to be done. Before that, the problem we're trying to solve is a problem where there's drugs with not very much evidence of benefit and very high prices and very high budget impact. And what I heard you say and I think the key thing, because I'm

making this speech now, is to make sure this is captured in the tone is our feeling is because we want the innovation, that that should be used very judiciously, and I think the concern is that the industry would have to understand that, because you wouldn't want to signal, if you had a very aggressive Secretary, that they would use it for other purposes, and so you need a guardrail of overapplication of that tool, because it's always tempting once the drug is developed to try and get a lower price.

Did I miss --

DR. NAVATHE: And that's in part, Mike, to borrow something that -- or to bring back something you said earlier, because we also have the tool of CED --

DR. CHERNEW: Yeah.

DR. NAVATHE: -- for extreme case where there's really very little evidence of any clinical benefit, something like that.

DR. CHERNEW: Right. So I do think this intermediate case where we want -- we don't want CED because CED really does limit utilization. There's drugs you might want to use. But there are egregious price -- I think what Stacie's saying is there are potentially

egregious pricing situations which we would like there to be a remedy for, but we only want them used when they're actually egregious as opposed to expediently it would be nice to pay less, because you won't get the drugs that you need.

DR. DUSETZINA: Yeah, I think part of this is having a credible threat for when there is just behavior that is beyond what any rational person would be able to look at. And this is why it's a little squishy, because we'll say, well, what does that mean? Well, you know, we're talking about a set of products that often in many cases have marginal benefits. You know, their clinical benefits might not be -- might not hold up, or that already have very, very high prices. So, you know, the baseline here is already very high priced, and sometimes small amount of benefit, although -- so I completely agree with what you're saying, with the way you've presented that. Definition under CED, yes, price gap. Still have the option in exceptional circumstances, then we -- you know, whether we can get to a point of defining exactly how that would be -- that bar would be met, I think that's tough.

I would say the other thing to remember here is

that this is a temporary, until you finish your confirmatory studies, cap. So it's not like saying that this is the price of the drug forever. It's saying, you know, if you choose to go down this pathway that gets you earlier access to the market, which is basically what this pathway does, do you have the ability to price in an unlimited way for beneficiaries even if, you know, the evidence is less clear, and companies could, you know, avoid that price cap as well by having the confirmatory studies done more quickly, which is better for patients. But I think we do want to keep those drugs coming early if we do think there are situations where the surrogate does likely prevent -- like closely relate to the clinical outcome.

DR. CASALINO: On this point - I'm sorry, Stacie. If I understand the discussion just now, it's that the capping would be used not that commonly for accelerated approval. If that's the case, it does seem that we -- it seems --

DR. NAVATHE: [Off microphone.]

DR. CASALINO: Right, I know, but -- well, but we don't know at the time when -- at the time when a drug

comes out, we don't know if and when the confirmatory trial is going to be done or not. Right? So a decision --

DR. NAVATHE: So you're saying that would be used only in certain -- in rare exception -- an exceptional basis in that time period pre-confirmatory trial, I think was the point.

DR. CASALINO: So -- right. But if that's the way it was done, then it seems that for all indications in which there was not a cap applied, there still would be no incentive to get a confirmatory trial done. It seems to me --

DR. CHERNEW: The trial takes a while to do, and so if they expect it -- I don't know -- pick six years, five years, whatever the number is, you would need to get going for -- because you would understand it if the confirmatory trial wasn't done at that period of time -- in the earlier material, there was a lot of evidence on how -- these situations, so you know that if you don't get going on your confirmatory trial, there's going to be a disincentive when you get to a loosely pre-specified place. Again, the Secretary would have some discretion if you've in good faith been trying to do the trial and you haven't

been able to recruit patients, which is a problem, or some other variant.

DR. DUSETZINA: Larry, I think to that point, those would still have the cap applied if they're delayed on the deadlines that have been set for their confirmatory studies. So I think my view is that it should be used up front under CED, potentially up front in some extreme circumstances, or the Secretary should have that latitude in some cases that they deem exceptional, but CED is not pursued. But then there's the -- if you're late on your study, I think it applies to all of those. So if you go beyond the FDA deadlines -- I would say for context, currently there's a lot of movement at FDA to make sure that studies are underway at the time they get accelerated approval, so that the confirmatory trials are not so delayed. There have been examples where they don't even start for years. So there's a lot of -- like a push at FDA to do more, that companies have to prove that they're well on their way to accruing in those studies. So I think this kind of would be a nice compliment to that work by saying we don't -- we won't continue to pay if you start missing those deadlines for your confirmatory studies, and then we

will definitely not pay if you fail your confirmatory trials.

DR. CASALINO: Let me see if I understand correctly. You're saying, Stacie, in some circumstances -- but these would be the minority, pretty much small minority -- there would be a cap applied at the time the drug came out, and that only if they're CED as well, or beyond that?

DR. DUSETZINA: I think definitely if they're CED, but also that there's the potential even without CED. But I think that the squishy part is we don't want to discourage companies from using the pathway when it actually would be a benefit to patients. So we don't want to say, like, every drug that goes through the pathway would get this, but I think there are some exceptions where either from, like, the quality of the evidence, like how well we think the surrogate might affect -- like be related to the clinical impact.

DR. CHERNEW: I want to go on to get us through the queue, and Lynn is going to be next, but I would -- oh.

DR. CASALINO: I think it's important we be clear about this.

DR. CHERNEW: I understand. I will say -- let me

just say one thing, and then if there's some on the points, we'll let you go through that. But I will say I think the win here would be that there was never any price capping approved because people understood that their pricing, if the evidence wasn't very good, had to be at a certain point to avoid that. I think you could have -- so there's a lot of ways you'd get a win, but I think the discussion we had was, we said we think real caution should be used by the Secretary about when someone would apply that because of this connection to making sure that the drugs that get developed would --

DR. CASALINO: Got it. But I'm still trying to make sure I understand. To put it very simply, your proposal, Stacie, if I can call it that, is it would be unusual, maybe not rare, for a price cap to be applied up front often but not always with CED. But price caps would always be applied if a drug doesn't meet the confirmatory trial deadline. Does that capture it? Okay.

DR. CHERNEW: I think the Secretary, because -- the Secretary would have the discretion. I don't think we're saying it would always be applied. But we would envision it very commonly applied in that case.

DR. CASALINO: If they didn't --

DR. CHERNEW: If they didn't meet the deadline. There has to be a reason that they would have to go through that you would have to think through what it would be. So we wouldn't say the deadline was 2025, you didn't do it, this is the price cap. The notion would be but we would expect if it wasn't done that you would -- the burden would then be on the company to explain why, and the Secretary would be much stricter in when they would apply it because they haven't met the confirmatory trial. And, again, if the FDA pushes that to when the confirmatory trial's done, it's really not going to be that big of a deal, and I think that would be fine.

DR. DUSETZINA: Yeah, and just one minor thing there is, you know, the FDA already has these deadlines, and they do -- you know, they're checking in, and there can be adjustments to deadlines. So I think it becomes fairly clear-cut when it's really beyond the deadline and no good reason. So I think we would kind of rely on that system that is in place today to know when a company is -- you know, they're trying but there are logistical things or other things that are outside of their control, that you

give leeway there, right? You want it to be based on the company doing their very best to --

DR. CASALINO: I hear what you're saying, and you know more about this than I do, Stacie. I would be concerned that if there is leeway, you know, there's all kinds of reasons why there might be, where a company might say there should be leeway. And I could imagine a court case every single time a cap is placed, attempted to be placed, if the data isn't met. And that's why I think at least more consideration should be given to, no, you don't meet the deadline, you get a cap. And that would be easier to defend in court, I think, than a case-by-case decision about whether you have extenuating circumstances or not.

DR. NAVATHE: Well, and to that point, you could give the flexibility to not apply that otherwise defaulted pattern -- right? -- which would less likely generate a --

DR. CHERNEW: So we have to avoid getting -- I'm now actually going to stop this. We do have to avoid getting into a Round 3 before we're actually at, you know, we've even moved through the Round 2. So I understand that a lot of people want to talk on this particular point. I think we have Betty and Kenny. But understand this is

Round 2. We're not going to have just a three-person interrogation of Stacie of how this goes on.

DR. RAMBUR: So I have a very burning question that's a very simple question, and it may be a very naive question, but I think it goes back to something Jaewon said earlier about clinical benefit. So you're talking about benefit, side effects, and drug interaction pairing and net clinical benefit and high prices. But I'm also curious -- and maybe it's implicit and I just don't get it -- about drugs with high potential for harm.

So I think about Aduhelm, so here's this proxy or -- what do they call it? -- surrogate endpoint that was squishy at best, a very expensive drug, but even more alarming, I think, to many clinicians, the enormous potential for very serious harm and then trade groups sort of pushing so energetically and patients who really want this hope.

So, you know, I'm hearing a lot about prices and all that, but I'm just not understanding --

DR. CHERNEW: So that's what I think "net" means.

DR. RAMBUR: I understand that's what it means, but how is that really enforced? I get that that's what

"net" means, but is that really laced through strongly enough?

DR. DUSETZINA: I mean, I guess -- because I wasn't reading it in that way, I think when I think about the way the evidence is presented or the idea of some level of uncertainty, it is that mix between the benefit and the harms. And maybe we could, like, include a little bit more on the harms.

MS. RAY: We could be more explicit about that, and I just want to interject two quick items specific to your comment. In the paper, we had a footnote that suggested one way to operationalize the accelerated approval payment would be through a modifier and a rebate, and that would lead to the accelerated approval drug getting paid one rate and then all of the other indications, if the drug had other indications, getting paid the ASP-based payment. Just to clarify on that.

The other issue, I'm just throwing it out there. So many accelerated approval drugs are cancer drugs, you suggested that if the drug failed the confirmatory trials, that Medicare no longer pay for it. So Medicare, according to the coverage, however, does cover off-label and

compendia. So that is an issue, I guess, very minor, but it's just something to think about, and we can talk offline.

DR. DUSETZINA: I do think that's a very important point, so I wonder if it fails but remains on the market for that or other indications, should the penalty be even greater? So it might be something that is like -- if it's running through some sort of rebate system, maybe it goes even more, like -- or you pay even less for the drug in cases where that has happened, because then that does allow for that. But great point on the cancer drugs.

DR. CHERNEW: Yeah, so this is not going to -- this detail is not going to make it into the recommendation per se, so we're going to be able to hash out some of this as one goes through the sets of chapters about how these issues are. So, Lynn?

MS. BARR: Thank you. So I'm glad you said that, Nancy, because I'm -- first of all, Policy 2, Policy 3, no questions, let's go, makes tons of sense. Consider adding Policy 4, which would change the level for orphan drugs, right? And so orphan drugs get lots of exceptions in all of this, and the level on orphan drugs, qualifying for

orphan drugs is ridiculous, like Revlimid is a great example of a billion-dollar orphan drug. If it's a billion dollars, it's not an orphan. So, I mean, would I adopt that orphan?

So, I think, you know, there might also be a place for us to consider some recommendations around what qualifies for changing the qualification for orphan drugs from strictly the number of patients to having a dollar cap on it so that we're not qualifying billion-dollar drugs as orphan drugs.

To Policy 1, I'm really concerned about the -- you know, so the drug's approved, right? And you can buy it at this price and give it to your patients, but if it isn't approved for this indication, it's going to have a different price. And I'm really concerned about the implications of that. You know, physicians do have the right to deliver drugs based on their own knowledge or their own assessment of whether there's a benefit of that drug to that patient. And so I'm not really clear on how, you know, you're going to cap a drug based on indications differently and how that works out. Am I missing something?

MS. RAY: Yeah, so I'll try to take a stab at this and maybe Kim can help out. I mean, I think there is going to be necessary some education of clinicians and beneficiaries on this policy, that, yes, if the drug has multiple indications but we're capping it on just the, you know, indication to make somebody's hair purple, that they have to then, let's say, for example, report a modifier, and that the payment would be different and the beneficiary's cost sharing would be different as well, would be lower as well, because -- if the price cap happened to be applied to that drug.

MS. NEUMAN: Yeah, and just to add on to that. Let's just say there's three indications and only one of them is an accelerated approval, and there is concern, and the Secretary has decided to apply the cap. Just to make it super concrete, what could happen is that Medicare keeps paying the provider the regular ASP+6 -- pretend we're in the ASP+6 world -- the ASP+6. Then on the back end Medicare looks at the claims and either looks for the diagnosis code associated with that one accelerated approval or maybe we've also said they need to put a modifier on for that diagnosis code. But you either use

the diagnosis information or even more enhanced information from the claim to see how much volume there was in that accelerated approval indication. And then on the back end the Secretary gets a rebate from the manufacturer to operationalize that cap for that accelerated approval utilization.

So from the perspective of the provider, they don't have to worry about being paid a different rate for one indication versus the other. It all happens on the back end, through Medicare.

MS. BARR: And it's all taken care of. So it's not going to be a burden on the clinicians. It's only going to be a rebate from the manufacturer.

Now let me just follow up that question, if you don't mind, Mike.

DR. CHERNEW: I have a comment on that point but go ahead.

MS. BARR: Okay. So what if a physician is doing something, you know, prescribing a drug off label. Then this doesn't apply, right, I mean, if they're using the drug off label. So I worry a lot, and we've seen it all, I think, a lot where you get the drug approved for X, then

there's a study published, and then the sales reps run around and they give the study to all the doctors, and the doctors start prescribing it for this other indication. How does that fit into this whole scene?

MS. RAY: So again, off-label use, that's more of a coverage issue, not so much of a payment issue than for coverage. I mean, if the off-label use is written up in the compendia, peer-reviewed literature then Medicare can pay for it, and sometimes the MACs will specify in their local coverage determination items, you know, when that happens and how to do it.

DR. CHERNEW: Let me just give a quick response. This relates to a complicat4ed issue of indication-based anything. I actually share your concern about a range of administrative issues, and we know that coding is problematic. So saying, well, you have to put a modifier on, particularly if there's any -- it just very hard. If the diagnostic codes, we had a whole session about why diagnostic codes aren't right.

I think that this issue, so how we will deal with that will be this issue will be dealt with in the chapter, not in the recommendation, and it is conceivable that there

will be a path forward that will simply not have indication-based capping, and there will be some other way of dealing with this issue if a confirmatory trial is -- so you could see a world in which even for the ones that were higher, and so that just makes a penalty for not getting your confirmatory trial done higher, and there are a bunch of problems with that, just to be super clear.

So we hopefully will be able to get to a set of recommendations that doesn't note this, but I think it is very clear that we need to be aware of the administrative costs throughout the system and the imperfection that we can't simply just -- well, then it has to be put on, because to your point, it often won't be. And we have to make sure that the writing around the chapter is such that that works.

And again, I think the key here is to signal enough stuff that you never have to apply the cap, that all the confirmatory trials get done, that all the initial pricing is reasonable, and you can go through a world where you don't actually have the cap and then having the authority to put in the cap means you don't really have to use the cap. We are not envisioning the cap being used as

much as we're envisioning getting confirmatory trials done and reasonable pricing related to evidence before that. That's, I think, the way that I would see it.

But all of this is going to have to be in the text.

MS. BARR: Right. Well, I just would say that I'm very supportive of the idea of the caps, particularly around new drugs. That seems like a no-brainer. I think once we start getting into indication-based issues, my mind blows with the complexity of it, and I don't know if we could even implement it. So I'm very, very concerned about that piece. But other than that I love it. Thank you.

MS. KELLEY: Scott.

DR. SARRAN: Yeah. I've been sitting here, and as I was reading this prior to the meeting I have been troubled for many years by the whole accelerated approval process. I mean, as a clinician and a taxpayer, I think that has been a net harm rather than a net benefit to our beneficiaries.

Now, I think much of that could be addressed by actual rigorous teeth applied to the requirements around completing studies and pulling coverage if those studies

are not completed on time and with definitive benefit. That's true.

But again, it's pretty clear the accelerated approval process is just not serving any patients, beneficiaries, well. And I'm wondering if a simpler approach might be to say that there should be a different payment for all accelerated approval process drugs until confirmatory studies are done. So rather than have this complex discretion left with the Secretary, all of which I bet would result in litigation, right? So rather than leaving the Secretary with this implied, big stick that he or she pulls out of a closet, you know, under special circumstances just to say, "Look, there should be a separate lower, finite payment until studies confirmatory studies are done," with the Secretary having some discretion to make an exception to that in cases such as public health emergencies, you know, overwhelming clinical benefit. So the default being apply it rather than not apply it.

And what that would do, I think, is first of all it keeps it much simpler, right, that everybody knows. It puts teeth sort of at the front end saying, "Look, we want

the FDA to approve drugs that we know are going to achieve a net, or have achieved in a study, a net benefit," rather than a proxy or a surrogate. I mean, as a clinician I'm really troubled by all these expensive, toxic drugs.

DR. CASALINO: How would the payment be determined?

DR. SARRAN: Well, I think there are ways to do that, but I just think the principle, I think, I think the beneficiaries would be better served by saying, "Look, there are teeth in this whole -- we really want to cover drugs that have proven benefit."

On the indication-based pricing, I mean, as a generalization coding sort or stinks in much of the fee for service world. I think when we're talking about low volume, very expensive, very toxic drugs for serious conditions, the coding is pretty good. Whether somebody has whatever, you know, stage lung cancer or they have something else stage colon cancer, that coding is pretty good. So I think that could be worked through.

But I keep coming back to this whole, you know, as long as we allow the accelerated approval process to be used without any real teeth on the back end, which is what

happens today, and we simply give the Secretary some potential discretion that could be used, all of which, again, I would bet would result in litigation around each of those, at least the first two, I just don't think it's going to work well.

Quick comments on Policy 2. I think it's really great the way that's laid out. And Policy Three, I think it's probably really good. The only concern I have at all is about potential unintended consequences in terms of, I think one of the things we don't want to continue to incent or enable or encourage is the selling of private oncology practices to either hospital-based systems or private equity. And we know that private oncology practices depend, for a significant amount of their revenue, on the ASP spread.

So I'm wondering if we have looked at all at whether the potential magnitude of impact of the specific numbers, we've got in policy three is, in fact, going to have a predictable, significant negative impact on private oncology practices' revenue. Because if it does, then I think that's going to further accelerate the selling of those practices.

DR. CASALINO: Especially combined with 340B.

DR. SARRAN: Yeah.

MS. KELLEY: Scott, are you done?

DR. SARRAN: Yes.

MS. KELLEY: Okay. Thank you. I think Stacie and Kenny had something in response to Scott. Is that still true? Okay. Kenny, did you have something?

MR. KAN: I think hearing Scott's comment and the exchange between Mike and Stacie earlier, what I'm sensing is how do you navigate this whole discretion to the Secretary. But I'm trying to ask a clarifying question. Even though we say that we give the Secretary some discretion, but presumably he's going to consult some panel of experts, right? I mean, the FDA and some panel, an advisory committee. So presumably there's going to be some hopefully objective basis that would underlie the discretion. And yet, at the same time, I'm trying to balance that versus how do I ensure that you have a certain amount of guardrail.

So what am I missing here?

DR. CHERNEW: So I want to just do some process things before we get through this. We could have this very

complicated Round 3 version of discussion when there are people in queue, and I can see exactly how it would play out. I don't want to do that. I want to go through the queue. We will then have some time to react. But I don't want someone to say something and then a bunch of people react to that and then someone else says something, and it goes back and forth.

It is indeed a challenge. I have my views. I'm sure Stacie has her views. But I think we need to give the people in the queue the opportunity to go around through the queue. I will then try and summarize at least where I am and where I think we are, and then maybe there will be time for Round 3. But I want to save the Round 3 actually until we get through Round 2.

So the question you raised is a valid one, Kenny, but I'm not quite ready to jump in on it. So I think Robert has been waiting.

MS. KELLEY: Robert is next.

DR. CHERRY: Thank you. Great report. You know it's a great report when it's generating this kind of high-quality discussion, so nice job.

I just wanted to make really high-level comments

here because I think a lot of the questions that are being raised -- you know, Amol, Greg, Lynn, Betty, for example -- the questions have a common theme which is around the execution of the policy. And I had the same sort of concerns pre-reading some of this as well.

I think the way it will eventually play out, because we're not going to think about every scenario and every contingency that's going to happen. It's way too complicated. Because this is basically going to be a policy format, legislative format to give to CMS.

Eventually what they'll do is they're going to have to issue interpretive guidance. They're going to have to have public comment period. They're going to have to set up focus listening sessions with manufacturers, pharmacy benefit managers, health plans, et cetera, to get feedback. And then ultimately, they'll finalize that interpretive guidance, but they're still going to need an operating manual and an algorithm in terms of how to make decisions, including creating a panel of experts that can assess clinical efficacy of trials and link that to caps and payment rates.

Where I think we need to clarify our thinking as

best as we can in the policy is where we're not going to make this perfect because CMS is going to have to take care of a lot of this, I think, on the back end.

That's just my comments. Thanks.

MS. KELLEY: Amol.

DR. NAVATHE: Thanks. I too will try to be brief here. First off, Kim and Nancy, very terrific work. I think the chapter outlines a wonderful set of policy options and by and large is very clear, so thank you so much for this work.

On the first policy option -- I guess the other thing I'll say is I'm supportive of all three of these policy options, and there are a couple of sub-policy options that I'll try to comment on here.

So with respect to Policy 1, the cap on accelerated approval drugs, well, I'd like to really make two comments here. First is that accelerated approval is fundamentally very important, I think, to our patients, to the program, to society, so I think we should be very thoughtful about how we think about this and the types of perturbations we are creating in the incentive structure for drug development. So I think we should be very

thoughtful about this.

At a very macro level, at the same time I think there are the sort of vagaries of implementation that are challenging, and I do share some concerns from Scott, Larry, and others around how this gets structured in terms of what the sort of default pathway, if you will, for drugs will be very important in terms of how this ends up playing out in practice, especially in our legal system.

So I think to the extent that we can preserve flexibility for the Secretary because of Robert's point, which is that we cannot anticipate every single version of what's going to happen in the future -- we just can't do that -- so allow flexibility but still create some sort of default pathway, if you will. So for example, something in the space of the confirmatory trials there could look like, the default would be that when the confirmatory trial period has passed, at that point there would be a cap placed on, but the Secretary has the authority to override that if there's some extenuating circumstance or some rationale for that.

I think that preserves this mark of kind of creating a default pathway that everybody can understand.

It also creates the right legal framework, I think, to help with some of the pieces that Scott is worried about, but at the same time allows the flexibility to understand that we can't anticipate what's going to happen in the future.

So I think to the extent that we can incorporate some of that kind of language supportive of that pattern would be generally helpful.

And specifically in terms of setting the capped price, I find this to be extremely challenging. Because on one hand I totally agree with Stacie and I would say we should definitely be thinking about net clinical benefit. On the other hand, the whole point of the accelerated pathway is that we don't really have a great estimate of what the net clinical benefit is, and the confidence interval can be very wide. So then how do we think about that? I struggle with that one a lot.

I would say of the three options that are presented, Option 3 seems to me to be the one that we should avoid, and I could probably live with 1 or 2. But I struggle with 1, even though I think, in a theoretical world, hypothetical world, that would be the preference.

For the other two policy options I have

thankfully less to say. For Policy Option 2, I very strongly agree with the sub-option of the weighted average or the blended price. I think that hits the right mark in terms of setting up the right incentives but also acknowledging the heterogeneity and choice of preference and clinical situation that likely is going to sit within a combined category. And on the third policy option, I support it and don't have any additional comments. Thanks.

MS. KELLEY: Cheryl.

DR. DAMBERG: Great work. I very much appreciate all that's in this chapter, and I want to say I'm very supportive of the three proposed policies. And listening to the discussion, obviously for Policy 1 there are a lot of complexities involved.

I do support allowing the Secretary to have some flexibility, but Larry, I take your point about the possibility of lawsuits in that space.

DR. CASALINO: About confirmatory trials?

DR. DAMBERG: Yeah. And I think in terms of how the cap on the payment should be determined, per Table 1, I favor the first alternative that's laid out there and agree with Amol. I think the third option is really problematic.

In terms of Policy 2, I agree this is very directionally correct. I think we need to work to improve price competition. I think that's exceedingly important. And I also favor a volume-weighted ASP approach.

And then Policy 3, I don't have any additional recommendations. I think it looks good as written.

MS. KELLEY: So Mike, that is the end of Round 2.

DR. CHERNEW: Right, which is good. So let me just tell you where I think we are. I'm going to go in reverse. I think there is widespread support for the ASP reforms. While there are some nuances there, I think the problem there, like Lynn said, about incentives for one way or another, the issues there on incentives are really problematic. The chapter does a great job of outlining it. I hear broad support for a recommendation along those lines.

I think with regard to the, I'll call it reference pricing type proposal, there's actually a lot of support for that. I think there is probably general support for the idea of using some type of weighted average, and I think the general tone would be the lowest hanging fruit is biosimilars. I think we could all get

behind that. And when you get out to other classes I think it's going to be on a case-by-case basis. Are these really the same or are they not? And I think if you stick with biosimilars a lot of the problems go away. As you extend beyond it you would only do that in a case where you could really show there are a lot of similarities and not a lot of heterogeneity in the group, because heterogeneity kills a lot of the reference pricing stuff, basically.

So again, I think we have some level of consensus around that.

Now let's get to Option 1, which we've made it to Round 3 before we were through Round 2. So let me tell you where I think we are.

There is a series of problems, and I'm going to lay out what I think the problems are, lay out where I think the solutions are, and lay out where I think the debate is, and then we'll see what people want to say about that.

So problem number one is somehow drugs got into the accelerated approval pathway when there's really not evidence that they're beneficial for Medicare beneficiaries. And the general sense is that the Secretary

already has authority to use CED in those cases, and they should, and I think there's probably widespread agreement that even in that context there could be some price version of that on top of that. And since they're restricting the use of CED, I don't think there's a lot of angst about that sort of extreme situation.

I also think -- and I think the chapter has done a pretty good job of laying it out and our past work is laid out -- there are situations where we really should have expected confirmatory trials were done, and they weren't. And so the problem we're trying to solve is non-conducting -- "non-conduction," is that an electricity term? Anyway, non-completion -- for those at home, I am an economist, and if I spoke well, that would ruin my credentials. But the point is non-timely completion of confirmatory trials is a problem we've highlighted. and the view is there should be some incentive. The notion here is we want some pricing there.

I think actually there's probably some consensus that even if that was not indication-based, that would be fine. We would just -- you know, you have an indication. You didn't get a confirmatory trial. Either pull it off

and keep your price, or keep it on, and then you get the whole drug in some price regulation framework.

I'm not saying we would do that. There's a question of what the price should be, but I think there's probably some sense that if really a confirmatory trial wasn't done within a period of time when it should have been completed, that we are okay with some pricing incentive. And, again, I think we would hope, ideally, we would never have to use it, because the confirmatory trial would actually be done, and as an aside, if the confirmatory trial fails, you should not be covered for the indication that it failed. And that means not paid for the indication that it failed, and that fits into broadly -- I think you answered it, Nancy -- a coverage policy kind of issue, which is just how we deal with off-labeled use, which is to some a different place.

So I'm going to pause for a moment.

The other thing that's nice about that last part is by the time you get there, you know, the confirmatory trial wasn't done, you're less concerned about where the evidence was or what's happened. A, it's been a lot longer, so there might be some real-world evidence, and it

becomes less of a problem.

So that's where I think we have -- for lack of a better word, I'm envisioning some staff-level conversation about this meeting, and that's a point where I think there's probably broad agreement amongst the Commissioners. And when we start Round 3, if anything I've said is something you feel vehemently against or when the policy draft recommendation comes out in March, you're going to say no, no, I can't live with this, tell me now. Send me a message. Tell the staff, whatever it is.

Okay. So then we get to where all of this debate has occurred, and what's nice is the vast majority of stuff, there's actually been agreement. So, when you're traveling home, just take away that we've had a large sense of agreement.

The one area there's some debate is what to do about another problem, which is drugs in the accelerated pathway, and for lack of a better word, we view the price is just egregiously high, relative to a reasonable interpretation of the evidence, accepting Amol's notion that by definition the evidence will be very unclear, and that has led to discussion of policies that one might deal

with that.

So I'll give you my view. Stacie, in a moment, I'm going to let you say -- I actually don't think the accelerator approval has failed patients. I think actually it's been quite an important, broadly speaking, pathway, and I think it's one that, by and large, we want to generally maintain. This is, again, a Michael point. Well, Amol said it, so it's in Amol point. I'm summarizing Amol's comment. I think Stacie said it too, but I can't remember. It's been so long ago.

So then the question is what to do in that space. There's some complications. The indication-specific part make it really hard to say we don't want to be in a situation where we discourage companies from doing work to see if something is useful for an indication, and in doing so, they get a huge price cut on all the other things that have passed the confirmatory trial.

So imagine the drug we know is working for colon cancer, and it's passed the confirmatory trial. And now there's some question about whether it works for pancreatic cancer, and we don't want to discourage anyone going into that pathway by saying, oh, if you go into that pathway,

you're going to get an automatic price cut.

We could try and make it indication-specific. That might work for colon and pancreatic cancer, but I think it becomes problematic, given some of the off-label use issues and other coding issues. But then that's worthy of some debate in this thing.

So I think the question then becomes -- and where I think I would probably have the chapter, and now I'm about to throw it open -- is that not be in the actual recommendation that we make, and we note this level of complexity about how one would deal with that. We note the problem where it is --

DR. CASALINO: How one would deal what, Michael?

DR. CHERNEW: How we deal with whether or not you should impose a price cap at launch.

I personally -- I think this is where Amol was, and, Amol, you can correct me again if I was wrong. The imposition of a price cap at launch in the accelerated approval pathway is something that Stacie can probably give examples of where we would have liked to have had that tool, because we would believe there's some abuse. I suspect there's some examples of where we would like to

have that tool. But the creation of that tool has a series of deleterious consequences where we might actually lose a bunch of other things that we actually really, really want.

And so we would -- to your original Round 3 question that was said in Round 2 and now we are back to Round 3, is we would envision it would be really a tool that would be used in -- the word I'm going to use is "egregious cases" of really incremental products, really incremental evidence, really egregious pricing. And we are trying to find some way to address that problem, and I am on the fence about whether the aspiration of doing that can meet the reality of implementing that. I'm just not sure, and I think that's going to have to be negotiated.

So now we are in Round 3, and I think the Round 3 queue, I'm going to go Larry -- I'm just reading the names -- Stacie and Lynn, and we'll see how we get through Round 3. But, Larry, you're up.

DR. CASALINO: I mean, earlier I was just trying to understand what we meant, not make a comment on it. But now I will make a couple of comments because I think I understand more now.

I'd say Policy 1, Option 1 is probably the most

difficult thing for me at least since we've discussed this, I've been on the Commission.

So just a couple of comments. One is I think there's two problems here, right? There's initial price, and there's getting confirmatory trials done on time. And I would add, above all of this, is not having a lawsuit about every single drug, right, about the initial price and/or the confirmatory trial issue.

So the issue of the initial price and make sure confirmatory trials get done in a timely way can be connected to each other, but they don't need to be. And so I think some thinking about is there a pretty hard-and-fast rule that could be made about getting confirmatory trials done on time that would not invite lawsuits every time.

One rule could be -- and this does connect it to the initial price -- you don't get it done on time -- well, let me back up. I would look for a hard-and-fast rule about getting confirmatory trials done on time. That would only be -- there would be an opportunity for exceptions, but it should be very narrow to try to reduce lawsuits.

This can or cannot be connected to the initial price. The initial price is tough. I actually have from

the very beginning, before this meeting in other meetings where we discussed this, kind of shared Amol's and I think Scott's -- and now it sounds like Michael -- skepticism. It would be very hard to do some really accurate quantitative way, I think, that's not reasonably challengeable at setting an initial price based on benefit. As Amol says, there's going to be wide confidence intervals and so on.

And Scott's suggestion of some simplified way that would be ethical across the board of determining an initial price, that would reward innovation but wouldn't require a complicated and very challengeable calculations, would be good.

So I don't know. I think it would probably be fairly straightforward to think of a way to put more teeth into getting confirmatory trials done. I think setting the initial price is really tough. If there was a simple and defensible way to do that, that didn't really involve the calculations of net benefit compared to the standard of care, I'd favor that. This is late in the process to be begin thinking about that kind of thing, but I think a lot of us have doubts about Option 1 -- Policy 1, Option 1.

Oh, and the other, last thing I want to say, just very briefly, I've said publicly and in writing numerous times that Medicare ought not to make policies without thinking at all about effects on consolidation. And it is true that although the Policy 3 about add-on payment, the ASP payments to providers for supplying these, for using these drugs, makes tons of sense. It will undoubtedly lead to more acquisition of oncology practices by hospitals, and oncologists are actually very highly paid. And the reason they're highly paid is because of the ASP+. Work can be done without that, I know, but I do want to raise the issue for thinking, because I think just ignoring it is -- it's not an inconsequential effect.

It could be that, I mean, hospital-employed oncologists would also be subject to this cap. So, in that sense, oncologists could just wind up getting paid less, whether or not they work for hospitals, except for the 340B thing, right? So the combination of 340B and the policy we're close to recommending here would just -- I don't know if there would be independent oncologists anymore after that. That's a consequence that may or may not be desirable, but it's something we shouldn't just ignore, I

think.

DR. CHERNEW: So patient.

[Laughter.]

MS. BARR: He's making a lot of noise over here.

DR. NAVATHE: She also set the bar for a long comment at one hour now, so --

[Laughter.]

DR. CHERNEW: That's not the bar anymore, given the clock. That was when the clock was at a different hour.

DR. DUSETZINA: Correct.

So I just want to react to a couple of things that have been said through the conversation. One, I think maybe going back to Amol and Larry's points, just then about the net clinical benefit versus some other way of thinking about what the price looks like, and I was thinking when Amol was talking about his preferences there, that maybe it could be some combination of one and two, a little bit like how we landed on the physician payment, like having some version of a multiplier of usual care or net clinical benefit, if it can be estimated.

I often think net clinical benefit, you could

estimate it based on what the surrogate shows and give the benefit of the doubt, that that translated perfectly into clinical outcomes. So there could be ways of doing it that are a little bit more generous or less generous, depending on who's doing it.

But I think maybe some combination that kind of flags that, you could think of this as an either/or, so that you don't end up overpaying relative to what you think should be paid.

But I think that detail is -- you know, getting to a consensus on where would we apply this or where do we think that the Secretary should have latitude to apply this idea would be, you know, this first -- has to get there first.

I think the other thing that was super helpful, Nancy and Kim, was reiterating those issues around how we would pay for the drugs up front and then get a rebate later, and I kind of missed that detail. I think it goes to Lynn's really good question. It tries to make sure it's clear that the physicians giving these drugs aren't going to be at a significant disadvantage or having paid much more than they get paid back, so I think a little bit more

in the chapter to emphasize that this could be operationalized through using the claims. I'm a little bit on the fence about modifiers, but that's partly because of how the drug waste modifiers have been underused in the cancer space to think that they might not have enough incentives to adopt those. So I like the idea of the drug indication on the claim, and the HCPCS codes, because those are already there together. It's probably a good way to think about operationalizing it in a way that is not too difficult.

I think, like Mike, to Scott's comments about the program, you know, I do think that, by and large, we've just had a couple of recent examples that show some abuse, what feels more abusive of the program that kind of, I think, gives us too much of a recency bias that this is a problematic program, but in a lot of ways, it has been really good in some areas. Originally, it was designed for HIV treatments, which obviously we know was a huge benefit to society, but cancer drugs as well, there are many of them that need to use this pathway or it's good that they use this pathway. So I think, by and large, I kind of lean a little bit in Mike's point around we want to still

encourage companies to use this pathway when it's appropriate for them to do so, but I think that's the question is maybe giving companies a little bit more of a pause of could I actually get to a hard clinical endpoint originally and not just be using this kind of in gaming the system.

So I think the way we've talked about having a little bit more of a credible threat of price caps, in giving the Secretary latitude to do that, maybe helps clarify when you should be pursuing this indication in a way that could help the pathway be used best by the companies that need to use it and doesn't discourage the innovation we want but also doesn't just kind of give a blank check to industry and for products where we are really worried that the benefits might not be there for Medicare beneficiaries.

And Dana had sent a note about indication-based pricing in other countries, and maybe Mike or others know a little bit more about this. I know often that happens in the context of initial coverage decisions. We've done some work looking, for example, at how France chose to reimburse for PCSK9 inhibitors, and what they often will do is, like,

even though that's going to be used in the same indications, they would, you know, price it a little bit more but restrict access to the second one in the group. So other countries, I think, do a little bit of a better job on this, but I don't know as much about it.

I know it just gets a little bit complicated in the U.S. to apply that, although I've definitely heard -- you know, there's been some conversation about in the new drug development space, especially with the Inflation Reduction Act, of would products that treat different indications kind of get different branding. Like, would you go in that direction so that it is a little bit more like each drug is kind of for a separate indication and not just changes in dose? So the industry might be moving in that direction anyway, which would make this job a little bit easier.

Okay, wait. One last thing. I think you made a comment about, like, potentially the price cap applying to all indications, and I guess I would -- I think that that might be overly burdensome. And this is just partly because a lot of the products, like many, many of the products have multiple indications, cancer therapies, the

immunotherapies. There are dozens of indications. And while I do agree that would certainly make companies more reactive about not dragging their feet on the confirmatory trials, I do think that it's worth trying to figure out is there a way from a payment perspective of gathering that information without over-penalizing.

DR. CHERNEW: [Speaking off microphone.]

Lynn.

MS. BARR: Thank you. So, as I think about Policy 1, I think we have to look at new drugs and new indications as two separate policies. I think we should look at them differently. If it's a new drug, they have a lot of incentive to get that thing approved, right, and get it through the process. And then we've got a different set of concerns. If it's a new indication, the manufacturer is only going through the expense of that trial so they can market it, so they can sell it more, because there's plenty of ways to sort of influence the industry without getting that indication approved. So they're only going to make that investment because there's a financial return for them.

So I would propose that we do something a little

different, that we look at new drugs and perhaps they set their price and we say, "Great. We'll pay you 50 percent of that till you get your trial done," or some percentage discount until they get the trial done. That allows us to gather information but reduces the burden to Medicare patients and the program.

Whereas, for a new indication, I would say you put a 25 percent discount on the drug until they get that indication approved because, obviously, there's got to be enough of a market for them to do it in the first place.

So those are just my suggestions of trying to simplify this in some way so that there's just a very simple, clear program that does reduce the cost to Medicare and the patients.

Thank you.

DR. CHERNEW: Scott.

DR. SARRAN: Yeah. So let me try to clarify some of my previous comments, perhaps. What's troubling to me is there's three features to the current accelerated approval pathway, the way I look at it simplistically. The first is that we approve drugs based on surrogate endpoints, and I think we -- for all the right reasons, we

want to continue to enable the FDA to do that and make their judgment. Yeah, I think everyone agrees they made a mistake in doing that with Aduhelm, but, Stacie, to your point, that's the exception rather than the rule. So we want that to continue to happen.

It's the other two features that combine to, I think, make the program problematic, and those other two features are that we give pharma monopoly pricing power, unfettered, uncontrolled monopoly pricing power, at least in Medicare. And the third is that there are no teeth around confirmatory studies because it's just -- they've not been operationalized.

So I think what we want to try to do is to dissociate the front-end approval process and enable that to continue to happen so that beneficiaries have access to drugs that the FDA believes in, you know, the preponderance of evidence says we should approve that drug but not enable the continued problematic aspects of monopoly pricing power and no-teeth run confirmatory studies. And that's where I keep coming back to. Let's strongly reinforce that there be teeth around the confirmatory studies, and let's incent to the -- let's try to find a way to incent the completion

-- not just the completion of those confirmatory studies but the early completion, because there is discretion, I think, confirming how and when they design the studies to achieve the outcome rather than the surrogate outcome.

So I think to the extent that we can have a simple, consistent approach that incents pharma to get those studies done, if possible on the front end -- if not possible on the front end, then as soon as possible, right. Then that's -- then we'll have achieved our, you know, overall goals.

DR. CHERNEW: Okay. So now I'm going to wrap up the actual real wrap-up. Before I do, let me be clear. We're going to -- after this process, there will be some draft recommendations. Then we will have another conversation. We will leave five hours for it, four for Stacie.

[Laughter.]

DR. CHERNEW: So here's what I think is true. First, on the indication-specific pricing, once you take away the indication-specific pricing, as Lynn said, and you make it sort of more of a penalty, sort of it's something that gets trued up at the end by the Secretary, it doesn't

have to be thought of as a price. It could just be if you don't get your confirmatory trial done in a particular way, you pay a penalty assorted to some amount. And that could be based on claims-based stuff, or it could just be some other penalty that you pay because your confirmatory trial is not done. And it doesn't necessarily have to be in an administratively complex way, because we're trying to get the confirmatory trial done.

And I actually think -- I actually think we could be pretty close to coming up with a recommendation that solves the problem of confirmatory trials are not done, and it's really just a question of figuring out how the penalty is, whether it be a price discount part -- and if you don't do an indication specific, if you just say you have to pay back to the program, some amount of money, because your trial wasn't done, is a function of something that's administratively easy to implement, I think that's easy enough to be done. And I think we can get there.

The part which, again, I have a flight to ponder -- you all can ponder as well -- is the concern I have -- Okay. I see there's other people with Round 3 comments that I missed. So we will do them, but let me just finish.

The concern that I have about giving the Secretary discretion to solve the most egregious problem, which I am empathetic to, is that if you believe that once the drugs are developed, the political pressure will be to use that discretion overly in situations we would rather not, then I can see the response of the industry being we are simply not going to go through this because we can't predict what the Secretary's discretion is going to be. That's been manifest in the discussion here about the lawsuit component of it, right, and I think is a general point, which again we will have this discussion again.

We just need to be very careful about setting up a rule. Discretion is always great if it's applied the way you would want to apply it, but it turns out not to be great if it's applied by someone else who you think isn't applying it well. And that is why the institutional notion of doing that becomes problematic.

So the concrete part about confirmatory trial was supposed to be done at this date, it wasn't done, here's a penalty, that I think is relatively easy. The rest of it, I think, is harder, and so we have some time to think about how to deal with that.

So, because of time, we'll do quick Round 3.

DR. NAVATHE: I can be really quick because I think you partly said it, which is I think it's just important for us to note in the policy options -- and then we'll eventually do this in the draft recommendation piece -- that the price cap at launch doesn't necessarily have to be the same price cap based on the confirmatory trial piece. Those are two separate things, and to your point, you could do penalty. You could do something else.

DR. CHERNEW: Yes.

DR. NAVATHE: And I think right now that's totally not clear, and I think we should make sure that that is very clear in there.

DR. CHERNEW: So, again, three problems. There's drugs that we don't think benefit Medicare beneficiaries that have been approved. We want to try and slow down their adoption and get more evidence in general. Problem two, the confirmatory trials aren't done on time. We can deal with that, I think, relatively. Problem three is this more complicated one about high prices during the accelerated approval process and how do we deal with that. That, we will ponder.

I think the consolidation point notwithstanding, I think the ASP+6 creates a lot of problems, and so we can think about how to deal with that. We can talk offline. I think the problem there is there's a lot of reasons why the consolidation -- this is sort of one aspect of it, but in any case, that, I think, is valid.

And then I think the notion that you're going to pay different codes for biosimilars for the extreme, for envisaging a price, is just a way of diminishing competition when there should be competition. So I think we can get around that.

So that's where we are. That was the fastest two hours, but it was a really -- it was a really outstanding piece of work and a really great discussion. And I actually feel a lot of engagement and passion around the table, so I'm glad about that. We will get to redo it again in March, and then it turns out potentially in April.

So, again, thank you all. For those of you at home, you may have the same level of passion. Please reach out to us through our website at MedPAC.gov/meeting or submit comments at MeetingComments@MedPAC.gov.

And a shout-out to Pat Wong who has been

listening and says hello. Hi, Pat. I hope she's still listening.

In any case, thank you all. Thanks to the staff, those here and those not, for all you've done, and we will be back in March.

[Whereupon, at 11:52 a.m., the meeting was adjourned.]