MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Thursday, March 2, 2023
11:16 a.m.

COMMISSIONERS PRESENT:

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AGENDA PAGE

P R O C E E D I N G S

[11:16 a.m.]

DR. CHERNEW: Welcome, everybody, to our March MedPAC meeting. We have a lot of important topics that we're going to discuss today. We're going to talk about the wage index, we'll talk about Part B drugs, and we'll discuss post-acute care. We're going to start it at the wage index discussion, and for that discussion we will lead off with Alison.

So, Alison, take it away.

MS. BINKOWSKI: Thanks, Mike, and good morning. I'm excited to present today on reforming Medicare's wage index systems.

A PDF of these slides can be found in the control panel on the right-hand side of the screen.

Today's presentation updates work from MedPAC's June 2007 report and builds on information presented in September 2022.

In this presentation, we will: provide a brief overview of Medicare's current wage indexes; summarize key concerns with the current approach; describe an alternative wage index approach and illustrative method; provide

examples of how the alternative wage indexes address concerns with the current approach, both for IPPS hospitals and for skilled nursing facilities; and conclude with the Chair's draft recommendation.

As a reminder, Medicare's wage indexes adjust national base payment rates for geographic differences in labor costs.

The current wage indexes: are based on data from IPPS hospitals' aggregate labor costs; are calculated for each labor market area, defined as metropolitan statistical areas and statewide rural areas; and include numerous and often non-empirical exceptions for IPPS hospitals and none for most other types of providers.

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

Consistent with MedPAC's 2007 report, the Commission's key concern with the current Medicare wage

indexes is that they fail to accurately reflect differences in labor costs across geographic areas and create inequities across providers. These inaccuracies and inequities stem from the data source, definition of labor market areas, and wage index exceptions.

In particular, the current use of IPPS hospital cost report data is circular for hospitals and can deviate from the market-wide labor costs faced by all employers of health-industry occupations; the current definition of labor market areas masks differences in labor costs within areas and creates large differences in wage index values across some adjacent areas; and the numerous IPPS hospital wage index exceptions can exacerbate inaccuracies and inequities, be manipulated, and add administrative burden.

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

First, Medicare's wage indexes should use all-employer, occupational-level wage data with different occupation weights for the wage index of each type of provider;

Second, they should reflect local area differences in wages between and within MSAs and statewide rural areas;

And, third, they should smooth wage index differences across adjacent local areas.

To develop illustrative alternative wage indexes consistent with this approach, we used all-employer data from the Bureau of Labor Statistics and the United States Census Bureau; developed a wage index for each county by using a blend of the MSA/statewide rural area wage index value and a county-level wage index adjustment, and capped wage index cliffs between adjacent counties. More details on the illustrative method is in the mailing materials.

The first key design difference between the current and alternative IPPS wage indexes is the source of data, including the set of employers included.

One result of the current wage index being based solely on IPPS hospital-reported data is that the highest wage index values have been growing and the lowest values decreasing.

For example, as shown in the left-hand graph, in 2022, the area with the highest current IPPS wage index

prior to exceptions was San Jose, California, with a wage index value of 1.86, a substantial increase from its value in 2007. When hospitals in high wage index areas are able to increase their wages much faster than the national average, those increases come at the expense of other hospitals that receive lower payments due to the budget neutrality aspect of the wage index.

This is a particular concern in areas where hospitals' labor costs are materially higher than those of other employers, as is the case in areas with current very high wage index values.

The alternative IPPS wage index's use of all-employer data more accurately reflects market-wide labor costs, which has the effect of reducing the spread between the highest and lowest wage index values.

As a result, under the alternative IPPS wage index, aggregate IPPS payments would shift away from hospitals in areas with very high current wage index values and towards those in areas with very low current wage index values.

The second key design difference between the current and alternative IPPS wage indexes is the geographic

unit at which variation in labor costs are reflected and constrained.

Because the current IPPS wage index aggregates data to broad labor market areas, it masks variation in labor costs within MSAs or statewide rural areas and can result in large wage index differences between adjacent labor market areas.

For example, as shown on the figure on the left, the Atlanta MSA has a single wage index value, and there are large wage index cliffs between it and surrounding rural areas.

In contrast, as shown in the right-hand figure, the alternative IPPS wage index reflects variation within broader labor market areas and mitigates wage index cliffs.

As a result, in aggregate, IPPS payments would shift away from hospitals in counties where labor costs are lower than their broader labor market area and towards hospitals in counties where labor costs are higher than their broader labor market area.

The third key design difference between the current and alternative IPPS wage indexes is whether there are wage index exceptions. While there are reasons for

each wage index exception, collectively they break the link between an area's relative labor costs and its wage index value.

In fiscal year 2022, 67 percent of IPPS hospitals' wage index values were affected by at least one wage index exception, some of which can be manipulated.

For example, in 2022 the Massachusetts "rural floor" was based on a single high-wage hospital that converted from a critical access hospital to an IPPS hospital when it joined a larger system. This floor then increased the wage index value for almost all Massachusetts hospitals, in some cases by up to 35 percent. And because the rural floor is budget neutral, these higher payments to hospitals in Massachusetts come at the expense of all other hospitals.

In contrast, the alternative IPPS wage index we modeled has no exceptions and would therefore remove opportunities for wage index manipulation.

As a result, aggregate IPPS payments would shift away from hospitals receiving wage index exceptions, especially when large, and towards hospitals currently receiving no exceptions.

A related concern with the current IPPS wage index exceptions is that some hospitals use them to gain non-wage-index benefits.

In response to a court ruling, since 2018, hospitals can have dual reclassifications that can be used to gain non-wage-index benefits for "rural" hospitals while maintaining (or increasing) their wage index value.

For example, in 2022, over 350 urban hospitals, including large hospitals in major metropolitan areas: first reclassified to a rural area and thereby gained a Rural Referral Center designation, which has lower eligibility for the 340B drug program; and for the over 250 that were teaching hospitals, increases to Medicare's IME residency cap for "rural hospitals." These hospitals then reclassified back to their home area (or to a different, higher wage area) for wage index purposes.

A related benefit of the alternative IPPS wage index having no exceptions is that it would remove inequities between IPPS hospitals and other types of providers.

As shown in the graph, under the current wage index systems, the wage index values for SNFs are generally

lower than for IPPS hospitals within the same markets, because only IPPS hospitals are eligible for wage index exceptions.

For example, SNFs and other providers located in areas with a very low wage index value (such as Puerto Rico, and rural Alabama) are at a hiring disadvantage relative to neighboring IPPS hospitals, as the temporary low-wage exception that significantly increases wage index values in these areas only applies to IPPS hospitals.

Turning to the hospital-level effects on payments, while implementing the alternative wage index in a budget-neutral manner would not change aggregate IPPS payments, it would significantly redistribute Medicare payments. Because of the large inaccuracies in the current IPPS wage index, the effect on many hospitals would be material.

For example, as shown in the figure, we estimate that once the alternative wage index was fully implemented, IPPS payments would decrease by more than 10 percent for 2 percent of IPPS hospitals. Most of these hospitals were in areas with very high current wage index values (where hospital-reported labor costs are much higher than those

among all-employers) or hospitals that currently receive very large wage index exceptions.

On the other extreme, we estimate that IPPS payments would increase by more than 10 percent for 4 percent of IPPS hospitals. Most of these hospitals are located in areas with very low current wage index values or areas where hospital-reported labor costs are much lower than those among all-employers.

Corinna will now discuss applying the alternative wage index approach to SNFs.

MS. CLINE: As a reminder, the current SNF wage index uses data from IPPS hospital costs reports and does not account for how the mix of labor employed varies across different types of providers. This results in the current SNF wage index inaccurately reflecting labor costs specific to SNFs.

The alternative IPPS wage index, as just discussed, would be an improvement upon the current SNF wage index because it uses all-employer, occupation-level data that more accurately reflects market-wide labor costs. However, the alternative IPPS wage index uses hospital-specific occupation weights, which heavily weigh registered

nurses' wages, as they make up nearly half of hospitals' labor costs.

To more accurately reflect the relative labor costs faced by SNFs, the alternative SNF wage index would use the same data as the alternative IPPS wage index, but apply occupation weights specific to SNFs, where nursing assistants make up a greater share of SNFs' labor costs.

Using SNF-specific occupation weights increases the accuracy of the SNF wage index because relative labor costs in an area can vary across occupations and SNFs employ a different mix of occupations than IPPS hospitals.

For example, the figure on the slide shows how relative wages for registered nurses and nursing assistants vary within two areas. As you can see, within rural California, shown by the left set of bars, registered nurses are paid wages 30 percent above the national average wage for registered nurses, while nursing assistants are paid only 10 percent above the national average. In contrast, in rural North Dakota, shown by the right set of bars, registered nurses are paid 10 percent below the national average, while nursing assistants in the area are paid the same rate as in rural California.

In general, because nursing assistants' wages make up a significant share of SNFs' labor costs, each area's SNF wage index should more heavily weigh the relative labor costs of nursing assistants than other occupations. This is different from the current and alternative IPPS hospital wage indexes, which heavily weigh the relative labor costs of registered nurses, as they make up nearly half of hospitals' labor costs.

Therefore, in our example, the IPPS hospital wage index value should be far higher in rural California than in rural North Dakota, as it should reflect the large differences in registered nurses' relative wages. However, the SNF wage index value for the two states' rural areas should not differ as much, as the relative wages for nursing assistants are similar.

Turning to the SNF-level effects on payments, while implementing the alternative wage index in a budget-neutral manner would not change aggregate SNF PPS payments, it would significantly redistribute Medicare payments. Because of the large inaccuracies in the current wage index, the effect on many SNFs would be material.

For example, as shown in left-most bar in the

figure, we estimate that once the alternative wage index was fully implemented, SNF PPS payments would decrease by more than 10 percent for 3 percent of SNFs. Most of these SNFs are located in areas with very high current wage index values and in areas where SNFs face materially lower labor costs than IPPS hospitals.

On the other extreme, we estimate that SNF payments would increase by more than 10 percent for 6 percent of SNFs. Most of these SNFs are located in areas with low current wage index values and in areas where SNFs face materially higher labor costs than IPPS hospitals.

And with that, I turn it back to Alison.

MS. BINKOWSKI: Thanks, Corinna.

In conclusion, the current Medicare wage index systems are broken and have become more distorted since we last visited the topic in 2007.

There are no perfect sources of labor cost data or definition of labor market areas; however, alternative wage indexes consistent with the proposed approach described in this presentation would be a substantial improvement over the current wage index systems, as they would more accurately measure relative labor costs, be more

equitable across providers, and be less gameable and less administratively burdensome.

Because many IPPS hospitals and SNFs would be materially affected by the move to alternative wage indexes, there would need to be a transitionary period.

For example, the transition could be phased in over a fixed period of time, or managed through a stop-loss policy so that no provider experiences changes in Medicare payments of more than a specified percent in any one year due to the transition.

The Chair's draft recommendation reads:

The Congress should repeal the existing Medicare wage index statues, including current exceptions, and require the Secretary to phase in new Medicare wage index systems for hospitals and other types of providers that use all-employer, occupation-level wage data with different occupation weights for the wage index of each type of provider; reflect local area level differences in wages between and within metropolitan statistical areas and statewide rural areas; and smooth wage index differences across adjacent local areas.

As the alternative wage indexes would be budget-

neutral to the current wage indexes, we expect the Chair's draft recommendation would have no direct effect on federal program spending relative to current law.

With regards to the impact on beneficiaries and providers, we do not expect this draft recommendation to materially impact beneficiaries' access to services or providers' willingness to treat Medicare beneficiaries.

However, transitioning to wage indexes that better reflect geographic differences in labor costs would make Medicare payments more accurate and equitable.

And with that, I turn it back to Mike.

DR. CHERNEW: Great. Thank you both, and Jeff.

It is just eye-opening to see all that goes on in this wage index world, and it really is remarkable, and there's gradations of how you might react to specific things that are going on. In a moment I'm going to open it up to Round 1, and then we'll have Round 1 questions.

But just to set the stage, first, note that the recommendation is more general than the illustrative alternative, and so there's -- you know, we illustrated an example of what one could do that would meet these principles, but the recommendation itself is not to do

necessarily exactly that. We want the principles to matter.

The second thing I'll say is this is moving towards a vote in April, so keep that in mind when you make your comments. If there's particular serious concerns or whatever we're going in this direction, we need to know sooner rather than later.

So that being said, I think we're going to start with Round 1, and if I'm right, Greg is first.

MR. POULSEN: Thank you. I guess my questions are fairly specific. I would frame them that I think this was a great chapter. I liked it a lot. It was really well done and illustrative and very compelling, so thank you.

I guess my questions are reasonably specific. Since clinical folks are such a big part of the IPPS labor group, how effective are we at eliminating the circularity that's there? I guess what I'm wondering is, you know, if this were a whole bunch of other folks that were brought into that, I can see how it would help us a lot. If a big chunk is registered nurses, are we effective at eliminating the circularity? That ought to be the first question. I have one more after that.

MS. BINKOWSKI: Great question. So, yes, it does not fully eliminate the circularity, but it does do a significant amount. For example, I will talk more broadly because I can't find my specific numbers, but I think registered nurses made up approximately -- registered nurses working at IPPS hospitals were approximately 30 percent of all registered nurses. When you bring in specialty hospitals, it brings it up again by another 10 percent; then outpatient facilities, home health centers. So, yes, I'd say the plurality or the largest employer of registered nurses in our clinical staff is general hospitals, but it's still a minority.

MR. POULSEN: Thank you. I came to the same conclusion. I just wanted to make sure that I was getting it right.

My other question is really related to the variation on the limits that are proposed, and I recognize this isn't part of the proposal, but as people read this and try and figure out how to do it, are variation limits between contiguous counties applied between adjacent states? So you could have two contiguous counties that are each in a different state. I can imagine the differences

that impact those counties would be more dramatic based on things like cost of taxes in different states and things than might be between contiguous counties within a state.

So I guess -- sorry for the commentary. The quick question is: Would those be applied across state lines as well as within state lines?

MS. BINKOWSKI: Yes, we did apply those across all adjacent counties, whether in a similar or different state.

MR. POULSEN: All right. Thank you.

DR. CHERNEW: That's the way it was modeled. There's limitations --

MR. POULSEN: I understand that, and I agree, and I think it -- your answers were the ones that I was hoping for, and so I think that's all good. I guess I just think it's important because we're implying this and because next time we may need to move to a vote. It's good for us to know what is envisioned, so thank you.

MS. BINKOWSKI: And I'll add, as Mike said, the bold-faced recommendation is broader in terms of the approaches, and ours is meant to be illustrative consistent with that. But through the notice and commenting period,

obviously there could be further refinements.

DR. CHERNEW: As an aside, I have a different preferred way of smoothing. It's really not the point. I think this is perfectly good getting at the main issue that's being raised, and I think the data's pretty clear that there's more cliffs than you would want, more exceptions than you would want.

MS. KELLEY: Amol?

DR. NAVATHE: Thanks for this great work. I have a two-part question.

The first part, I just wanted to make sure I understood. So on page 10-11 of the reading materials, we highlight that there's about two-thirds of hospitals that qualify or that get an exception, and that the resulting impact essentially on the IPPS payment rate, writ large, is 2.2 percent down because of the budget neutrality. So I just want to make sure I -- I think I'm restating the obvious, but just to doubly confirm here, that means that a third of hospitals are essentially getting a cut of 2.2 percent to their IPPS revenues because of the exceptions that are in place?

MS. BINKOWSKI: Correct. Or stated another way,

all hospitals are getting that minus 2.2 percent and some are getting it offset by an exception and that approximately one-third are not.

DR. NAVATHE: Great. Okay. So having established that, the second part of my clarifying question here is: So if we think about the characteristics of those one-third of hospitals that are only getting the 2.2 percent cut without any offsetting benefit from an exception, I'm curious if we've characterized who those hospitals are. And I'm guessing that it's going to be highly correlated with some of the simulations of our illustrative proposal and how those might be creating shifts. Essentially, I guess my question is: Do we know who those hospitals are? Are they identical or very similar to the hospitals that would benefit from our illustrative proposal? Or are there other meaningful differences between those groups?

MS. BINKOWSKI: Yes, I don't have specific numbers on the characteristics, but there is a table in the paper that shows what the effects are based on hospitals that receive different exceptions, including those that currently receive none, and the effects on them in

aggregate is actually relatively small because there are subsets of them that are receiving no exceptions and would benefit substantially, such as those in certain really low-wage areas right now; and there's other ones that are currently receiving no exceptions, such as those in some of the really high-wage areas that we've pointed out that are not getting exceptions, they just have a high wage because of this circularity and labor market dynamics and market power, and so -- and those would come down on the alternative wage index. So it is not a heterogeneous group of those that are currently receiving no exceptions.

DR. NAVATHE: Okay. Thank you.

MS. KELLEY: Okay. I have a question from Cheryl. Was there any consideration given by the staff to excluding Puerto Rico since it seems such an outlier?

MS. BINKOWSKI: So, yes, some of our -- you know, in our presentation right now, we did exclude Puerto Rico because it's an outlier, but it is in all of our results because it is paid currently under the IPPS, and all of the same approaches we think do apply to it. It does continue to be one of the areas with the lowest wage indexes by far and, therefore, one of the areas that is disproportionately

affected by the current temporary low-wage index exception.

MS. KELLEY: Betty?

DR. RAMBUR: Thank you very much. Very, very important work.

I have a question that I brought up last time, and I'm still just not clear on it. It may be clear and just not clear to me. First of all, I really appreciate the conclusion about the between and within effort, but on page 16 it talks about the occupational mix reflecting, for example, the acute care as well; the SNF will reflect SNF. And here's my question: If, for example, a person -- a pediatric trauma surgeon, they are going to be only recruited certain kinds of places, and traditionally nursing assistants have been disproportionately in nursing homes, in long-term care, and LPNs somewhat. That's shifting a little bit where hospitals are hiring LPNs. But RNs are generalists that can work in either of these settings, and traditionally, the salary has been much lower in skilled nursing facilities.

So as I read this, this does not address that particular problem. Is that correct?

MS. BINKOWSKI: So I think it does indirectly.

So we're not trying to make comparisons about the amount that registered nurses are paid in different settings, but, again, it's relative to the way registered nurses are paid in an area relative to the national average for registered nurses, and each area includes a mix of these different types of settings. So this would only be a problem in areas where there's a substantially different mix of, say, the share of RNs that are in general acute-care hospitals in that setting and skilled nursing hospitals in that setting. So we're not -- it's implying that the payment rates in those two settings are the same, but that, when pooled together, you get similar relative wages.

Did that answer your question or --

DR. CHERNEW: Let me just jump in. So, one, I think that's the right answer, and I think the tradeoff here is, if you thought there was dramatically different skill differences with the same occupational category or whatever such that RNs -- an RN is not an RN, and that they're dramatically different in one setting versus another, moving away to the area level approach that we have wouldn't fully recognize that if you had to hire a subspecialized version of a particular occupation. And I

think the tradeoff, which I think is my personal view, as the chapter says, is sure, you could then try and get it exactly right; but when you do that, you create this really other very destructive dynamic where you're basically saying what you pay then feeds into your wage index in ways that, you know, creates the problem that was outlined in the chapter. So I think that's the tension. I think it's how you would recognize that. I think the -- again, I'll defer to you all, but the basic assumption is that the occupation categories are granular enough to capture what it costs to hire a person of that occupation category --

DR. RAMBUR: Just so I'm clear, so there will be sort of a pool, for lack of a better word, that is the skilled nursing facility registered nurses and then there's sort of a different reference for acute -- is that not correct? Okay. Okay, good.

DR. CHERNEW: I'm saying that is not the -- the way it works now is based -- again, this may be a Round -- one and a half, Betty.

DR. RAMBUR: I thought it was one and a half --

DR. CHERNEW: Just so everybody knows, Betty said this was one and a half, and I guess I'm the half. This is

based on the occupational categories and the granularity of the occupational categories, and so the extent to which the occupational categories aren't as granular as you would like, that's a reasonable thing to say about this. And I'm sure a lot of people will say something about that. I think our view is of the -- my view. I won't speak to "our view." You guys can comment. It's that the deleterious consequences of doing it the current way is worse than the risk you would face otherwise. But that's a topic we'll have to discuss.

DR. RAMBUR: I just would say I think a little more discussion on page 16 might help, and I can just talk to you offline about that, because it wasn't clear to me reading that. Thanks.

MS. KELLEY: That's all I have for Round 1. Did you want me to move to Round 2 now?

DR. CHERNEW: Cheryl had sent a comment which I think was more appropriate for Round 2. Why don't we start with Cheryl's comment?

MS. KELLEY: Of course.

DR. CHERNEW: It was just a general view, and then we can go with the queue that we have.

MS. KELLEY: Okay. Cheryl has this to say: My thanks to the staff for an excellent chapter. I concur that the current wage index is rife with problems, and the chapter does a terrific job outlining the issues. I agree with and support the approach outlined on page 16, particularly the no exceptions element. The proposed changes would address the myriad distortions under the current wage index. Hospitals should not be allowed to reclassify to game the system.

I found the statement at the bottom of page 10 about the exceptions being paid for by reducing the base IPPS payment rate to all hospitals to be very compelling and would encourage the staff to bring this forward at the start of the chapter to ensure additional emphasis on this point.

And I have Kenny next for Round 2.

MR. KAN: Thank you for a very insightful analysis. I especially like how the analysis or discussion of how the numerous exception issues are resulting in accurate measures of labor costs while fostering a greater inequity among providers. I am enthusiastic about supporting the Chair's draft recommendation.

MS. KELLEY: Jonathan?

DR. JAFFERY: Thanks, Dana. And thanks, this is a great chapter. It always feels like learning about the wage index is like trying to learn a language as an adult.

[Laughter.]

DR. JAFFERY: It is great. I'm supportive as well. I think in particular I really like the stuff you presented about the smoothing by counties, the county data and the illustrations just really pop out as why that -- how that works and makes sense.

The only other thing I just want to emphasize is I'm very strongly supportive of the notion that any recommendation we come to does build in some transition period, and it can come in different ways. I don't know how granular we want to get. The presentation talks about a transition time or a stop-loss. Those are not necessarily mutually exclusive either. So I just want to emphasize that point. But thanks again. This is great.

MS. KELLEY: David?

DR. GRABOWSKI: Great. Thanks. First, great work. I'm very supportive of the Chair's draft recommendation here.

Several people have already noted this about the smoothing, but these cliffs are really large. I know it's hard to think about that in the abstract, but I'm smiling because there's been several health economics papers that have actually exploited those cliffs to look at kind of wage differences relative to true costs and found that they have a huge impact on access and quality of care. So this smoothing is really going to do a lot of good. Economists will lose an identification strategy, but maybe they'll get a new one here with this new payment system. I know everyone feels bad for us.

I wanted to focus my remarks on the SNF wage index, and I think this is a major step in the right direction. It has always struck me as sort of strange that we just take this, you know, wage index off the shelf from hospitals. Researchers do it. Policymakers obviously do it. And it's a very -- as is noted in the chapter, a very different mix of laborer in SNFs versus hospitals. So I think all the problems, the inaccuracies, the inequities that are present in hospitals are only more so in SNFs, and so this will have a huge impact there. And as was noted in the chapter, they aren't eligible for the wage

reclassification, so it has certainly been magnified for SNFs.

Two comments. The first -- and I'm trying to think through this -- I guess if you're taking kind of the hospital kind of wage index and applying it to SNFs but reweighting for the job classifications, there's an assumption that kind of those differentials are consistent across different sectors. And I think that's something we may want to think about here, right? It's obvious that you have a lot more certified nurse aides and fewer physicians in a SNF relative to a hospital, but is that kind of wage differential comparable? And this kind of relates to your first-round question, Betty, that I'm trying to think through those kind of differences.

Then the second comment is that the hospital wage index shows up in other parts of our payment system. Home health would be another example, and are we thinking about kind of fixes elsewhere? Maybe we should start where we're starting, but there are other applications here where we might apply this.

Thanks.

MS. BINKOWSKI: Thanks, David. I'd say two

things on that.

One, you mentioned physicians, and physicians are completely out of this. They are paid on a separate basis, but yes. And then we did do some more preliminary work looking at applying the same approach to other sectors as well, and the way the current Chair's draft recommendation is worded, it would be broad and it would apply across the board, including to, for example, home health, and that's saying you guys can discuss more.

DR. GRABOWSKI: That's great. Thanks.

MS. KELLEY: Jaewon?

DR. RYU: Thanks. I also like the approach; I think for all the reasons stated. I'm also supportive. I think it leads to a more precise kind of approach and seems to also mitigate some inherent inequities with the current system.

I think that's especially important now because some of these job classes, I think nurses being the best example, you know, there really is a cross-market dynamic, and it's become more of a national market than ever before. And so, you know, look no further than the traveler dynamic and what we saw over the last several years. I think this

work is very important, but especially so against that context.

I think the one thing that -- and this may be overcomplicating. I certainly don't want to expand the scope beyond what we had set out to do and may be not even feasible. But I think all of the approach, it's still within the health care occupational category, so it's sort of within the occupation. And I wish there was some way to capture outside the industry occupations and labor costs that may exist in same or similar wage bands, because I think the competition for labor is not just within health care. It's now spanning into other industries that are in your local markets, and if there was some way to capture that dynamic -- because I think there is a relativity dynamic there as well -- you know, depending on your mix -- let's take the SNFs as an example. Depending on your mix of staffing, you're competing not against just other SNFs and hospitals for labor; you're competing against other industries, whether it's retail or warehousing or call centers or what have you. And, you know, that disproportionately hits depending on what market you're in and what those dynamics are like and what those labor costs

are doing.

And so I don't know if there's a clean way to capture that, to be honest, but if I had a dream, I think that would be one element to incorporate.

MS. BINKOWSKI: Can I make one response to that? I appreciate you sharing your dream, and knowing it's partially incomplete, but that our -- the current BLS data we use is cross-industry, so, for example, things with registered nurses would also include those employed by schools or other non-health care, and it also includes IT staff. You know, they're weighted smaller than, say, registered nurses, but those are across the board. I think you were suggesting dreaming even further about competition, but it is not limited to the health care industry right now.

DR. RYU: Yes. I think that's one step, but absolutely. What I'm saying is one step further, not just cross-industry but it's also cross-occupation, so not just limited to nurses that are, you know, employed in school districts and so forth, but occupations that have nothing to do with health care.

DR. STENSLAND: You're saying more like they do

physicians where you compare the physician GPCIs based on what they pay for accountants and lawyers and that kind of thing.

DR. RYU: Similar. That's right. That's right. And you would only incorporate folks who were in a comparable wage band. You would not incorporate the software engineer in the Bay Area to estimate labor cost dynamics in the ambient market. You would only look at folks in similar wage bands.

DR. CASALINO: Could I ask a question about this?

MS. KELLEY: Larry.

DR. CASALINO: This wouldn't be taken care of by the proposal as you have it now, which includes all occupations in the wage index? Because, presumably, if you're in an area -- maybe this isn't true, but if you're in an area where you have people that could either work as housekeepers in the hospital or work at McDonald's, say, wouldn't the way you have of calculating the wage index now take that into account the all-occupation way?

MS. BINKOWSKI: So trying to say this one more time, I think we'd get one step towards Jaewon's dream. Housekeepers, we have a housekeeper category, and that

would include those that are employed in hospitals and, say, hotels and other non-hospital sectors. But it doesn't include reference occupations that are not housekeeper -- that are not employed by hospitals at all but maybe are in a similar wage band.

DR. CHERNEW: You don't have to necessarily stay in that particular occupation if you were to leave doing it. That's what I think the issue is. It's within occupation, not within health care per se. It's some occupations are more transferable outside of health care than others.

DR. GRABOWSKI: And on this point, that was what I was trying to suggest. If that got bid up, I think, Jaewon, you know, if Amazon came in and bid up the wages for certified nurse aides in the SNF market and that -- I don't think that would be accounted for. It's a relative wage issue.

MS. KELLEY: Robert?

DR. CHERRY: Yes, thank you. First and foremost, I'm supportive of the proposal, and I want to thank you for all the detailed work here in unpacking a new model.

I do want to mention -- and it's not a new

comment -- about this all-employer approach, because it's pretty much a misnomer. And I do realize that CMS has historically excluded certain groups, like physicians, from the wage index for the Prospective Payment System, and this really should be, I think, re-evaluated because we're missing a substantial portion of the labor costs for hospitals by excluding those groups. So hospitals, you know, commonly employ emergency medicine physicians, intensivists, hospitalists in order to make, you know, their clinical operations work, as well as in selected specialties, too, based on their community need, and that could be orthopedic surgeons or neurosurgeons, and they're actually on their payroll as part of their labor cost.

There also may be contracted services across all specialties that could range from radiology to dentistry to podiatry as well, and so I don't think this is taken into consideration as well.

And these databases around what these salaries cost for various specialties are readily available, MGMA being one database that could be tapped into.

So although I'm supportive of this model, I'd like to see future models that take into consideration

total labor costs, including those of physicians and other specialists.

MS. KELLEY: Amol?

DR. NAVATHE: Thank you. First, I just wanted to voice strong support for this work. I think it's clear that this is, I think, as the chapter uses the word, a Byzantine system that kind of in aggregate -- I recognize that this has happened in a kind of step-wise progression here. It's not that policymakers designed the system the way it looks right now. But it ends up in a policy system that kind of defies common-sense policy, I think, or defies common sense.

So regardless of that, a couple of comments. One is I think it would be helpful -- I did try to take a look, Alison, at that table that you were pointing me to. I think that there are -- there's the problems that the current system is sort of creating, and then there's that illustrative solution, and I think they're kind of correlated together, obviously, because the illustrative solution is trying to solve the problem. But I think one of the pieces that is in part lost is I think we -- the chapter does a nice job of characterizing which hospitals,

if you will, are benefitting from the current exceptions system, but it doesn't do as good a job of characterizing which hospitals are actually harmed by these exceptions, and I think it's at a very high level. I think actually it would be really helpful to build that out to better understand, because I think we're kind of looking at only one part of this equation. We're not looking at the other part of the equation. And, presumably, one of the main reasons and motivating factors across the inequities element is because there are hospitals that are being harmed by the way that the budget neutrality works in the context of these exceptions and the structure of the system in general.

So I think I would advocate for us trying to be a little bit more specific, if you will, to point out where these harms are actually translated into that one-third of hospitals that don't receive any exceptions.

I think the second point I wanted to make is that there's a statement or two in the paper that basically talk about -- recognize essentially that any change is hard, and any change essentially in the context of our policy recommendation and the illustrative scenario that we've

put, that there are hospitals that do suffer or would suffer hypothetically large impacts. And there's a narrative in there, in the paper, that highlights that. The goal here is not to harm any particular hospital, but to recognize that if any hospitals were to be harmed, the current system is not the best way to solve that, that there are other elements, and we've done a lot of work as a commission around safety-net work -- for example, safety-net hospitals -- that is aiming to support organizations that are serving beneficiaries that are marginalized or that face undue challenges in getting access to care. And so I think it -- it's in there. I think to the extent that we can, I think I would elevate that a little bit because I think it is a really important aspect of how the Commission views this work, that this is not in some sense in isolation; it's in the context of the fact that we have already made strong recommendations around the safety net.

Thanks.

MS. KELLEY: Greg.

MR. POULSEN: Thank you. I'd like to begin by sort of piggybacking on what Amol just said. I think that this is going to be a really, really heavy lift politically

because there are a group that are going to be impacted negatively. I think that emphasizing those that will be benefitted is really going to be somewhat helpful.

What I really wanted to say, though, is I really, really like the focus and refocus, and it's stated several times, the no exceptions. I think that that is so beneficial, and there's so many things that we've gotten ourselves in trouble over the years by giving one little exception, and then, of course, that is unfair to somebody else, and so we do another exception, and we build on that. And, candidly, I think that Amol was being really kind when he said "Byzantine." It's worse than that. I mean, it's -- it really does lead to just compounding of those problems.

So I almost just snuck this in on my Round 1, but I didn't want to get smacked by Mike. So I just want to say thanks for what I think is a really, really good set of recommendations.

MS. KELLEY: Larry?

DR. CASALINO: I also agree that this is really great work, and the standard for the slides here in general from the staff is extremely high. The slides are routinely

good. These were really an excellent set of slides, I think, made complex things much clearer. I strongly support the recommendations.

I have two pretty minor comments and then a question. The minor comments are just similar to what some have said earlier about another issue. I think the fact that the administrative burden is much less not just for the -- not just for CMS but for hospitals is really important, and I think that should be stressed in the executive summary, which it isn't right now, I think.

The other thing I think that's important that's in the report, in the chapter, but not stressed and not in the executive summary, I do not believe, is that this is kind of a model that could be applied not just to SNFs and hospitals, but elsewhere perhaps.

So those are my two suggestions.

That's all I had, but then Robert's question or comment about physicians made me think a little bit. Hospitals really vary a lot in how many physicians they employ and what specialties they employ them in. There are some hospitals that employ orthopedic surgeons, for example, and then there are lots and lots of hospitals that

don't employ any orthopedic surgeons at all.

There's also -- it's not quite employing physicians, but they're just paying physicians in various specialties quite high daily fees for taking a call in the emergency room in addition to their regular work. And I'm trying to think, if you were a large hospital, a big employer in an area, and you employed lots of physicians in highly paid specialties, would that -- I realize the wage index is figured on just more than that, so it's not a completely circular thing. But I think you could drive up your wage index quite a bit that way in that particular situation. Am I understanding that correctly?

DR. STENSLAND: You could, but they don't include those physician wages when they're computing the average wage right now. So those physician wages are intentionally taken out.

DR. CASALINO: No, I'm saying, Jeff, if one were to follow, I think, the intent of Robert's comment, unless I misunderstood it, I thought it was looking to putting them in. Then would the problem that I just mentioned actually be a problem potentially?

DR. STENSLAND: I think that could be a problem,

and I think more fundamentally what we're thinking is -- the way the system is set up is we wouldn't include them because they're being paid on the physician fee schedule, which is adjusted by the GPCIs, which is a separate wage index system from the hospital wage index system. So whether physician wages are higher or lower in some market would be proxied by what the wages are for these other people that go into the physician's version of the wage index, which is the GPCI, which is separate for this. So you've got to think these are in two separate rows, like a divided highway where you have a lane for the hospital and a lane for the physician, and the physician relative wages are in this wage index, and the hospital relative wages are in that wage index.

DR. CASALINO: In a non-physician wage -- right, this wouldn't affect that.

DR. CHERNEW: Effectively I think you would be double counting. If you put the physicians in, you'd be paying more for the physicians for the physician stream of money, and then you would be paying more for the hospital in for the non-physician labor. So this is basically the hospital wage index that we're talking about now, is

basically reflecting the non-physician -- you could think of it as the facility part of the stream of money, right? The physician wage index part is through the separate system. Did I --

DR. NAVATHE: It's like Part A versus Part B, essentially.

DR. CHERNEW: Yeah, right.

DR. NAVATHE: That's the easy way to think about it, I think. This is the Part A.

DR. CHERNEW: Okay. So if I'm right, that was the end of Round 2.

MS. KELLEY: Yes.

DR. CHERNEW: So what I want to do -- and we'll see just how time plays out. I just want to go around to get a sense -- I'm not asking for a comment as much as affirmation or not about your support for the direction of where this recommendation is going, because we're going to come back in April with a recommendation. It's going to look quite similar to this one given what we've heard in this discussion, but I just want to make sure I'm not missing anything. So I'm just going to start with you, Jonathan, and I'm going to end with Kenny. And Cheryl I'm

not going to ask because she's going to have to be through Dana, anyway, and she already said that she was supportive.

DR. JAFFERY: As did I. Supportive.

DR. CHERNEW: Okay.

MR. POULSEN: Yep.

DR. CHERRY: Yes, I support as well.

MS. GINSBURG: And I support.

DR. CASALINO: Likewise.

DR. RYU: Same.

DR. RAMBUR: Yes, I support.

DR. NAVATHE: Yes, I support.

DR. GRABOWSKI: I'm still supportive.

DR. RILEY: I too support.

DR. DUSETZINA: I also support.

DR. SARRAN: Yes, very supportive.

MR. KAN: Yes, very supportive.

DR. CHERNEW: [Comment off microphone.]

MS. KELLEY: Mike, your mic.

DR. CHERNEW: For those at home, that wasn't a vote. That was just our way of making sure that in the public record we got a sense of where people were when we came back. So thank you for that.

I am also obviously very supportive of the work and where this direction is going, so thank you all for your comments. I do think this will be a challenge in a number of ways, as Greg pointed out, and I do think it's in part because we've allowed the system to get a little bit out of control -- a little bit. And so I think that just requires us to make changes that are otherwise more impactful than they otherwise would have been. So we'll keep doing this, and obviously, again, I will emphasize the illustrative alternative is not necessarily -- all these other issues we've raised, they would be issues that would have to be taken into account by CMS as they began to deal with it, so the heterogeneity within occupations, adjacent counties across states, some of those other types of things. But I think directionally what is very clear to me from this chapter is that we have created a wage index system in the hospital space and beyond that isn't really capturing -- it's capturing a lot of things beyond legitimate wage differences, and that becomes problematic, particularly in the budget-neutral context where others get hurt.

So at any rate, that's where we are. The answer

to your question you sent me, Dana, is, yes, we can start lunch earlier. So we are going to -- barring any other comments, we are going to take a break now. We are going to come back at -- I think we come back at roughly 2:00. We will have what will be a -- oh, yes. For those at home who want to comment on that, please submit your comments to MedPACcomments@medpac.gov or you can go on the website and there will be a place where you can submit your comments. We sure do look forward to hearing them. Some of you have submitted other comments. You know we will engage.

We'll be back at 2:00, and we will be having what I'm sure will be a very lively discussion on pricing for Part B drugs.

So that's where we are. Okay.

[Whereupon, at 12:11 p.m., the meeting was recessed, to reconvene at 2:00 p.m. this same day.]

AFTERNOON SESSION

[2:00 p.m.]

DR. CHERNEW: Hello, everybody. Welcome to our afternoon session, and welcome to Lynn, who has made it out of, I think -- what was it? Nine feet of snow, Lynn? Twelve feet of snow? Ten feet of snow? So we're glad to have here, and this is obviously going to be a particularly important discussion -- I think, Nancy, you're starting -- about the price of Part B drugs. Nancy.

MS. RAY: Good afternoon. The audience can download a PDF of the slides in the right-hand side of the screen.

Before starting, I'd like to thank Corinna Cline for her help with developing this chapter.

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 in our June 2022 chapter, we added to our agenda addressing the payment of accelerated approval drugs and improving

financial incentives under the Part B drug payment method.

Today's session is a continuation of our June 2022 work focusing on approaches that aim to maintain incentives for innovation with affordability for beneficiaries and taxpayers.

Specifically, during today's session we will continue our September and January discussion of the three policies to improve Medicare's payment for Part B drugs.

While the Inflation Reduction Act contains changes to Part B drug payment, it has not negated this policy package that we are discussing today.

The first two policies address manufacturers' pricing behavior and uncertainty about the clinical benefit of some accelerated approval drugs and the lack of price competition among drugs with similar health effects. And the last policy addresses concerns about the 6 percent add-on and providers' financial incentives.

There was good consensus among Commissioners for the policy package we discussed in January. Now we are at the stage to present the Chair's draft recommendations. The goal for today's session will be to solicit feedback on each of the Chair's draft recommendations with the intent

of having final recommendations for you to vote on in April and publication of this work in the June 2023 report.

I am going to move through things at a high level. You have seen this material in January, and there are more details 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.

Estimates suggest that U.S. drug prices are roughly double the prices in OECD countries. The higher prices in the U.S. reflect higher launch price and more post-launch price growth than in other countries.

Part B drug spending is concentrated with the top 20 drugs accounting for more than 50 percent of spending that's used to treat cancer, eye, and inflammatory conditions.

Most Part B drugs are paid at a rate of 106

percent of 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 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 drug prices. 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 price 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 Chair's package of draft recommendations aims to address payment for accelerated approval drugs, spur price competition among drugs with similar health effects, improved financial incentives under the Part B drug payment system, and maintain incentives for innovation.

This policy addresses payment of accelerated approval drugs. The accelerated approval pathway is designed to expedite the approval of potentially promising products for cancer and other complex or rare conditions by reducing the development time needed to bring a drug to market compared with the traditional approval process.

At the time of their approval, for some accelerated approval drugs there is uncertainty about their impact on beneficiaries' outcomes because accelerated approval is based on a surrogate or intermediate clinical endpoint that is reasonably likely to predict a clinical benefit rather than a direct measure of clinical benefit.

According to the Food and Drug Administration, using surrogate endpoints creates a risk that patients could be furnished a drug that later is shown not to

provide an actual clinical benefit. Although the FDA requires manufacturers to complete confirmatory post-approval trials showing clinical benefit, some trials are delayed. According to the Office of Inspector General, more than one-third of accelerated approval drugs have at least one trial past its completion date.

Medicare's payment for Part B drugs does not spur manufacturers to complete their confirmatory trials on time because current law does not differentiate Medicare payment between a drug approved under traditional versus accelerated approval.

Despite the lack of evidence about a drug's clinical benefit, some accelerated approval products are launching at high prices with uncertain clinical benefit. Aduhelm is a recent example of a drug in which the manufacturer originally set a price that many considered excessive because of its uncertain clinical benefit.

This leads us to the Chair's draft recommendation 1 which aims to make Medicare a more prudent purchaser of health care services while ensuring access to high-quality care for Medicare beneficiaries, spurring manufacturers to complete their confirmatory trials in a timely fashion, and

maintaining incentives for innovation.

The recommendation reads: The Congress should give the Secretary the authority to cap the Medicare payment rate of Part B drugs and biologics that are approved under the accelerated approval program if they meet any of the following criteria:

A, did not complete their post-marketing confirmatory trials within the deadline established by the manufacturer and the Food and Drug Administration;

B, offered a clinical benefit that is not confirmed in post-marketing confirmatory trials;

C, are covered under a coverage with evidence development policy;

Or, D, have a price that is excessive relative to the upper-bound estimates of value.

This draft recommendation is expected to decrease program spending relative to current law. The draft recommendation is expected to generate savings for beneficiaries through lower cost sharing, and it is not expected to adversely affect beneficiaries' access to needed effective medicines.

This draft recommendation is expected to result

in more timely development of evidence about the clinical benefit of accelerated approval drugs for beneficiaries and providers. We also expect continued provider willingness and ability to care for beneficiaries.

In terms of implementing this policy, here's how it could be structured. Once a manufacturer verifies a drug's clinical benefit, payment could revert to current law. During the January meeting, Commissioners supported setting the payment cap based on the clinical benefit and the costs of the new drug relative to the standard of care. We envision that the Secretary could operationalize the cap using a rebate under which manufacturers would pay Medicare back for the difference between Medicare's payment rate and the cap.

MS. NEUMAN: We next turn to a policy that addresses concerns about pricing for drugs with similar health effects. Because Part B pays each single-source drug and biologic and biosimilar based on its own ASP, it does not spur 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, a policy to extend reference pricing beyond biosimilars by applying a single ASP-based payment rate to drugs and biologics with similar health effects would spur price competition.

To that end, the Chair offers the following draft recommendation. It reads: The Congress should give the Secretary the authority to establish a single average sales price-based payment rate for drugs and biologics with similar health effects.

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

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

In terms of providers, aggregate payments to

providers are expected to decrease over time as manufacturers reduce drug prices and that translates into a lower ASP. However, provider profitability might increase because of the two-quarter lag in Medicare's ASP payment rates and declining drug prices and providers opting for the lower-priced product.

Under this draft recommendation, we expect continued provider willingness and ability to care for beneficiaries.

In terms of implementation of the policy, here's how it could be structured.

Each product in a reference group -- that is, a group of products with similar health effects -- could remain in its own billing code. Medicare could set a payment rate for the reference group based on the volume weighted ASP of all products in the reference group similar to how payment is determined for brand and generic drugs.

To define reference groups, the Secretary could consider various factors, including organizing reference groups by clinical indications and drug classification and ease of implementation, beginning with:

One, biosimilars and originator biologics;

Two, drugs approved under FDA's 505(b)(2) pathway and related brand and generics products. Your paper has more detail on this, but 505(b)(2) products typically have the same active ingredient as existing brand or generic drugs and are approved by the FDA under an abbreviated pathway where they can reference clinical studies by the original drug's manufacturer.

And, three, drugs for which reference pricing has been implemented or previously considered -- for example, viscosupplement for osteoarthritis and erythropoietin-stimulating agents for anemia.

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. 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 patient's condition.

To address concerns about incentives associated with the percentage add-on, the Commission has developed a three-part approach to restructure the ASP add-on that

could improve financial incentives. That approach would: maintain the current 6 percent add-on for lower-priced drugs; reduce the add-on for higher-priced drugs, by reducing the percentage add-on to 3 percent and adding a fixed fee of $24; and for the most expensive drugs, placing a fixed dollar cap on the add-on of $220 per drug per day.

Although most Part B drugs are paid based on ASP, when ASP data are lacking, drugs are paid based on a percentage add-on to wholesale acquisition cost, or WAC. WAC is generally a higher price than ASP because it doesn't incorporate discounts. A policy to eliminate the WAC add-on would improve incentives and reduce excess payments.

This brings us to the Chair's draft recommendation. It reads: The Congress should direct the Secretary to reduce add-on payments for Part B drugs paid based on average sales price to improve financial incentives, and to eliminate add-on payments for Part B drugs paid based on wholesale acquisition cost.

In terms of implications, the draft recommendation is expected to decrease Medicare program spending.

In terms of beneficiaries, it is expected to

generate savings for beneficiaries through lower cost sharing and is not expected to adversely affect beneficiaries' access to needed medicines.

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

In terms of implementation considerations, a couple of things to note.

When implementing the reduced add-on, CMS should assess the separate drug administration payment rates under the physician fee schedule and outpatient prospective payment system to ensure they are adequate.

Similar to other payment changes, CMS should monitor utilization patterns among providers following implementation of the policy.

So this brings us to the end of the presentation. We are happy to answer any questions on the material presented or in your paper.

As mentioned at the outset, the Chair's goal for today is to get your feedback on the draft recommendations.

DR. CHERNEW: Great. Kim, thank you. Nancy, thank you.

I will make some broader comments, so maybe I'll do that between Round 1 and Round 2, and we'll just start with Round 1. I think we can jump in, and if I'm right Jonathan is the first person in the queue for Round 1.

DR. JAFFERY: Thanks, Mike. Thanks, Nancy and Kim. This is a great chapter and a really clear, excellent presentation. I have two questions. The first one is on Policy 1. You talk about operationalizing the payment cap through a rebate potentially so the question is how do you see that impacting beneficiary cost. And the second question is on Policy 3. I'm just wondering what you are thinking about with dollar add-ons, the inflation index or index in some other way?

MS. NEUMAN: On the first policy, if it's operationalized through a rebate, it is possible to share the savings with a beneficiary by reducing the beneficiary's cost sharing up front. Currently that is how it is going to work with the IRA’s inflation rebate for

Part B drugs. The beneficiary shares in the rebate. And so it could work the same way with this policy.

DR. JAFFERY: [Inaudible.]

MS. NEUMAN: Yeah.

DR. JAFFERY: Okay, great. That's good to know.

MS. NEUMAN: Yeah. And then the second one was on indexing the add-on.

MS. RAY: The add-on.

MS. NEUMAN: Yeah. So we have added into the paper the idea that that is the policy choice, that you all or policymakers in implementing this could consider. You could potentially index that flat add-on to some measure of inflation, either CPI -- that's sometimes used in certain drug policies -- or drug price inflation, or some combination of that kind of approach. That would be one option to think about.

DR. JAFFERY: Thank you.

MS. KELLEY: Lynn.

MS. BARR: Thank you. A great chapter and I really enjoyed the work. I have one question, and I'm really glad you brought this up, about sequestration. So we're not really talking about ASP+6 versus ASP+3. We're

talking about 4 and 1, right? And I have a concern -- right, because you said that it's actually 4.3 percent -- and so we go down to 3 and this payment is meant to cover the fact that not everybody gets the average, right? And so this is to help pay for the acquisition cost of the drugs. So if we're really only giving them -- and the lowest of the three is the option -- we're going to give them 1 percent of the cost of the drugs, in many cases. And I'm just wondering, do you have data that shows that that's enough?

MS. NEUMAN: So data on providers' acquisition costs for drugs is limited. We have some discussion in the paper where we talk about what has been done to look at that in the past. We've done analysis looking at sort of invoice prices for Part B drugs, based on limited data from a while ago. And what that analysis showed was that manufacturers have responded in the past to policy changes, like the implementation of the ASP payment system in 2005, and then the sequester in 2013, in ways that the data suggest they have changed their pricing patterns in response to the policy to mitigate their effects on providers. So there is the potential for manufacturer

response to this policy as well.

MS. BARR: But since we are doing a "lesser of" they have got a lot less wiggle room, right? Yeah, I'm just concerned. That's my question, is 1 percent enough, and I'll leave it those in the room.

DR. CHERNEW: I'm sorry for having to jump in. The clarifying question, for which I think you were spot on is, the 6 is not really a 6. There is a sequester which was noted. And so ASP+6 is sort of what it is known as, but because of the sequester the effective amount is less. Whether or not we believe -- and we can have a separate conversation -- the details of the alternative, once you apply the sequester to it is enough, is a completely valid point. I just want to reserve that point around too.

MS. BARR: Oh, okay. Thank you.

DR. CHERNEW: So I mean, again, I'm just trying to keep us -- we're good?

MS. NEUMAN: Yeah, I agree, and just to add on to that, just the clarification portion of it, in your paper, in Table 9, you can see what the percentage add-on would be for differently priced drugs, and you can subtract the sequester off if you want, which is about 1.6. So you can

see at the lowest it's going to be, as you said, the 3 minus the 1.6. For drugs that are not quite as expensive it ratchets, and that table can show you sort of. It can help you think through that.

MS. KELLEY: Greg.

MR. POULSEN: Thanks. This is just a little bit related to Lynn's question, and probably the most naïve question we'll have. What is the reason for having a higher total amount for more expensive drugs than for less expensive drugs? Is it for the potential loss of inventory, for the holding cost? What is the validity for having Payment X for a $1,000 drug and Payment Y for a $5,000 drug? What is the difference in the underlying cost for the provision of that?

MS. NEUMAN: Are you asking what was the rationale for the 6 percent add-on?

MR. POULSEN: Well really, yes, but it's maybe, if we think that they are all essentially the same cost for provision, why would it not be a consistent amount rather than a consistent percent, if that makes sense. And I applaud what we are already doing. I'm just asking the question (a) why was it the way it was in the first place,

and (b) if there's no justification for that should we be looking at a solid amount rather than some sort of graduated percentage amount, if that makes sense. Because you guys have put solid amounts on both ends of the spectrum. But anyway, just a thought on that.

MS. NEUMAN: So originally when they established the 6 percent add-on there was no explicit statement of its purpose. One theory is that because prices can vary around the average that the percentage add-on gives room for some variation. And so as we've thought about the policy, we have structured this illustrative example as keeping the percentage add-on in there for the lesser expensive drugs, where it's not as big a dollar amount, so that that still remains. But as the drug gets more and more expensive you reduce that percentage portion of it, so that you are still allowing a bit for you're ratcheting it down as the drugs become more expensive.

MR. POULSEN: Gotcha. That makes sense. I just wondered if there was a -- actually, I think a number of us, and I certainly have, have seen the perversity of the percentage as it has been, and that it's led to different clinical decisions which I think were inappropriate. And I

think you've got that.

I guess what I'm wondering is as opposed to this recommendation, or its actually not part of the recommendation but the lead-on up to the question, why are there percentages there at all as opposed to flat amounts representing the costs associated with that? Thanks.

That may not be a clear question.

DR. CHERNEW: I think it was a clear question. I will try and answer it. I'm not sure. I was just looking at Nancy and Kim and they were looking at me, and I'm looking at Larry. It's just the way that the whole guy vision goes. Larry, you were going to say something, and then I will say something.

DR. CASALINO: Yeah. This is something that I never understood and I'm not sure I do now, but this might help. You know, in ophthalmology, for example, the price of an intravitreal injection medication, Lucentis, is like $1,700 now per dose, and for a cheaper alternative it is about maybe $50. And that's definitely affected ophthalmologists' use patterns.

The reasons they give, at least, and I think you probably know these already Greg, and they are related

reasons, one is that the drug is really expensive to the practice, and so it has to be stored carefully and you have to try to make sure to use every dose, and to do that you have to hire someone to do it, and then you're still going to lose some doses. So those are the costs.

But yeah, so you can why for a really expensive drug there might be some higher add-on, but why it should be $224 or whatever is a question I will leave to others. There's some validity to those arguments, in my opinion, but what it translates to and what it actually is --

MR. POULSEN: No, I think that makes total sense, and I'd assumed that there was some sort of inventory holding cost, something like that, loss, things like that. That all makes sense. I just wanted to make sure that we have been thinking about that explicitly.

DR. CHERNEW: Again, I'm going to try to give a clarifying answer to what was, in fact, a clarifying question. A few things that it's important to acknowledge, and I think Kim, and it may have been Nancy, said this point. It is important to get the admin fee part right. It is not clear that the costs of administering the drug varies with the price of the drug, but it is important, as

with all fees, that we get them set correctly. So the argument you need to pay us more because of the admin fee isn't a very compelling argument to me. The solution is to fix the admin fee. Don't pay more for the drug.

The issue you asked explicitly was why the percentage formulation, historically, because as the chapter, I think, lays out correctly, when you pay, as a percentage of the price, there is a whole lot of distortion area effects, and there are two. One is which drug is chosen, which has been emphasized, but also, and I think answered this in your other answer, what the actual pricing of the drug is. Like my incentive to set the price changes if the users of the drug are going to get paid a percentage of that price, and that's another sort of a problem.

The advantage of the percentage rates, it did, I think in an easy way, account for variation in the price of what people actually acquire, because they're not all acquiring it at the same price, and it does account, to some extent, for inventory holding costs, which may be a percentage actually of the price. The problem is the deleterious consequences of that approach seem to outweigh the benefits of that approach, and to the extent that we

want to solve some of those problems we might try and do it in a way that doesn't create the other disadvantages, which is what is basically going on here.

The recommendation of what we have, the policy option if you will, is an explicit notion that a fixed percentage across the entire range of price just seems way too dysfunctional. Whether, as it moves through the process, we end up with exactly these numbers or exactly these cut points in particular ways, that is a somewhat separate issue. I think the broader point is to move away from a flat percentage add-on, certainly one of this magnitude, towards a system that pays differently for drugs that are very expensive and not as expensive and in the middle. I think that's, again, a reasonable view. I wouldn't hang my hat on should it be 3 percent plus $24 or 4 percent plus $30.

MR. POULSEN: No, I get that, and I appreciate it. I think this discussion has clarified it for me, because I think we've seen, I've certainly seen the corrosive effects of what I think was the distortion you've talked about, and I also think that the three approaches make sense. I just wanted to make sure that we all

understood the reasoning behind that, and I think it's done thoughtfully. So thanks.

MS. KELLEY: Scott.

DR. SARRAN: I had two questions. First, it seems to me, in both the first and the second proposal, there's a certain amount of almost clinical discretion that's going to need to be factored into the process of setting either the price, in the first proposal, and when is the price greater than the expected benefit. There's some inherent subjectivity in that, I think. And then the second one, in terms of when you move beyond the first sort of groupings that you would do to the sort of simple ones, biosimilars and things like that, there is some clinical discretion, I think, that comes into play in terms of defining the relevant grouping.

And so my question is, how do you see that discretion getting managed and adjudicated, and a corollary of that is do we think we need to be, no pun intended, more prescriptive or directive on how that should be handled?

And quickly, my second question is a straightforward one, unlike my first one, which is, I'm just curious. What percent of Part B drugs lack a relevant

ASP and therefore need to be adjudicated on WAC?

MS. RAY: Okay. Let me take your first question on the clinical discretion. I think one way that the Secretary could operationalize it is to use some of the same tools that commercial payers and Medicare Advantage plans use in developing their formularies and prior authorization policies that they implement for both Part B and Part D drugs. So they could rely on the same group of -- the acronym is escaping me --

MS. BARR: P&T?

MS. RAY: Yes, that's right. Thank you. Thank you -- those committees to help advise the Secretary in identifying, for example, the reference pricing of drugs with similar health effects. P&T. That's right.

DR. SARRAN: So those groups don't really exist on the fee-for-service. It's just something to think about.

DR. CHERNEW: Yeah. There are layers in this, so the easiest one is the top bullet points, where it's like biologic, biosimilar, right? As you get further down the requirement of clinical expertise becomes a bigger deal. I don't think we would expect, and I think the chapter

outlines this, to go all the way right at once. I think the way you should think through this is when there's an opportunity, CMS should do this, but they don't have to go build everything around this area where there's going to be some level of clinical nuance. But I think there are a lot of places where the clinical nuance of biologics and biosimilars where it's less of a concern.

I don't know if that's a good answer to your question, but that's --

MS. RAY: Correct, and, in fact, in the paper we do explain that in prior years the agency did apply a type of referencing called the least costly alternative for certain groups of drugs.

DR. SARRAN: I am sure we all know this, but there will be a lot of noise around that, exactly how that gets operationalized, if we get that far.

MS. NEUMAN: So the second question was about drugs paid based on wholesale acquisition cost. New drugs, when they are first launched, we lack ASP data for two to three quarters. And for those first quarters the drugs will be paid based on WAC. There can also be situations where ASP data is not reported and a drug might have to be

paid based on WAC. That should be less common than the new drug situation.

DR. CHERNEW: I think there is a Cheryl --

MS. KELLEY: There is a Cheryl question. Two, actually. Her first question is, is there a reason why provider acquisition costs for Part B drugs are not made transparent, and is this something that could be required?

MS. RAY: So provider acquisition costs, I know the OIG has, in the past, studied that for specific drugs, but it required obtaining the cost information from actual providers. They were, I believe, eye docs they did one report on, and, of course, they did a report on dialysis facilities -- it always come back to ESRD.

I mean, I think it would be helpful to have more information about provider acquisition costs, but it is an undertaking I think the OIG would have to consider.

MS. KELLEY: And the second question is, could drug manufacturers game the set of indications to limit the reference groups in which the drug would be grouped? How much of a risk do you think this is?

MS. NEUMAN: So the way the chapter has discussed reference pricing is for the Secretary to begin with those

areas that are the most straightforward to implement. And so those would be products where all indications could be included in the reference group. So that's where we would envision the Secretary would start.

MS. KELLEY: Go ahead, Larry.

DR. CASALINO: Sorry. I just came in at the last minute. I decided it was a Round 1 question.

I think this has been indirectly alluded to already, but the question about putting the burden on the Secretary to determine net clinical benefit is tricky, I think. And we haven't talked about it today but you go into some detail, which I think is good and well done, and you do reference some organizations that make these kinds of estimates.

But you did talk about the effectiveness analysis, and although I don't think you used the word QALYs, quality adjusted life years, both of which I think have been historically unpopular with Congress, to say the least, in certain constituencies. And then on page 4 you also talk about a good faith effort toward doing the post-marketing studies.

So I don't disagree, necessarily, with any of

this, but I just want to ask, I guess, as a Round 1 question, would you expect -- supposing that this was actually done, would you expect just endless lawsuits around, well, what is the net clinical benefit? Was this a good-faith effort or not? No, you're not allowed to use QALYs or CEA? What's your sense of that?

MS. RAY: Oh, that's a good question. So, yeah, there are other -- so let's just take on the QALY issue first, and I think there's other options besides QALYs that researchers can use in conducting cost-effectiveness analysis in comparing, you know, a drug to its alternative, such as the equal value of life year is one way to, I think, address that issue.

I think in -- I think in terms of the setting the cap based on the net clinical benefit of the product, I mean, I think that takes into account both the price of the new product as well as its expected benefit over the standard of care versus just some discount off of -- I don't know -- either the manufacturer's ASP or the standard of care, as we've laid out in the paper.

Do I think that requiring -- do I think that such a -- do I think that that would result in lawsuits? I

mean, I don't know. I don't know. I think one way to get – yeah, go ahead Mike.

DR. CHERNEW: What I took from your answer is there's not a clarifying answer to -- it's a reasonable question. I don't think we have a strict answer, yes, no, whatever it is. I have a mild hunch -- not that I have more information -- that this broad issue is going to come up again when we get to Round 2 in how it goes around. I will say that there's a distinction between the two examples you gave. The way this is phrased now, I just want to point out, the recommendation is phrased "The Secretary shall have the authority to..." not "The Secretary shall..." The good-faith effort part is, again, a little bit of a negotiation back and forth, but I think it's pretty clear the FDA says the trial should be done, it's not done. The way it's set up now the Secretary has to decide what that is, be some discretion, and it's really about the confirmatory trials.

The value part, which is -- we'll call it Bullet D -- is a much more complicated issue. It's unclear how that's going to play out, and I'm hoping that much of the discussion we're about to have is around -- I'm sure we

will have some of it. If not, I'll raise it. I suspect others will. That will actually be a core issue for us to think through how the recommendation is playing out.

So I'd like to save the narrow question of will there be litigation to a broader discussion about how we should think about that bullet.

DR. CASALINO: The reason I was hesitating, whether this is Round 1 or Round 2, I think if I wanted to say this is unworkable so think of something else, that's clearly Round 2. And that's actually not an argument that I want to make. So that's why I asked, you know, what did you think about what's likely to result and would this be too complicated, endless lawsuits. But other Commissioners may have Round 2 --

DR. CHERNEW: So, again, I am going to allude to a version of this in a moment, but now I think the Round 1 queue keeps...

MR. KAN: Sort of an adjacent question to Larry's question -- and, by the way, this is great work. Thank you. It's very thought-provoking and intellectually stimulating.

Sort of an adjacent question to Larry's question

on comparative effectiveness. I'm curious. Is that -- I'm supportive of all three recommendations, but on Policy Recommendation No. 1, were there any learnings that you may have gleaned from looking at how some of the European countries do this?

MS. RAY: I think -- in our -- which year report? -- we looked at the process for Germany, and in terms of how they approach the pricing -- the pricing of a new drug. Even in -- I think there are some lessons learned there. It was in our June 2019 report.

DR. CHERNEW: If I can take that as a jumping-off point for some of this, first, just to respond to that. There's obviously a lot of information about how one might assess value, in particular, whether or not a drug is priced above what I think the wording -- and I should know the wording better, I apologize -- the upper-bound estimate of value, some version of that. But I will just emphasize for those who stay at home, this recommendation is nowhere close to doing what they do in many other European countries in terms of drug pricing. It's limited because it's through the accelerated approval process. It's about a cap; it's not about setting a price. It's about doing it

when the price is really egregiously high. It's not about sort of finding some price we think is reasonable in the negotiation phase. I think it's really -- this, what I'll call Bullet D, is really about where -- I don't know what the right word is here, and I think we're going to have a big discussion of it -- where there really is something that you look at it on the outside and you're, like, this is just not right. It's not sort of getting to where you might ultimately want to be in a different world. It's about figuring out where there's a real egregious pricing problem and trying to prevent that from happening. At least that's the spirit of it, which is very different than what they do in a lot of the other European countries, although certainly some of the analytic things that are done might be reasonable. We don't envision -- I don't envision that being where this is.

So we're about to go into Round 2, but I want to emphasize two points. This is a little complicated because there's three recommendations, and they all address somewhat different issues, and each of them have different nuances. Somewhere I think we would start in widespread agreement, like how we think about the pricing of biologics

and biosimilars. That's not so controversial. When we get to similar drugs in the same thing, that becomes a little bit more of a stretch in certain ways. When we think about the recommendation on the price caps, there's four bullet points there, and the ones about you haven't completed your trial is a very different situation than you have launched -- you have set an excessively high price or some version of that. So I want to just say two things and then we'll go to Round 2 questions.

The first one is -- and it's important to say this for our audience at home and for us here -- one of the big challenges with drug price anything is the interaction between the pricing and innovation. And as I think I have said in the past, and I believe I am a believer that there is a connection, whether you want there to be or not, in the way in which drugs are paid for and the amount and type of innovation you get. We can debate the merits of that, but I think there is a discussion of that that will grow, and actually you guys did a great job of that in the chapter, so I want to acknowledge that.

In that spirit, I want to also make sure that people understand that as a general point I think the

Commission -- and I'll let Nancy and Kim respond, but I think it's true in the material -- is very -- I will emphasize that -- very supportive of the accelerated approval pathway, that it is a really -- we often talk about Adulhelm, but understand it's also COVID vaccines, right? So there are a lot of new cancer medications there, things that we really do want patients to have access to and we really should be appreciative, I think, of the great strides that have been made in collective innovation. And I want to make sure that it's clear that we are very aware of both the value of that innovation and the connection of that innovation to the various rewards.

That being said -- so I don't want anything in the tone of this discussion and what you hear to make people think that we are trying to shut down the accelerated approval pathway or discourage innovation in a significant way. I do think there are aspects of it that are problematic in how prices are set, particularly like the timely completion of trials that I think deserves some attention. That's in some ways a different body of thought than, say, high prices at launch, and we'll have a discussion there. So that's just one -- I wanted to

emphasize our support for the accelerated approval pathway and innovation more broadly.

The second thing I want to say, which is on a different part of this, and at risk of triggering Larry, although better sooner than later, is there's a concern -- and I think it's a legitimate concern -- that if we change some of these things related to ASP+ or whatever it is that's going on, that we will induce consolidation of certain specialties into big systems, and when you do that, there's a whole series of other problems that arise. You have site-neutral issues we'll discuss later and a whole bunch of other things.

And so I will say that that is an issue that I'm quite aware of, actually quite sympathetic to, broadly speaking. My general view is you shouldn't pay a percentage of drugs and cause -- I don't know what words you used, Greg -- cause all the other problems associated with this method of payment because you're worried about consolidation. I think there's other things, too, to deal with in consolidation. Site-neutral, by the way, would be one. But there's a bunch of other aspects of things that we have to worry about in terms of payment.

I think the point of that is it is important to make sure that independent specialist practitioners can survive in a reasonable way with whatever new pricing models comes in place. I generally think that should be done through things like the administration fee and other processes, because if you do it as a percentage of the drug price, you create a whole other set of pathologies. But I want to make sure, because it hasn't come up a lot, that this issue about consolidation or not and the impact on consolidation is one that has been front and center in a lot of the general thinking about how we do these, and I think it motivates why the presentation emphasized the importance of the admin fee and related things.

So, Larry, if you're triggered, get in the Round 2 queue. You're already there, actually.

[Laughter.]

DR. CHERNEW: Or you soon will be. But I did want to emphasize those points, and now we're going to go through, and I know...

MS. KELLEY: Mike, I think Stacie --

DR. CHERNEW: Yeah, Stacie -- well, Stacie is first, and she has been so, so, so patient. But, anyway,

thank you. Go ahead.

DR. DUSETZINA: Okay. Thank you so much for this great work. I really love this chapter, and I'm really proud to be able to be a Commissioner while you all are working through this important chapter and topic. So I'm going to start with the easiest ones and then work my way to harder ones.

So Policy 2, the single payment ASP blended, love it, love everything about it. So fully supportive of that as is.

For Policy 3, modifying the add-on payment, absolutely supportive. There are a couple of just minor notes of things. I've had different conversations with people who would be differently affected by the policy changes over the last month or so, and I think that it could be beneficial to be clear about the 6 percent versus 4.3 percent issue in the chapter, or clearer, because I think to Lynn's comment, I guess when I read it, I thought we wouldn't go less than 3. But if we're saying we'll reduce it and then there's sequester on top of that, I think we just want to be clear if that's what we mean.

I guess I was thinking it would be, like, 3 after

having accounted for moving from 4.3 down to 3, instead of going from 6 to 3. So I just think that we want to be really clear about that.

I think the other would be how we got to that $220, and from re-reading it, it seems like it's the 75th percentile or something, and then -- but making sure that that's really as clear as possible in the chapter so that, you know, people who are affected by this payment change really understand the logic of how we got there.

And then I think to Mike's last point there about, you know, how we're paying for things, there's so many different work streams that we have going on that I think touch on how we might pay other sites of care better, so that the ones that are like stand-alone infusion or physicians' offices, they have payment challenges, and they're using drugs to subsidize more of their services than other sites of care. And so it might just be worth pointing to some of these other work streams about how to pay better in different sites of care. I think we kind of get there with the recommendation that points to like monitoring, are we paying enough for administration and things like that. But it's probably that it's gotten us

most of the way there, but just having heard from stakeholders in this space, I think it is a legitimate thing that they point out. They're fairly efficient sites of care delivery, and we don't want to actually penalize really efficient and convenient sites of care. But we don't have to subsidize them through the drug payment, so I think it's very much our principles, pay for the things that we want to be paying for, or pay them better in different ways.

Okay. Now for the accelerated approval. So I think going back also to -- okay. First, totally supportive and I'm very glad we're doing this. The three first pieces of this are easier than the fourth one. So when we talk about having a cap or a rebate whenever the confirmatory trials are delayed, when they fail their confirmatory studies, or when there's coverage with evidence development, to me those are absolutely clear-cut, slam-dunk yes, like no question. And part of me wishes we could just say "The Secretary shall do this..." I would love to be able to be that strong on that language.

However, Bullet 4, the piece that's the price that is excessive relative to the upper bound of the

estimates of value, I don't know that we're there yet to be able to say concretely enough that the Secretary shall do that. So in some ways, it almost feels like we have to -- we have language that isn't as strong as I would like on the first three bullets, because the fourth bullet is just a little bit trickier.

For the fourth recommendation, I think he challenge I have, you know, I kept trying to figure out like how could you set parameters that were really clear for when it met these goals, and I think you all have done a great job of trying to outline some of the things from our discussion last time. But it still feels a little bit squishy to me, and it's just -- it's really hard to define. I've been trying very hard personally to think about how to set a parameter that could say here would be the rules when this would happen. But it trips me up a little bit because I guess in my mind, I would hope that if we really were concerned about the safety and effectiveness of the drug and Medicare beneficiaries, there would be CED, and then it would be covered in one of the prior bullets.

So I guess what I would say is I am still very supportive of this, this fourth item. I just struggle with

whether it's as concrete as it needs to be in order to, like, be as directive, I guess, with the -- if we were able to say more solidly these first three, absolutely this should just be not just have the authority, but you should do it.

The fourth one I think we're close, we're getting there, but I still struggle with it a little bit.

DR. CASALINO: Would you make a recommendation for the fourth one yourself, Stacie?

DR. DUSETZINA: I think that -- I would still be comfortable with the Secretary having the authority to do it. I just -- it seems the other three are so clear-cut to me that being able to say this should just definitely be done -- go ahead.

DR. CHERNEW: I'll try and be more explicit, which is good that Stacie was the first one to speak because this can then hopefully shape some of the discussion, at least on this point. So if you change the recommendation so the wording was "The Secretary shall" instead of "The Secretary has the authority to," that would be something that would be, I think -- now, I'm trying to speak for you, Stacie, so check me if I get this wrong.

That would be okay on the first three bullets, not for the fourth. The fourth bullet there are basically two possibilities. Possibility 1 is you just keep it separately where the Secretary has the authority to, and you carve it out, which is complex -- again, I'm parsing Stacie's language -- because there are a whole bunch of unknown things there. We can try and be more concrete. And you worry about a bunch of the innovation in our actions because you don't know when you're developing a drug where it's going to end up in the whole grand scheme of things.

So an alternative would be to have the chapter discuss this potential problem and what's going on but not have it in a recommendation. That has the disadvantage of, if the Secretary is going to be the authority, you say, "We worry a lot about this but now it happens. What are you going to do?" And that's sort of where the problem is.

And so the thing that I grapple with that's problematic is if you trust the Secretary is going to be reasonable on how they apply all of this, then you don't worry about it quite so much, and you think if you have a good drug, or a reasonably good drug, you will end up being

safe. If you are worried, though, who knows who the Secretary is going to be or how it's going to be applied, given it's vague, it could have really deleterious, potentially deleterious consequences or -- and I don't think Stacie said this, but in a separate thought I'll say it now -- you worry that, for example, a drug that is reasonably good, the company decided not to go through accelerated approval. They decide to just go through regular approval, denying people the access to it for two years but avoiding any price cap risk.

I don't know, Stacie, if you want to comment that that is a risk, but I think that is the tension -- again, Stacie, I am going to turn it back to you -- the tension is how to balance the wording or the inclusion of the last bullet when there's a very legit case -- and again, I'm going to let Nancy and Kim comment -- that for drugs that really have pretty, pretty weak evidence that they provide any real, meaningful -- they might be better but really marginal, at best, with an exorbitant price, and you want some mechanism to prevent that from happening. That's the concern.

On the other hand, you really, really, really

don't want to deny people access to drugs that really could be improving because of the process of innovation and then the pathways of approval that go on. That is the balance.

DR. MATHEWS: I'm going to jump in here. First and foremost, from a very mechanical perspective, depending on how the rest of this conversation goes, parsing out those first four bullets is something we can easily contemplate, and if the first three are covered by something more prescriptive, if that's where the Commission ends up, and given, I think, the technical term was "squishiness" of the fourth one, that might require some different wording and could even compose a standalone recommendation in and of itself.

I do understand the squishiness here. There is a lot of ambiguity in the phrase "as written," and it involves a lot of value-laden words -- you know, egregious, price relative to the standard of care, what does egregious mean, how do you measure the standard of care. I get all that. I think we have 17 people around this table who could help clarify and put some more specific parameters around this.

But I still think there is some value in pursuing

this. One, it is the only one of these elements that would allow the Secretary to deal with a situation like Aduhelm. And the second is one of the reasons that prior attempts to do this kind of things have foundered -- and Nancy, here I'm thinking of least costly alternative back in, what, 2010, thereabouts -- it was challenged in court on the basis of an improper application of the Medicare reasonable and necessary standard. And I can't remember what happened to functional equivalence along that same period of time.

But what something like this would do would be to explicitly clarify in law that the Secretary does, indeed, have the authority to do something like this. Again, a totally different layer of how do you do it, what is the evidence, do you do it for notice and comment, what are the technical advisory panels. All of that still pertains, but at least giving the Secretary the explicit authority would be an improvement over where things stand now.

DR. DUSETZINA: I think it sounds excellent that you can parse those bullets out with a slightly different language in those recommendations. That would make me extremely happy.

You know, I actually think that the language that

is used in the chapter is very good. I mean, I realize it is very difficult to say what this is, but I do think there is more kind of -- you know, would this mean that we would have to do cost effectiveness or whatever we decide, on every single product to be able to identify which ones meet that threshold? Because I think we kind of feel like we have a gut reaction of something that's coming through that meets the threshold, but it's like that seems like, to Larry's points about lawsuits, one that would get the Secretary into a lot of trouble.

But I really like the idea of parsing them out so that the first set are stronger and the other one is still, we think this is important because we actually do think that this is important to have tools to be able to intervene if necessary.

I think the other kind of broader point is that it is really easy to get hung up on the Aduhelm example, but, you know, and Mike points this out more often than I do, but a lot of these drugs are really good drugs and it just takes a long time to get to the clinical benefit piece. And so we want to keep that balance and keep those incentives there, and recognize that we don't want to harm

drug development that actually is good, but we also know that there's a lot of taking advantage of this time on the market when you can set a high price. And maybe you're more inclined to do that if you don't think your drug is that effective, or might not make it through the clinical benefit kind of level.

So I really appreciate the idea of breaking those apart, a strong recommendation on the first three but still should have the authority to do the fourth one.

Thank you both so much for this excellent work. It really is fantastic.

MS. KELLEY: I have Lynn next.

MS. BARR: Thank you. I'm very enthusiastic for this work and I think you did a great job. I am fully supportive of Policy 1 and Policy 2. I am supportive of Policy 3 and eliminating the WAC add-on. That just seems to be obvious.

I am struggling a little bit with the idea that this 6 percent is to pay for inventory costs. That's what it is. I mean, you asked, Greg, so let's just say this is the cost of managing an inventory, right? You get a separate administration fee. Right?

MS. RAY: You get a separate administration fee but some have also interpreted the plus-6 as to account for price variation among individual providers.

MS. BARR: But that's inventory costs, right? So when I say inventory costs, it cost me more than the average sales price. It cost me less than the average sales price. So I've got cost of acquisition. I've also got waste, right? I've got a drug that I don't use. So these are typically multiuse vials, right. So I buy the drug, I dispense it, and that 6 percent is to keep me whole in all of that, right?

MS. NEUMAN: From the waste point, we pay for the full single-use vial, whether it's used or not, Medicare does. For the multiuse vials they would pay only for what's used. So it depends on which products. Some in just single dose, some do come in both, and a few come in multi only.

MS. BARR: Got it. So for multiuse there is a risk.

I mean, where I'm getting on this is the question of volume. Is there high-volume providers where their inventory -- so if I'm a big company, my inventory costs

are a lot less than if I'm a small company, because I don't have that kind of turnover. And I wonder if we need to be thinking about the add-on payment differently. And I've heard other comments from the Commissioners about physician offices.

And so I'm just worried about physician offices, low-volume rural providers, that aren't going to be able to buy these drugs and provide access to them if there's too much of a financial loss. And so I'm wondering, should we be looking at this a little bit -- so there could be a mechanism where you'd say, "Okay, you know what? If you order this much of the drug you get the 6 percent, but if you order this much of the drug, you're in the 3 percent," or whatever that number is. I think we might want to think about it differently because I imagine their costs are different. Do you disagree?

DR. CHERNEW: Well, we will have a discussion about that point, more discussion, but I will say -- and you answered this in response to a few of these questions -- the actual price you're being charged is a little bit dependent on the way that they get paid. So the drug companies have an incentive to make sure that people get to

buy the drug. And so if you don't pay as a percentage of fees, they have an incentive to give you a price that will enable you to still use the drug. So the price that you see now isn't necessarily the price you would see if the payment mechanism was different.

MS. BARR: Right. They don't go to single-dose vials because nobody is able to buy it?

DR. CHERNEW: My view is -- and we can have a broader discussion. I'm not an expert and I would defer to others who are -- is I would expect that they would find a way to make sure that their customers get access to the drug and that a lot of this would be taken out, and where the pricing ends up and other sort of financing ways of dealing with this problem.

MS. BARR: Well, but as a business, I'm going to pay attention to the 80 percent of business, and I'm going to price for the 80 percent. I'm not going to price for the 20 percent that are small.

DR. CHERNEW: No, but the price --

MS. BARR: Okay, discriminate.

DR. CHERNEW: Yeah. In other words, they're not charging everybody the same price anyway.

MS. BARR: Right. But as a small provider I don't have the negotiating power. I just wondering, I would suspect the 6 percent came from somewhere, and it was probably based on physician offices. And now we've got hospitals. No, you don't think so, Jim? Who knows. All right. I'm just worried about low-volume providers and how this would affect them.

MS. RAY: Yeah, and I just want to point out, for the lower-volume rural providers, I mean one thing to keep in mind in this policy is that for the lowest cost drugs their payment remains the same. It is still 106 percent of its ASP. So if you think that the low-volume rural providers are more likely to be furnishing the less costly, non-cancer drugs, then their payment rate under this policy is not affected.

MS. BARR: Yeah. I think it's mostly around the biosimilars. But again, if we do reference pricing it's going to take care of a lot of problems. So obviously, like reference pricing would sort of solve a lot of the issues that we worry about, like people using things differently.

I also want to comment on Stacie's point that I

think for a long time I thought we were talking about 6 percent versus 3 versus 4.3 versus 1, and I'm just not sure it's enough. And I'm particularly concerned about low-volume providers.

Other than that -- and eliminating the WAC add-on seems like a no-brainer, 1 and 2 seem like a no-brainer as well. Thank you.

MS. KELLEY: Amol.

DR. NAVATHE: Thanks. I also want to voice that this is fantastic work and I really appreciate you taking this on and driving it forward. I will also try to organize my comments around the recommendations, although I might go into reverse prioritization of what Stacie did, because [inaudible] to an extent.

Maybe I can start with Recommendation 1. I think Larry's points actually really resonate with me in a very broad sense, which is that we are in a very tricky situation around these drugs, in general, because the whole idea behind an accelerated approval pathway is that we want to get drugs to patients faster, drugs that have promise, drugs that explicit, not even implicitly, explicit we know are being approved on surrogate endpoints and therefore we

have less clinical data on their effectiveness.

And so defining something like what is the clinical benefit ends up with a presumably large confidence interval, and we don't know where we're going to land in that confidence interval either. And so defining value, defining clinical benefit, all these elements is really challenging.

The second contextual point is at the same time I strongly believe aspects of what Mike said and Stacie said, which is we do want innovation to continue, and at least conceptually or theoretically, based on how these sort of pricing cap type policies end up getting implemented, I think the economics literature would say that there's certainly a way that they could have a chilling effect on innovation, and that affects generations of people down the road. So I think we have to be very careful and thoughtful.

The third contextual point, I think, is that many of these elements, we have the word "value," I think, in Part D right now -- sorry, Bullet D I think is what Mike termed it -- in Bullet D, and there's a lot of value ladenness to the question of what a cap should be.

And I think one of the amazing things about our U.S. society, but one of the things that makes it really hard to agree upon anything in American society is that we have a lot of different values and the heterogeneity of opinion and preferences around how much we would pay or not pay for things, which is different than I think many other countries that sometimes we look to, for example, just to pick some Scandinavian countries which are a lot more homogenous and have much smaller populations.

So I think that context is really important, I think, for us to approach this work because we have to be careful. We have to be careful that we are not just using, quote/unquote, Commission values to then make recommendations. We should make recommendations that I think our flexible enough, to some extent, to be able to be implemented in ways that reflect broad heterogeneity of values that exist in our society.

So those are my broad contextual points, but I think are relevant and inform the next set of comments that I am going to make.

For Recommendation 1, I think it might be useful to think about this in the context of what we think we want

to happen generally versus what is going to happen on an exception basis. In other words, let's view the world for a second, Recommendation 1, through the world of exceptions. And I think if we look at A, B, and C, those seem like relatively clear situations where they are, either through volitional intent or not, something that is agreed upon such as a confirmatory trial isn't happening in the time that it should happen, or doesn't happen. It's very clear there's something agreed upon, something that's not executed.

So I think to some extent there we would say to the extent that we don't want a price cap to occur in that setting it should be on an exceptional basis. We would generally want it to happen, and there might be some cases where there's something completely unforeseen -- COVID pandemic, something else happens that really disrupts the way that a confirmatory trial could occur, and so we would want the Secretary not only to have the authority and perhaps be driven through language like "shall" to institute a price cap, but we may also want them to have the authority to call an exception and say, "You know what? This doesn't really make sense in this case, on an

exceptional basis." And personally I think that applies nicely to A, B, and C, this nothing that it should happen usually and we may only not want it to happen in an exceptional basis.

To the extent that we all agree upon this idea of having price caps for this notion of excessive pricing relative to value, which is, I think, the way that it is currently worded, I think there we probably should think about this on an exception basis of, well, for the most part it should be okay, but we want the Secretary to have the authority to do this, in the exceptional circumstance where we truly have this excessive situation.

And I think that does lead us to Jim's point, to very explicitly different language that we want tied to Bullet D -- I'm trying not to call it Part D -- to Bullet D than to A through C.

And so I'm also fully supportive of this idea of we sort of separate out how we think about this language, because the way that we want these, I think, based on the Commission dialogue and chapter and the data that we have, that the way want this to work is conceptually very different for A through C than it is for D. And I think

that would strengthen A through C, which is basically saying that by default we are going to get a price cap, but on an exception basis we won't, and on D we are, by default, essentially we wouldn't get a price cap on an exception basis, we would.

And I think it does have some risk, Larry, that you're pointing out, around litigation, but I think another part that's broadly important is I think if we do look across the pond, if you will, at other developed countries, I think oftentimes the way the aspects of those drug pricing systems work, to some extent, are on, quote, "threat of some government intervention."

And so I think to the extent that we can bring a little bit of rationality to how manufacturers would be thinking about this, using this notion of granting the Secretary authority to intervene on price caps if it is required, I think we might be able to accomplish what we need to accomplish without getting this chilling effect on innovation and without creating some sort of undue litigation or other things that we would otherwise want.

So those are my thoughts on Recommendation 1.

Actually, I'm just going to go through and say

Recommendation 2 I have no further comments and I am fully supportive of.

Recommendation 3, so in general I am very, very supportive. I think the work is really strong. I think that I fully ascribe to this point that manufacturers will respond their pricing based on the pricing system that we have in place, and I think they have a clear incentive, in a good way, to get patients to use their drugs, and so they will help us, effectively "us" being the broader we of society, solve this issue of how to get smaller clinics or others access to the drug.

My thought here, actually -- and this is a little bit of a late-breaking one -- is in the context of the way that Recommendation 3 is worded, it is very broad in the sense that we are saying reduce the ASP add-on. And I wonder if that's insufficient, if that doesn't quite get us there. Because that means reducing the ASP add-on could just mean moving ASP+6 percent to ASP+5 percent or 3 percent, or something else like that. And based on the presentation today and some of the dialogue, at least, it seems that what we want to do, in fact, is we are perhaps less worried about whether it's $220 or $250 or 3 percent

or 4 percent. What we are more interested in is mitigating this ASP+6 percent way of pricing, that is inducing this distortion.

And I think that's not currently captured in the language of Policy 3 recommendation, and I would be curious to hear other Commissioner thoughts on whether we should be articulating that in the language of Policy 3 to get at this point that we want to move away from a system that is predominately, particularly for the non-low-cost drugs, one that is a share, a percentage of the price but rather one that ends up having some kind of flat, fixed fee at the higher end, whether it's 75 percent higher or something else.

So that's one thing I just wanted to add, and I thought it would be useful to get Commissioner feedback on that point, because right now we have a very high level but vague recommendation that perhaps doesn't get us to where we exactly want to go, based on the presentation.

Thank you.

MS. KELLEY: Robert? Oh, I'm sorry. Greg is next and then Robert.

MR. POULSEN: Well, I was going to start where Amol ended, so thank you. I'm very supportive of the recommendations overall, and I think that's great. I had really one tweak and one ongoing concern, and my tweak, which may be a little bit more, is just where Amol came from. I think that, you know, after our discussion, if we were to head down the path of something that -- and I assume there isn't a holding expense. I assume there is an expense associated with inventory, and it's going to be more for a $10,000 item than for a $10 item, and I get that. And with that in mind, I would be inclined to do something that looks like the middle of your three suggestions, which would be a percent plus a dollar amount, and the percent would be small. I don't know what it should be, but let's for the sake of argument make it 2 percent plus an X dollar amount associated with what we think is appropriate from that perspective, and that it would look like -- the total would look not radically dissimilar than what we have here, so we wouldn't spend more or less money than what's here, but that we would tie it to something that reflects that there is an expense associated with very expensive drugs, but that we don't

want it to be any more than, Amol's point, the amount that is an actual expense, because I have experienced the perversion that it creates among clinicians, and I think we'd love to get rid of that. I think that is something that is worth getting rid of in the system today.

So if we decide not to go down that path and stick with the language and the examples that we have, I would still say that's a big step in the right direction and I like it. I think we could take it one more degree along that path and it would be beneficial.

The other thing I guess I would throw in -- and I don't want to just be the person with the wet blanket here, but I like this. I think all of this is good. I'm absolutely positive I think it's one step that we need to take before we take more steps, because the fact of the matter is, given the capabilities that we have with pharmaceuticals, I can easily imagine a situation where 50 percent of Medicare beneficiaries, including me, will in any given year be using one of these very, very capable and expensive drugs. Let's assume they are very capable. They do great things. We love the idea of having them. But they are very expensive, and they're likely to continue to

be, even with these recommendations.

And I think that there -- I don't think that the recommendations here will materially change our United States position relative to other countries. I think we're still likely to be dramatically more expensive.

And I think there was a case to be made for that back in the -- maybe back as far as 1975, you know, when the United States stood out distinctively economically in the world. That's no longer true. There are many, many countries on a per capita basis that do just as well or better than the U.S., and I don't think it makes sense for us to be spending X times what other countries do. And I think this is an appropriate and progressive step to help us along that pathway, but I don't think it changes our position. It doesn't fix the problem. I think that we're going to have to pick up the very, very unpleasant and unpopular idea of looking to international comparisons at some point in the future, and there's no reason we should be paying X dollars more for a new drug than is paid in Sweden, Switzerland, Great Britain, France, Japan.

Thanks.

MS. KELLEY: Robert?

DR. CHERRY: Thank you and, you know, hats off to the staff for this exercise in threading the needle. Really difficult to do, and I think really a heavy lift, so thanks for all of that.

I think like many of the other Commissioners, I was also tripping up with Policy 1, Bullet 4, regarding how the Secretary is to determine the upper-bound estimates of value. And there are examples, you know, within the body of the pre-read materials about how that might be done.

I think at the end of the day, though, it's going to require the development of a detailed objective tool to really determine what value is. That's not currently outlined in the proposal, and that may, in fact, be okay. It might be in some aspects out of scope, you know, for this particular proposal.

With that being said, on my part, anyway, there's a healthy dose of skepticism whether that can be applied universally to drugs that are brought forward through an accelerated drug approval process, mainly because we're in a market-based price system, and so that makes it really challenging.

If I were to put some nuanced language around

this, around Bullet Point 4, I probably would say, you know, if feasible or whenever feasible, because that would give the Secretary some more latitude regarding that bullet point. I think in the body of the report, I might add, you know, that the Secretary shall have the authority to develop such a tool to determine the upper estimates of value when applicable, because I don't think that whatever tool is going to be developed is necessarily going to be universally applied to every drug that's brought forward to them. So there could be a couple of nuances that could be introduced that might make, you know, some or many of the Commissioners comfortable.

The other thing regarding Policy 2 -- and I know Stacie was very comfortable with it -- it actually seemed also, you know, challenging in some aspects. I'm in favor of it. Don't get me wrong. But if you think about just like one class of drugs, low molecular weight heparin, which these drugs work with a very similar mechanism of action, they each have different efficacies. And so because of that, you know, one may be applied for treatment and prophylaxis for DVT, or deep venous thrombosis; another might be applied for unstable angina; another one might be

applied for heart attacks or myocardial infarctions that are non-Q wave, another one for ST wave elevation for myocardial infarction.

So because of all those differences, even with similar mechanisms of action, I could see there being a lot of wrangling going on in terms of the reference pricing even within similar classes of drugs. So it doesn't mean that it shouldn't be done. I only mention it because of the level of difficulty regarding this particular proposal and series of policies.

Nevertheless, I'm supportive of it, though. Thank you.

MS. KELLEY: Stacie, did you have something on one of Robert's points?

DR. DUSETZINA: Yeah, I think this is maybe going to that kind of value assessment or the way we -- like, one piece maybe to think about for framing here, it goes also to Larry's comment about lawsuits, is we could add something in the chapter to maybe point to the Inflation Reduction Act and the methods that, you know, they're working to define what is a fair price for a drug. They mentioned cost-effectiveness. They mentioned not using

QALYs. But they have a lot of detail in there about information they could collect from manufacturers for deciding what is a fair way to pay, and maybe that does sort of de-risk the -- like, we won't know as much about these drugs at that time, but we could kind of reference that there are methods that are being developed and defined right now by CMS for the purposes of drug price negotiation or setting a new fair price. I think we should reference that and say that would be one way or a key way to maybe think about doing that and kind of avoids the guardrail issues that were just mentioned, I think.

DR. CHERNEW: One of the few things I'll just point out is the difference from the Inflation Reduction Act is there's drugs that you believe -- that you now have a pretty good sense of pretty high value. Then there's drugs that you're really pretty sure they're priced above what you think would be reasonable by most analyses. There is a very wide gray area. Bullet Point 4 in this recommendation is really designed basically to give the gray area more to the firm as opposed to not, because of the innovation incentive. When you're out in the Inflation Reduction Act world, you've been out for a longer period of

time, and they're trying to do a different activity. You could still use the same -- I do think there's something to learn about what they're doing --

DR. DUSETZINA: Well, you --

DR. CHERNEW: -- but our whole point is the threshold and the way we envision the threshold being is very different because of the --

DR. DUSETZINA: But I think even just as a framework, I mean, they include a substantial amount of information that's collected from the companies, and you could weight that in different ways because it's newer versus older and things like that. But I think it would be a shame not to at least point out that that's the type of language they're using in their recommendations. And I think also to the point about the Recommendation 2 and the other classes and drugs, I completely agree, and I wonder if maybe mentioning something more about the formularies and P&T committees and a little bit more explicitly that that would be more complicated as you get a little bit farther away from the biosimilar or the alternative pathway that they're sort of like the easy ones that we would start with. But I think that it would be important to say this

would have to be done with intentionality around putting those same products that have different -- potentially somewhat different uses. I think that could be done through just being more explicit about the need for clinical input.

MS. KELLEY: David.

DR. GRABOWSKI: Great. Thanks. First, great work, Kim and Nancy. Overall very positive about where we're going with this body of work.

I'm going to focus, similar to other Commissioners, on Policy 1, and I'm really glad I'm following other Commissioners here because it has really helped sort of shape my thinking.

The four bullets, similar to Stacie and Amol, I'm -- I believe we should strengthen those first three bullets. I think Amol said that really well. The first three are very discrete or kind of black-and-white. You know, they did not complete post-marketing confirmatory trials, did not have a clinical benefit, are covered under a coverage with evidence development policy. I can really see kind of how those would play out.

I am, similar to Stacie and Amol, very worried,

though, about Bullet D. It just seems quite sort of gray, I think was -- or "squishy" was Jim's word and "gray" was Mike's. But, you know, this issue of what is value, Jim, I was going to tease you. When you said the 17 Commissioners could help, I was going to joke back, and say you're going to get 17 different opinions and hear about what is value, and then to Amol's point, if we take that out, I don't know if our collective kind of views are going to match everyone else's.

But I'm also worried beyond just the squishyness, this issue of kind of the potential drag on innovation, I think Larry's point about the risk of litigation really kind of makes me pause there and think we should sort of strengthen language on the first three bullets under Policy 1, but maybe kind of take -- talk about Bullet 4 in the text, but I wouldn't favor kind of the current language there.

Thanks.

MS. KELLEY: Scott.

DR. SARRAN: Yes, as I read through the materials and then listened to the presentation and particularly listened to comments, there were three pieces of context

that went through my head that lead me to a suggestion.

The first is I think we have to recognize we have in the U.S. neither a cultural nor an operational framework for dealing with value or cost-effectiveness. It just doesn't exist. So that's a reality, whether we like it or not.

And the second is with respect to potential negative impact on innovation and funding of innovative therapies, I think it's useful to recall that it's not just the absolute amount of dollars that might be impacted in terms of downstream ability to recap investments via high sales prices, but it's the uncertainty of those dollars -- right? -- because if you -- in classic business truism is you can bake in almost anything if you know what it is. You can work your way around that. Uncertainty can have a chilling effect.

And then the third is just this whole concept of let's not let perfection be the enemy of good. So pulling all those together, my suggestion on Policy 1, which is largely consistent with what we just heard, is let's strongly double down on the first three scenarios. They get us, I think, a lot of value for beneficiaries and for

CMS, and they're straightforward, they're hard to argue with in the public domain, you know, huge amount of value creation.

And then maybe for the fourth, which I think does have the potential to be, you know, chilling and adversarial and all of that, maybe we -- and, again, since we don't have a framework for dealing with the fourth bullet point in the U.S., and the fourth part of Policy 1 really sort of jumps past our not having a framework, maybe the language could be, should be something to the effect of "The Secretary shall develop a framework for evaluation of potentially inappropriate, out of boundary" blah, blah, blah, you know, value. Because if we get to there, then operationalizing that is a lot easier. But we're trying to kind of jump past there. So maybe there's a way to do that.

And then just a very minor point on Policy 2, which I think is just so darn good, and it a little bit, Robert, builds off you, I think there' a little lack of clarity about how we'll define the relevant drugs for comparison, and I might suggest we incorporate into the phrasing "similar mechanisms of action." And, Robert, you

point out even when you have similar mechanisms of action, you can still have some significant nuances. But I think at least including that as well as drug classification -- because I think, again, we want as little uncertainty as possible in that so pharma can understand, okay, this is when I might get pulled into that grouping versus, no, I don't need to worry about it in these other circumstances.

MS. KELLEY: Larry.

DR. CASALINO: We always say "Great work," but that's because it is. I think the Commissioners are constantly amazed at the quality and consistently extremely high quality of what we get, so thank you.

I agree, I think pharmaceutical innovation is incredibly important, and I would say it's only going to keep becoming more incredible and more important even in our lifetimes. It's incredible what that industry has done in our lifetimes and what it can do. And I do agree that price and innovation have some relationship, as Mike has emphasized a number of times.

That said, you know, I don't -- I'm with Greg in that I don't believe that the U.S. needs to finance the cost of pharmaceutical innovation for the world. And to a

considerable extent, that's what we're doing, right? I mean, we really are. And I do think it's true that if the pharmaceutical companies couldn't make quite as much on the price side in the U.S., they would be tougher in their negotiations with other countries, with some success.

So I guess, first of all, I'll tie that into something in just a minute. I think there has been kind of a consensus, at least at this end of the table, with Jim and Amol and Stacie and Scott on the first three bullets under Policy 1, and the fourth bullet, some good suggestions. And I do think we need to do something there, and maybe Scott's suggestion about something, which I think Robert also essentially suggested, just "The Secretary shall develop a way to do this" is good. But this might be a part, I would strongly suggest, in the chapter to bring in the rest of the world issue, not in the sense of who's going to finance drug innovation, but in the sense of there are other countries that pay half what we do for drugs, that do have methods, standard methods that are pretty good for evaluating the benefit of drugs -- right? -- and for us to kind of ignore that almost and just mention it -- this is not a criticism. I'm talking about it's a constant

frustration to me with the U.S. health care discussion, we can't learn anything from the rest of the world, it's un-American, right?

I think the 1-D would be the place to say we pay twice as much, other countries have a way of determining the clinical benefit, the Secretary should take a look at that and develop a method for evaluating net clinical benefit. So that's all I'll say about Policy 1.

Policy 3 I want to jump to, just I actually like pretty much all the suggestions for Policy B. I think that I just want to provide a little more context there, the large practice issue. So there's a paper out there, a pretty good paper that estimates that the average retinal specialists makes $237,000 a year more if they shift most of their use of intravitreal injections to Lucentis rather than the cheaper alternative that costs about $50. You know, that's substantial, and ophthalmology practices depend on that, right? Rightly or wrongly.

So a couple of points that leads me to -- oh, and the other thing they did, by the way, large practice, small practice, the large practices do get large volume rebates or discounts from the pharmaceutical companies that are not

available to the kind of practices Lynn is talking about. But they also make 2 percent buying these things with credit cards. This is not anecdotal. This is in the article. They pay for these hundreds of thousands of dollars, easily, quickly, adds up to many hundreds of thousands of dollars, they pay for them with credit cards. They use credit cards that they basically get 2 percent back on. That's pure profit for them, and it's a big enough number to not be ignored, if you compare it actually to the kind of numbers we're talking about in the paper, for Recommendation 3. So that should be understood, I think.

And one thing that hasn't been mentioned is transition. So for practices like oncology practices and ophthalmology practices that are raking in that kind of money off, you know, very expensive drugs at the ASP+6 percent, like Greg and all of us, I think, that's not a healthy incentive structure to have in our system. But stopping it overnight might be disruptive, too. So as another policy recommendation in other areas, we might want to consider some kind of transition. But I agree with the recommendations as they are.

Then the last point, I don't think we've had enough discussion about Policy 2, and it may be simply that I don't understand it. Is there any reason that there couldn't be -- I think the recommendation as it is now is for some form of reference pricing, but not -- but to continue letting each drug have its own ASP in the classes we're talking about? Did I get that wrong or is that correct?

MS. RAY: Each drug would remain in its own billing code.

DR. CASALINO: That's what I meant.

MS. RAY: But it would be assigned a reference price.

DR. CASALINO: So why couldn't we -- would it add anything to give each drug -- to give the same class of drug the same billing code instead of letting each one have their own and still do some form of reference pricing? Is there any reason that couldn't be done?

MS. RAY: So I think that could be done. What we discussed earlier, I think in the September meeting, is that for various reasons we might want to -- certain Commissioners felt like keeping them in their own billing

code would be more advantageous in terms of the use of claims data, for example, for pharmacoepidemiology purposes, and in those instances in which a medical exception would be necessary.

DR. CASALINO: Wouldn't it be possible to let them have their own identifying code for research purposes but -- just not possible? -- but to give them all the same billing code in terms of payment purposes?

DR. CHERNEW: I think -- I'm going to -- just for time I'm going to push on because this is beyond what we contemplated. So I think there's -- we'd have to really think through the benefits of that relative to just doing this and all the administrative costs of how that all would play out. But I think what I will say, which I think is important as we go through here, because we are getting toward the end, is right now the recommendation is general, and you could read the recommendation as let's do least costly alternative, and then you could focus on the places where that's really hard or -- which is how I read the chapter -- let's do it in the easy places and, you know, it's not a call for the Secretary to do least costly alternative across the board. It's a call to start with

some of the low-hanging fruit places, the biologics, the originators and biosimilars, the 502 whatever letter, right?

When you get to this other thing, which is taking all of the air time, I think you get into a lot more of this complexity, and I'm uncertain about whether or not the recommendations should maintain that level of breadth, which I think has some value in particular cases where you'd to want to do it, but it does add to a level of confusion. And so that's a recommendation tension that, based on this discussion, I'm struggling with.

DR. CASALINO: So, Mike, this is actually a separate point that I was just asking about, which is separate billing codes. But that's okay. I'm happy to pass that by now. But are you saying we should have a recommendation that basically says let's do some form of reference pricing?

DR. CHERNEW: No. I think what I'm leaning towards is the following: keeping it exactly the same, and making sure in the text that we are very clear -- and I think we are, by the way -- that what we are really recommending is do this in the places where we know you can

do it, where there's not all of these complications being raised, so biologics, the originator and the biosimilars; and that while we understand there may be other places you can do that, and so that's covered by the recommendation, we recognize that is a much harder thing to do, and this recommendation shouldn't be interpreted as telling the Secretary they need to go across all of the drugs and build a full-fledged, complicated reference pricing or least costly alternative model. I don't think that's the way -- that's not the way I read this recommendation. I read the recommendation as let's take the ones where I think we all agree, and there's probably some other ones clinically that we could get to agree to easily; we want to make sure that's included. And when it gets really complicated, the Secretary can ponder how that plays out. But that's not really the crux of what this recommendation is. And I think the text has to make that distinction. The recommendation right now is just vaguer, somewhat intentionally.

DR. CASALINO: No, I'm good with that.

DR. CHERNEW: Okay. Just to get -- so we have one, two, three, four more people -- four more people left,

and I think the first of those people is Betty, if I have this right. And just be aware of the time we have.

DR. RAMBUR: I will be very --

DR. CHERNEW: We'll go a little long, but we have about ten minutes.

DR. RAMBUR: I will be very brief and just try to amplify, if I may. I really appreciate the insights of the Commissioners, and I just want to comment to the staff that I think you did a brilliant dissection of the issues and the trade-offs, and I think it should be required reading for every person in the United States who's interested in drug prices and every health professional student.

I can't help but think about this issue from the perspective of the end user, the person using the drug, including the false hope and the harm and the suffering, so I strongly support the strongest language in Recommendation 1 and 1 through 3. And I wanted to comment on the statement that caps have a chilling effect on innovation. I have to ask you, does that also have a chilling effect on patient outcomes? Because as we see it, those are not always the same. So I really like Scott's suggestion about thinking about some kind of framework for value. It may

not be able to be in this time, but what are the trade-offs in terms of what we're really getting?

I also very much like the inclusion of the international pieces that were mentioned, I think, by Larry and Greg and others, and so I'm very enthusiastic about this work and having a bit more, you know, description in some of these areas will take us far. So thank you.

MS. KELLEY: Kenny.

MR. KAN: Outstanding work by the staff in balancing many complex issues. I'm very enthusiastic of the Chair's recommendation on all three policy proposals.

Regarding Policy 1, Bullet Point 4, Stacie's concern regarding the squishyness of the price capping framework resonated initially with me, back in January and even today. However, I still remain comfortable with this price capping proposal as the recommendation is to grant the Secretary the authority and thereby the flexibility to cap prices when drug prices get egregious.

However, as a guardrail gains potential abuses of such authority, I support Robert's and Stacie's idea of possibly inserting a value assessment nuance in the report which references the need for clinical input, potential

consistency with the spirit of the IRA, and a price setting framework of tools.

Finally, I wish to pile on Amol's and Scott's idea of not letting perfection be the enemy of the great.

MS. KELLEY: Marge.

MS. GINSBURG: Right after I posted my Round 2 comment, Robert stole my thunder.

[Laughter.]

MS. GINSBURG: That always happens.

About Policy 2 and the reference pricing, it's been troubling me all along and then he was able to effectively articulate why it's a problem, and I really do think it's a problem because I think every drug manufacturer will find variations in the health effects of their drug that will make the reference pricing almost impossible. And I would love -- I love the concept of reference pricing. I'd love to see if there's a way it can be applied here. But I have to admit I'm really cynical about whether that is going to work in this whole area of medical care.

Otherwise, great report, love it all, and very excited about what the next steps will be. So thank you.

MS. KELLEY: I have a Round 2 comment from Cheryl.

She says: I agree with Greg's point that these steps are improvements, but there is still a great deal of work to do to stimulate more competition and reduce drug spending. She supports Policy 2 and 3. She concurs with Stacie's recommendations to separate the A through C under Policy 1 to state that "The Secretary shall" do those three things, and then to have D stand alone and give the Secretary the authority to do this, to provide discretion. This may serve to temper the launch prices to avoid the Secretary needing to trigger the D option.

She suspects manufacturers will want to get the drugs to market faster to recoup development costs and will choose the accelerated path rather than run them through the standard process.

Note on page 3 the CED policies have been rarely applied to drugs, only three times since 2005. She concurs that determining value is complex.

That was the last person in Round 2, except that Stacie, I think, had another point she wanted to make if there was time. I do think there's time, Mike. Is that

all right?

DR. CHERNEW: We'll have an abbreviated Round 3. I think Stacie and Amol wanted to make a Round 3 comment. I don't know, Stacie, if you added your comment earlier.

DR. DUSETZINA: No. I just wanted to make -- so Cheryl's comment was a great tee-up for this. It sounds like mostly consensus around the separating out the points on Recommendation 1. In addition to saying the Secretary should have the authority to do that, I do think that going to maybe Scott's comments about being really clear or trying to develop some sort of framework when this would be applied to de-risk it, you know, so it would -- it would be the Secretary, you know, shall have the authority to do this, but should create criteria by which -- you know, so that companies can understand, you know, if you meet any of these things, you will be evaluated and potentially have a price cap. So I wonder if we can include a little bit more language about them defining when this would be triggered as clearly as possible, because I think that is the risk of the piece today.

DR. NAVATHE: I'm next? Okay. So two quick things.

One thing is on Rec. 1, I would personally urge us to include something about exceptions for A to C as well, so allowing for exceptions.

[Comment off microphone.]

DR. NAVATHE: For A to C, just allowing the Secretary to also have exceptions, you know, as I was saying kind of in the context of whatever, unanticipated COVID pandemic.

And then for Rec. 3, I wanted to actually offer potential alternative language that is in spirit raised somewhere but tries to capture some element of we don't want to just go from ASP+6 to ASP+5 percent, that we want to actually shift the system a little bit. So, very quickly, my restatement would be something to the effect of: "The Congress should direct the Secretary to shift add-on payments for Part B drugs paid based on average sales price to methods that lower payments and improve financial incentives, and to eliminate add-on payments for Part B drugs paid based on wholesale acquisition cost."

DR. CHERNEW: As an aside, we're not going to have a discussion of that point.

I take that back. We will have a discussion of

that point. We're not going to have it now. So let me do just -- did you want to add --

DR. MATHEWS: [Off microphone.]

DR. CHERNEW: Do you want me to go first?

DR. MATHEWS: Yeah.

DR. CHERNEW: Okay, so let me try and summarize where I think we are.

There will be recommendations in April you will be asked to vote on. I'm not going to go around and ask you your opinion of them now. There's three different recommendations and the recommendations have different points. It's pretty clear where there's consensus on the bit about -- with Recommendation 1 on the first three bullet points, I think we have reasonable consensus on wording, and we should get close enough to where I think we can be -- you'll see more material.

On the fourth bullet point, what's clear is there's a lot of discomfort with aspects of it. What's not clear is whether that's simply solved by making it "The Secretary shall have the authority to..." and then keeping it; or whether it needs to have more explicitness about, you know, what the criteria are and stuff, and so we will

talk about what to do with the bullet point given this conversation.

With the issue of the similar drugs being -- we've been talking about reference pricing. It's pretty clear there's consensus about what to do in the sort of cases where it's really basically the same thing, today there's some biosimilars, and there's uncertainty about what to do when you're trying to think about a more broad reference pricing mechanism. And I think we're going to have to think through how that plays out in the text to be clear what we want and how we may have to change the wording on the recommendation to be clear. But I think there's actually widespread consensus on the points; there's just uncertainty about what it means for the actual wording of the recommendation and implementation.

On 3, I think, again, there's widespread consensus on the point that the existing broad system creates a bunch of bad incentives, but there's some clarification about where the sequester comes in; is this pre- or post-sequester? What do we actually -- how specific is it? You know, the recommendation doesn't actually have in it the policy option. As I say, the

recommendation is more general as written and even as Amol said it. So I think we will think through the actual wording of Recommendation 3, but I think there's general consensus that we are balancing a desire to make sure that people can hold the drugs, we don't drive consolidation, that the administrative prices are right, but address what we see is a really serious incentive problem associated with the current way in which the drugs are paid for, ASP+X percent, because the X percent seems to be big enough that it's causing some problems.

So we will -- I think the right word is "massage" the language and keep the spirit of where we were, but I thought in general there was a lot of enthusiasm for the spirit and a lot of massaging going on. So I'll just -- well, Jim's going to say his conclusions, so I will give mine as thanks to Kim and to Nancy for all of this. This is really a big area, and I think it's outstanding work, and I look forward to working over the next month to come back with refinements to this.

Jim, you're up.

DR. MATHEWS: Just a final comment to set expectations.

One, this was an extremely productive discussion, especially given the complexity of the material that we've been dealing with. And I think the guidance we have has been helpful to get us to the April meeting and the June report.

Obviously, one of the most complicated issues does relate to Bullet D in Recommendation 1, and to just do a sidebar a little bit, the point that the United States does pay multiples with respect to the price for drugs relative to other developed countries is -- it resonates. It carries a lot of weight. And at one point in this process, we did contemplate using international reference pricing in order to kind of temper that phenomenon, and we wrote this up, I believe -- I can't remember the chapter -- 2019 where we looked at the pros and cons of using international reference pricing, and it involves things like trying to crack open proprietary contracts between a manufacturer and another sovereign government, things like manufacturers using different NDCs in the United States than they do in other countries, making comparability difficult. And so at the time the Commission did not pursue an international reference pricing approach.

Part of that, the way other countries do this does indeed involve a value assessment framework that does not exist on a national basis in the United States, but there are private entities that do this kind of thing.

That said, I am, as an institutionalist, looking at this from a MedPAC perspective, I am extremely hesitant to try and develop a recommendation that the Secretary develop such a framework in the time between now and the April meeting, which is effectively tomorrow in the world we operate in. It's not to diminish the substance of the idea, but we have not had a public deliberation of how it's done in other countries, what kind of inputs are involved, what kind of processes are involved in terms of public presentation, appeals, that kind of thing. And so I'm extremely hesitant to embark on that for the April meeting, and my preference would be -- obviously we'll talk with Mike and Amol -- would be to sort of work with the current -- you know, Bullet D construct in light of this conversation.

DR. CASALINO: I think I agree, Jim. I'm not sure anybody was saying that we should make a recommendation that, you know, we will use the European way

of doing it, or whatever. I think it was more the way the text is worded that we move the information about how it's done elsewhere, and the question of proprietary companies in the U.S. It is already, I guess, in Bullet Point D, but I think it should be prominent there. I see our role as making policy recommendations to Congress, but I guess -- and maybe you may not agree with me. I think it also inevitably has to be helping Congress think about things. And if we -- the frame of thinking about things about how other countries are doing it, not so popular in Congress or the U.S. but that's not a reason for us not at least to throw it out there, not as a recommendation but as something that's more prominent in the report. We don't need to get into the details of how they do it or anything like that, just, yes, it can be done; because, otherwise, D looks really squishy. But the idea is that if you get the idea that there are ways to do it, and here they are on a very highly level, I think that's helpful.

DR. CHERNEW: We are going to take a break and come back, because I want to have enough time to do the post-acute chapter. But I will say for those at home, this issue about the gap between America and international

prices, which is a much bigger issue than we're talking about here, which is really largely accelerated approval drugs to one particular pathway. And so it is certainly a feature of the American system that we pay more than other countries. The problem we were trying to solve was not that problem, just to be super clear. We're trying to solve a much narrower problem in a much more specific place. That doesn't mean we can't allude to bigger problems in the American health care system, but we are -- and as I think I said before, the processes that are used in those other countries, for a whole range of reasons, are much -- are trying to solve a much different problem because they're setting prices, they're setting much lower set of things for the international system than what we're trying to do here. We're trying to -- one way to think about it is this Bullet Point D is designed to give a tool to cut off the very worst abuses, not solve a broader question about what a fair price would be for a drug to accelerated approval. And because of some nuances in the American system, like if you get too strict, this will go through the other process and you won't get the drugs, how one would deal with that is much more complicated than

we're anywhere close to doing, at least in this chapter.

So I guess it's my prerogative to have the last word, so I'm going to take that. We're going to take a five-minute break. We're going to come back and talk about unified PAC. So, again, thank you all.

[Recess.]

DR. CHERNEW: Okay. We are back, and we are going to now hear a presentation on unified post-acute payment, which is a long body of work that we have been doing for a quite a long time, and I think Carol, you are going to start, and then Kathryn.

DR. CARTER: Mostly just me.

DR. CHERNEW: Okay. Mostly just you. For moral support. That's the kind of teamwork we --

DR. CARTER: She was very involved.

DR. CHERNEW: Yeah, I'm sure. It is wonderful to have both of you there. Carol, go ahead.

DR. CARTER: Okay. Good afternoon. Before I get started, I want to remind the audience that they can download a PDF version of these slides in the handout section of the control panel on the right hand of the screen.

Today's presentation is the third in a series to prepare a mandated report on a prospective payment system for post-acute care. This draft is our best attempt to reflect where we think Commissioners are with regards to recommending a PAC PPS. We've shifted the emphasis from stating that implementing a PAC PPS is imperative to outlining the key design and implementation issues that will confront policy makers if they choose to move forward with a unified payment system.

Today, I'll briefly recap the Congressional mandate and its rationale for a unified payment system and summarize the conclusions about the design that we've already talked about. Then I'll present new material on considerations for implementing a PAC PPS, including whether there should be a transition, the level of aggregate payments, and companion policies that would need to accompany a PAC PPS. I'll highlight the key takeaways and then present the chair's draft recommendation.

The IMPACT Act of 2014 required the Secretary to develop uniform patient assessment items and quality measures so that patients and outcomes in the four settings could be compared. It also mandated three reports on a

prospective payment system for post-acute care.

The last report is due on June 30, 2023. The PAC PPS design must span the four PAC settings -- that is home health agencies, skilled nursing facilities, inpatient rehabilitation facilities, and long-term care hospitals -- and base payments on patient characteristics, not the setting.

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

There were a couple of reasons why policymakers were interested in a PAC PPS. Our work and that done by others had found that beneficiaries who look similar in terms of their condition and comorbidities can be treated in different settings. But because Medicare uses separate payment systems for each setting, payments can differ substantially. A unified payment system would change that and base payments on patient and stay characteristics.

In addition, there were shortcomings in the payment systems in place at the time. The home health and SNF PPSs encouraged providers to furnish unnecessary rehabilitation therapy, while the LTCH payment system encouraged LTCHs to admit low-acuity patients. Since the

IMPACT Act, CMS has made substantial changes to these payment systems, and I will note that no changes have been made to the IRF PPS during that period.

Turning to the design of a PAC PPS, our study and that done by CMS and ASPE demonstrated that a unified payment system was feasible and could establish accurate payments. The designs could also establish relatively uniform profitability across different types of cases that would dampen the incentives to selectively admit or avoid certain types of cases.

We concluded that the CMS/ASPE prototype would be a good starting point for a design. In large part, it is consistent with the preferred features identified by the Commission. However, it adjusts the payment rates by the setting, thereby undermining the design's uniformity. If CMS proceeds with refining a design, this feature should be phased out over time.

As I said at the beginning, we are not recommending the implementation of a PAC PPS. But if policymakers choose to proceed, there are three broad considerations for refining the design. The first is whether to prioritize uniformity or accuracy when there

would be a tradeoff between them. To support the main objective of a PAC PPS, policymakers should accept less accuracy for uniform design features. Deviations from uniform elements should be limited to those needed to avoid access problems for beneficiaries or that would otherwise create large distortions in payments. For example, an adjuster for home health stays would be needed to avoid large overpayments to home health agencies and large underpayments to institutional providers.

Second, policy makers would need to re-evaluate each payment adjuster. Adjusters should have a conceptual relationship to the costs of care. And then question would be, should Medicare pay for those cost differences? The need for the adjuster and its size should be based on empirical evidence.

Finally, CMS should consider the incentives inherent in the design. For example, do they encourage efficient care? Do they discourage patient selection?

Turning to implementation, there are two issues that I'll briefly discuss. The first is whether there should be a transition to a PAC PPS and the second is whether a PAC PPS would be implemented to be budget neutral

to current levels of payments.

A transition policy would help avoid payment shocks to providers. It would give them more time to adjust their costs and practices to the new payment system. However, a transition would delay redistributions of payments. During a transition, payments would be a blend of current, setting-specific payments and PAC PPS payments.

Our estimates of the impacts on payments suggest the need for a transition. Changes in payments would vary widely across providers. Obviously, the magnitude of the impacts would depend on the details of the design.

We estimated that over half of providers would experience changes in payments of 10 percent or more.

The wide range in impacts and the size of them indicate that a transition would make sense.

We also evaluated whether the transition would need to be long or short. One way to think about this was to look at the relationship between the current levels of profitability and estimated changes in payments. If the providers that would experience the largest decreases in payments were the most profitable or if providers that would experience the largest increases in payments were the

least profitable, then maybe a short transition would be preferable.

We found that changes in payments were generally inversely related to provider profitability. Of the providers whose payments would decrease by at least 10 percent, the majority were relatively profitable. They had payment-to-cost ratios greater than 1.1. That is, payments were 10 percent higher than costs. Of the providers whose payments would increase by at least 10 percent, the majority were relatively unprofitable. Their payment-to-cost ratios were below 1, at 0.9.

We concluded that a transition should be short so that the redistributions in payments would occur sooner.

Turning to the level of payments, if a PAC PPS is implemented, policymakers would need to decide whether aggregate payments under the new system should be set to equal to those under the current PPSs, that is, or whether the level of payments should be lowered to more closely align payments to costs. A reduction could be implemented at once or over multiple years. We modeled three scenarios. Our results are similar to our analyses in 2018, when the Commission recommended lowering the level of

payment and having a short transition.

Our updated results are shown in the table. On the left, we see that if a PAC PPS were implemented with no transition and no reduction to the aggregate level of payments, then aggregate payments would be 14 percent higher than aggregate costs. In the middle, you can see the results of if the level of payments were lowered by 5 percent, but there was no transition, aggregate payments would be 8 percent higher than costs. And on the right, we show what the results were if a 5 percent reduction was phased in over three years, and that is the first year we are seeing, in that year payments would be 12 percent higher than aggregate costs.

So far, we've focused on the design of a PAC PPS, and that is the circle at the top. Our work and the work done by the Secretary have demonstrated that a uniform payment system is feasible. But implementing a PAC PPS would require companion policies identified by the other circles. They include aligning benefits and cost sharing, implementing a value incentive program, and developing a common set of conditions of participation for providers.

These companion policies pose additional

challenges to implementing a PAC PPS, and we are going to talk about each one in turn.

Currently, coverage and cost sharing rules vary depending on the PAC setting where beneficiaries receive their care. For example, a prior hospital stay is required for coverage for SNF services, but not if the care is received in the other PAC settings. Co-payments are required when beneficiaries use institutional post-acute care but not home health care.

When distinctions between settings narrow, benefits and cost sharing should be aligned. Changes to coverage and cost sharing could have significant implications for some PAC users and program spending. For example, requiring cost sharing for home health care could restrict services for some beneficiaries. Eliminating the prior hospital stay for PAC coverage is likely to raise program spending.

We expect that aligning benefits and cost sharing would be controversial and would be a multi-year undertaking.

Currently, Medicare's Conditions of Participation differ by setting, each with its own cost implications.

When providers are paid under a uniform payment system, they should face the same regulatory requirements and the associated costs.

In the past, the Commission proposed shifting requirements that are based on setting to requirements that would be commensurate with the acuity of patients the provider treats. This proposal is described in more detail in the paper. An overhaul of the Conditions of Participation to a common set of condition-defined requirements would be a substantial departure from current policy and could raise requirements, and the associated costs, for some providers. This is another dimension of a PAC PPS that would be a multi-year endeavor.

Another companion policy would be having a value incentive program. By tying payments to a provider's performance on a given set of measures, Medicare would increase the value of its purchases. Especially under fee-for-service, a value incentive program dampens the incentives to generate unnecessary care or to lower costs in ways that could harm patient care.

The Commission has done extensive work on the design features of a value incentive program for post-acute

care. In a congressionally mandated report in 2021, the Commission evaluated the current SNF value-based purchasing program and recommended eliminating it and replacing it with a new program. In another mandated report, in 2022, we outlined the key decisions policymakers would need to make to develop a value incentive program to span the four settings, and we have discussed the key design features, shown in the middle box. Since the IMPACT Act was enacted, CMS has developed several measures that are consistent across the four settings.

In addition, we underscored the need for CMS to develop measures of patient experience and measures of functional status that are accurate. And we also discussed the need to define and measure the social risk of a provider's patient population.

The companion policies present a host of challenges to implementing a PAC PPS. Aligning benefits and cost sharing will involve tradeoffs that are likely to be controversial.

A common set of Conditions of Participation would impose new requirements for providers, and some of these would be relatively easy to align but others will be more

complicated.

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

Two separate bodies of work, ours and that completed by CMS/ASPE, found that designing a PAC PPS is feasible and could establish accurate payments. And while designing a payment system would be relatively straightforward, implementing the companion policies would not be. Each is likely to be controversial, will require considerable resources to develop, and take many years to implement.

The changes CMS has already implemented to the SNF, HHA, and LTCH PPSs are substantial and corrected shortcomings in the then-current PPSs. Given the considerable agency resources that would be required to implement a unified payment system, CMS could consider smaller-scale, site-neutral policies that would address some of the overlap in the patients treated in different settings.

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

At the outset, I mentioned that the Commission will not be voting whether to implement the PAC PPS. This is because the complexities to implement such a payment system and CMS's limited resources, the changes CMS has already made to three of the setting-specific payment systems, and your feedback over the past three discussions of a unified payment system. Rather the Commission will vote on whether to forward the entire report to the Congress, with the report outlining the considerations policy makers would need to make if development work proceeds.

The chair's draft recommendation reads:

The Commission forwards to the Congress the report on the unified post-acute care payment system required by the Improving Medicare Post-Acute Care Transformation Act of 2014.

This language is essentially identical to the

recommendation that was made back in 2016.

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

DR. CHERNEW: There's a lot of history at MedPAC. I have been around MedPAC for a long time and I have seen a lot of history, others even further than me. Nothing captures that history as much as the work we've done related to this sort of post-acute care activity. It is unbelievably important. So I guess in the spirit of Larry's comment complimenting the staff, I will say both great job, but understand that is a blanket great job for this report, past reports, reports prior to the past reports, and all the stuff in between.

This has been a long time coming. As the materials point out, since we started there has been a lot of movement in the direction that we encouraged when we started the idea sort of unifying post-acute care.

So that was a longer, but I think deserved, exceptional thank you for all that was done here. There is a lot of, lot of, lot of complexities, and I am guessing that even David has learned a ton about the regulatory nuances about what it takes to be different types of

providers and what means to be the same type of service, and all the rules that these providers have to live under, which is really extraordinary.

Anyway, all of that said, one reason why my speech is a little bit longer is I'm waiting for the Round 1 queue to fill up. How is the Round 1 queue looking, Dana?

MS. KELLEY: I don't have a Round 1 queue.

DR. CHERNEW: There we go. We are going to start with a Round 2 comment, and that is going to go to David. So David, why don't you start us with Round 2.

DR. GRABOWSKI: First, thanks, Carol. Super work. Amol just joked. You threw a perfect game here. No Round 1 questions, so you've done it. Congratulations.

First, I'm definitely in favor of the Chair's draft recommendation. I like the design features outlined in the chapter regarding the PAC PPS. I think the point was made during the presentation, but I'll just reemphasize it, that the policy landscape has changed considerably, and Mike, I loved the way you framed that, that it's really changed in a way that's very consistent with a lot of our recommendations over the past 7, 8 years, in terms of

shifting from SNF and HHA payment systems very much built on therapy to ones built on patient characteristics, and that is very consistent with our unified PAC work, and then obviously the site-neutral payment system for LTCHs.

So I just wanted to make a series of comments, largely on the new material that was in the readings. I won't subject anyone to my comments again from September, Part 2. One thing I did learn -- Mike was teasing me there, but I had learned and forgotten. The issue that I think I and others had raised back in September was just the importance of functional status, and that needs to be coded accurately. It is currently not. It is self-reported by the different post-acute care providers.

You make this great point on page 13 about the activities not attempted, or ANA, coding and how if that's coded it immediately defaults to the most dependent category. That's ridiculous. Like it's hard to get providers to code accurately, but that seems like low-hanging fruit we could fix. I had lost sort of track of that point, so that was something that Mike, said, yeah, that's a red flag. There you go, something that we could really implement, to hopefully make the coding a bit

better.

I do think ultimately it is going to take greater oversight and auditing on the part of CMS to really enforce the quality of the coding, but at least in the short term maybe there are some other steps we could do.

The second point I wanted to make was around implementation. I think you don't need the three years. I don't want to sound like our former colleague, Bruce Pyenson, here, who wanted to sort of implement everything tomorrow. I think you can take a year or two, but I don't think you need a long runway here, just given we have already made this transition in home health and SNFs. So I don't think you need a lot of time.

I really like that bullet point -- I think it was on the second-to-last slide, the designing of payment system will be relatively straightforward. Implementing the accompanying policies would not be. I think those companion policies are really tricky.

I was just going to run through three of them with some thoughts, the first being cost sharing. I know we have talked about this at prior meetings, how we have just really kind different cost sharing across fee-for-

service sectors here, home health no cost sharing, SNF starts at Day 21. It's a real kind of mix and match. So, in theory, unified payment would have kind of unified cost sharing.

I like the concept that was raised in the chapter around could you think about this from more of a value-based perspective, and I'm not just sucking up to Mike here. Could you actually think about directing folks to kind of higher value settings, and you mentioned maybe kind of greater cost sharing and some of the lower value settings for particular types of patients. I like that concept a lot. It would take a little more thought about how that actually gets set up. I don't necessarily -- I think you need unified cost sharing or a form of cost sharing. You could think about very different levels across the four sectors.

The second point I wanted to make was on the three-day rule. I have been a big supporter of the three-day rule. This is a requirement for SNFs, that in order to qualify for services in traditional Medicare you need to spend three days in a qualifying hospital stay.

During the pandemic we have been studying what

happened, and not surprisingly there was a big increase. But what we are finding is a lot of that increase was for COVID patients, and it seems like it really kind of increased during periods of big COVID outbreaks and then was a lot lower when COVID was less prevalent.

And so I'm wondering. You know, I've historically been very resistant, especially for the long-stay nursing home residents, but I don't know if the three-day rule is quite the deal breaker, I once thought it to be. And I wonder if there's a way to kind of think more carefully about that, that if you really wanted to have uniform requirements and needed to drop the three-day rule, I think there is a way to do that such that you wouldn't see the floodgates open in terms of SNF use.

The final point I just want to double down on, on the PAC VIP. I think that's a great idea, and that's something that I hope MedPAC continues to pursue, regardless of where the unified PAC goes, but thinking about common measures across the four settings, also thinking about patient experience measures. Dana is not here for this meeting, but I know she has been a big proponent of trying to identify better measures across the

four post-acute care settings. So I want to see us continue to pursue that work, regardless of how the unified PAC payment plays out.

I'll stop there and just once again say, Carol, great work, and I'm very excited about where we've ended up with this. Thanks.

DR. RAMBUR: David, I was wondering if you can just clarify a bit why you've been supportive of the three-day rule, because I've always been a little bit on the other side of it, because it seems hard to imagine that people are going to be breaking down the barriers to get into a skilled nursing facility.

DR. GRABOWSKI: Certainly community. It has never made a sense. But for long-stay nursing home residents it's been a way to take somebody who is associated with a $200 payment rate, send them down the street to the hospital, they stay the three days, they come back at $600, $700 a day. And so it's been an incentive to actually hospitalize folks. The three-day rule is a way to guard against those kind of unnecessary hospitalizations. In a world without kind of the three-day rule the concern was that it would just convert long-stay nursing home

residents who are $200 a day to $600 a day, without any kind of intervening health care.

DR. CASALINO: In the community, you're right. It drives clinicians nuts.

DR. GRABOWSKI: It drives them nuts, yeah.

DR. CASALINO: You want to spend days on hospitalization? Fine. I'll put them in the hospital and expose them to all kinds of things, and so on and so forth. It made no sense for a community.

DR. GRABOWSKI: No, and I hear this all the time from physicians.

MS. KELLEY: Greg.

MR. POULSEN: Okay. I really like this as well. I support the recommendation completely. I guess I just wanted to maybe take a quick trip down memory lane because I may be the only person here who was actually involved in discussions about whether to implement DRGs or not. That was a while ago, folks. Okay, Betty, great. Thank you. Bless you. I feel better.

But some people may not remember, and you probably don't, that there was a big discussion about whether it would put sophisticated, big hospitals out of

business or little community hospitals out of business. You're going to pay the same to both of these radically different sized and capable organizations? It's kind of worked out. So I think that there is history here that suggests that people will figure out where the appropriate place to locate folks is, and that that doesn't necessarily have to involve differences in payment for that to work. So I think we've got history here that suggests that that's capable, and it was right here with CMS.

The other thing, though, that I guess I would say is as I reread this and reread some of the other things, I think there's an implication that some people might read into this that home health -- it's the thing that's not like the others in the three. And you could read into it, just kind of the way the tone is in some places, that while we really overpay for this, and it may imply that it's low value, and I think that the contrary is frequently the case. That's the place that, if it works, that's the most cost-effective place for people to be. You can tell that from the capitated groups. That's where they want to get people. That's where they'd much rather have them in than any of the other three.

So it's just tone. I just want to make sure that we don't imply that home health is -- we agree it should be paid less. I voted for that along with all of you. It clearly has a lower cost. But that shouldn't imply that that's not the place that people should be. The in-fact is that we're getting tremendous value there in part because we're getting a whole lot of free caregiving that's being implied.

And there was one implication there that I think is important and that is should the cost sharing to the consumers be differential for home health? My argument is it already very much is because it's family members and others that are paying a big portion of the pay by providing the caregiving.

So that's not a big deal at all to me but my sense was that you could read this and imply that you think that home health is lower value thing, and I just wanted to make sure that the way we do the tone doesn't ever feel that way. Thanks so much.

MS. KELLEY: Robert.

DR. CHERRY: Thank you. Great report, really well done. Just constructive feedback.

In the pre-read materials on Table 1 it does mention that these patient characteristics would establish accurate payments across the patient populations based on currently available data. I have no doubt that of the accuracy of the data. My question is, is it both accurate and equitable, because I don't think race, gender, ethnicity is currently taken into consideration into the model, so the social risk factors is not really fully elucidated.

So I mention this with a cautionary tale. For quite some time kidney function has been evaluated using a blood test called a creatinine test, and you had to adjust for race in order to understand the accuracy across different populations. And now many practitioners are now using a blood cystatin test instead, which doesn't need to adjust for race.

So when we are talking about various patient characteristics, and particularly when using coded data, there could be problems where there could be inequities in terms of using this particular model, particularly if the model is going to be used for beneficiary cost sharing.

So I would suggest, actually, to be able to

actually analyze this across different demographic groups, just to make sure that it's both accurate and equitable. Otherwise, really great work. Thank you.

MS. KELLEY: Amol.

DR. NAVATHE: Thanks. I also wanted to echo Commissioner comments that this is a fantastic portfolio of work that has evolved over many years, and I commend you, Carol, on driving a lot of that.

I just wanted to highlight a couple of points. I think generally, of course, the work is really strong and I support the draft recommendation. I think there are a couple of pieces that are in the report that are worth highlighting, and I think one of the points was it's really important to get the incentives right here. I think, for example, on page 27, I think, essentially there's a discussion of there's a tradeoff between model accuracy and getting incentives right, and we need to get the incentives right, perhaps acknowledging that we're going to have a little bit less, quote/unquote, "pure model accuracy" in terms of the spending model itself. But that paired with the transition that actually offers an opportunity for us to get to a payment system that is more rationalized and

that works better for beneficiaries and the like.

In terms of some of the other additional points that David covered also, I'll just touch on them briefly. I also support the value incentive program. I think rethinking cost sharing here is important. For example, even if it's modest, I think a small amount of cost sharing in this space of home health may be warranted, given what we see in terms of use and payment rates and the like. And if this kind of mechanism, if you will, of the unified PAC PPS, where we are headed, can be a mechanism to do that, along with, I would say I'd support the reduction of payments to a certain extent, given that there's so much overpayment that hasn't been addressed, despite our payment update recommendations over several years. I would definitely support that, again, importantly, in the context of the transition period that you have outlined. Thanks.

MS. KELLEY: Lynn.

MS. BARR: Thank you. Great work and I support the Chair's recommendations. I'd like to just plus-one on Amol's comment, and sorry Greg, but there's so much abuse of home health in certain parts of this country that I think actually coinsurance would be really important to try

to rein it in.

DR. CHERNEW: I think MedPAC has a recommendation about that, that was probably my first time around. But anyway, sorry. I don't remember DRGs, just to be super clear.

[Laughter.]

DR. CHERNEW: Okay. So I think now we have one more. I think Marge wants a Round 1 question. This is Round 1 now. We're just repeating.

MS. GINSBURG: Sort of.

DR. CHERNEW: You can make it a Round 3, Marge.

MS. GINSBURG: I guess this is more of a comment to the other comments about home health. Fifty years ago I was a home care nurse with the VNA in San Francisco, but it had a big impact on my views about home care, which back then, of course, was fabulous.

What I'm commenting on is I've always been opposed to the idea of the consumer cost sharing for home care, and the abuse of home care these days, they were coming from the clients. They are not demanding this. They are not asking for more than is needed. My concern is that people will refuse it if they don't have the cost

sharing adequately covered by a supplemental plan or something.

When the doctor says you need to go to a nursing home or you need to go to a sub-acute setting or something else, that's fine when you're going to another setting. But somebody's coming to my house to help me figure out how to use my walker and how to make sure that I'm taking my meds right? Very important things. I worry that they are more likely to turn it down if they have to pay for it. It's a very different view than when you are moving a patient to a different inpatient setting. It really is different.

So I just didn't want to put all the blame of the abuse of home care, put any of the blame on the abuse of home care on clients. That's not where it belongs. So thank you.

MR. POULSEN: Which is not to say that it doesn't occur. I totally agree with you, it does.

MS. BARR: It's anecdotal but the stories that I hear is that the home health agencies are offering basically, "We'll come to your house. We'll do your dishes. We'll clean up a little bit. It's free." And

people are like, "Okay." And so it's that little bit of cost sharing. And again, 80 to 90 percent of our patients have supplemental insurance.

MS. GINSBURG: Right, and I agree. I'm probably naïve. Fifty years ago home care was probably very different than it is now. None of that happened back then.

MS. BARR: But it is a really important service, and I do value it highly.

DR. CHERNEW: So we are not making a recommendation, in case those are listening at home, about cost sharing or not. We are raising a bunch of issues about how to unify across these things.

And if I have followed this correctly, Dana, that was the end of Round 1, and de facto, the subsequent Round 2.

So let me make a general comment about where I think we are and how we've come to this position. There have been incredible improvements. There are a lot of nuances. The chapter is unbelievably good at both raising the issues, in general, comparing them to what CMS has begun to develop, that they may or may not do. I'm not sure what will happen given the ways at getting at some of

these issues in a much more targeted as opposed to unified way. But I think what happens often is you start with, there are a lot of similar patients that are overlapping. Let's unify this. And then you realize these places where they're not overlapping becomes a really big problem, and I think actually the path that the world took was probably better than the path would've been otherwise.

I'm going to give Cheryl the last Round 2 question in a minute.

But the only other thing I would say about some of this is, as important as this is, if we move to more population-accountable models we have less of a concern about all of these. Some of these problems are exacerbated, in my mind, by complex fee-for-service interactions, and one of the motivations, I think -- and I think we've seen in all the alternative payment models that post-acute is the ATM for ACOs, is my general view, and to some extent all the episode models as well.

I think that's valuable in figuring out, to the point of this conversation, where the incentives need to lie. And so, again, we have a report that I think does exactly what it should do, and I think it sets the exact

right tone, and we hope that the readers of this report, those people listening, really find value in it. I think all of the Commissioners did. But I think where policy is now is actually probably a reasonably good place, and to the extent that it is going to help continue to move the ball forward, I think that's all probably a good thing.

You were going to say something with Cheryl. So Cheryl now has a comment. Dana is going to get the last Cheryl word. Dana.

MS. KELLEY: Okay. Cheryl says, "This is important work and many thanks to the staff for all the work in this space over multiple years." She supports the Chair's proposed draft recommendation. She would encourage staff to ensure that the language in the report strongly recommends advancement of the development of the VIP, even if CMS does not move towards a unified post-acute PPS. "Measures to ensure that post-acute care providers are not stinting on care are critical, as are measures of overuse of care."

She supports inclusion of outcome measures and measures of patient experience, and also strongly supports the need to address the problems in coding functional

status. "And we should recommend that CMS should move on the proposed strategies to improve this information, even without a unified PAC PPS."

DR. CHERNEW: Okay. So again, thank you for this. Are there staff comments, any reactions? Jim? Other Commissioners on this or other things you want to revisit?

Okay then. We are going to close. I would like to invite all of the folks at home to send comments to meetingcomments@medpac.gov or go to the website and you can send us comments on any of the topics we discussed today or anything else that you happen to be thinking about.

We really do appreciate the staff for all of the work that you have done. Thanks to the Commissioners for, I think, a wonderful set of comments. And thanks to the people at home for tuning in.

We are going to start tomorrow, with, I think, will be lively discussions of site-neutral payment and Medicare Advantage. Actually, it's in the other order. I think it's Medicare Advantage first, and then site neutral.

So again, thank you very much, everyone. Have a wonderful night, and we'll see you tomorrow morning, 8:30.

[Whereupon at 4:52 p.m., the meeting was recessed, to reconvene Friday, March 3, 2023, at 8:30 a.m.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Friday, March 3, 2023
8:31 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
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AGENDA PAGE

P R O C E E D I N G S

[8:31 a.m.]

DR. CHERNEW: Good morning, everybody, and welcome to our Friday session. We have two terrific topics. The first one happens to be a passion of mine and has gotten some attention lately. That's Medicare Advantage. And then we'll talk about site-neutral payment, another topic we've spent a lot of time on here at MedPAC.

So, without further ado, I'm going to turn it over, and I think, Luis, you're starting.

MR. SERNA: Correct.

Good morning. Medicare beneficiaries who have both Part A and part B can enroll in an MA plan. In 2023, the majority of eligible beneficiaries are likely to be enrolled in MA. In today's presentation, we are going to discuss the challenge of determining MA payment rates in an environment where using fee-for-service as the basis for MA payment rates creates the bias in favor of MA plans and where MA is the predominant.

We'd like to thank Katelyn Smalley for her help with this presentation. As a reminder, 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'm going to start by discussing how Medicare uses fee-for-service spending to pay MA plans and explain how this creates a favorable bias for MA plans. Then we will note some concerns about the effect of declining fee-for-service enrollment on MA benchmarks and present three alternative approaches for setting MA payment rates that are less dependent on fee-for-service spending data.

We plan to include the material discussed today as part of an informational chapter without recommendations in our June report.

The MA program allows beneficiaries to receive their Medicare benefits through private plans. These plans cover the standard Medicare benefit, and nearly all offer extra benefits. Payments to MA plans are based on plan bids, benchmarks, and quality scores. Each year, plans submit a bid for the amount they think it will cost them to provide Part A and B benefits, including medical costs, administrative expenses, and profit. Each plan's bid is compared to a county payment benchmark, which ranges from 115 percent to 95 percent of local fee-for-service

spending. By law, the MA benchmark is the maximum amount Medicare will pay for an MA plan to provide Part A and B benefits. Thus, the key takeaway for this presentation is that MA payments are directly tied to fee-for-service spending.

County benchmarks are based on the average fee-for-service spending for a beneficiary with average health status. This is calculated by standardizing spending to a risk score of 1.0. Risk scores increase payment for MA enrollees who have higher expected costs based on their demographics and medical conditions. On average, risk scores predict costs accurately but will underpredict or overpredict costs for each beneficiary.

Underpredicted costs occur when actual costs are above the predicted costs. Overpredicted costs occur when actual costs are below the predicted costs.

MA benchmarks assume that on average the accuracy of the risk adjustment model will be the same per fee-for-service and MA enrollees.

However, MA plan and beneficiary incentives may cause differences for MA enrollees that are not accounted for by the risk adjustment model, leading to favorable

selection for MA plans. This favorable selection occurs prior to any differential coding between MA plans and fee-for-service.

MA plans may influence favorable selection through care management restrictions that are unlikely to occur in fee-for-service, such as narrow networks and prior authorization.

In addition, MA plans have an incentive to require at least some cost sharing for many services to avoid unnecessary care. These plan incentives may influence self-selection of beneficiaries by avoiding beneficiaries or encouraging disenrollment from beneficiaries who have certain health conditions and seek care from providers that may be out of network, such as cancer centers and psychiatrists.

In addition, some beneficiaries may seek to mitigate perceived delays in care that may result from prior authorization.

Further, beneficiaries who expect to use more medical services may prefer to stay in fee-for-service and purchase comprehensive Medigap coverage.

The research literature suggests that risk scores

on average overpredict spending for the MA population. Again, this is before any coding differences occur between fee-for-service and MA. Because MA benchmarks rely on risk-standardized fee-for-service Medicare spending, they reflect the higher level of costs associated with the fee-for-service enrolled population rather than a plan's enrollees. This results in MA plans experiencing favorable selection. To the extent favorable selection occurs, it allows plans to bid lower than fee-for-service spending before producing any efficiencies in care delivery. This creates both overpayments for MA plans and introduces bias in the comparison of risk-standardized spending between MA and fee-for-service enrollees.

We conducted an analysis to understand the extent of MA favorable selection and payment benchmarks. We compared the last year of fee-for-service spending for beneficiaries who switched from fee-for-service to MA with the spending of beneficiaries who remained in fee-for-service, and we adjusted for the geographic distribution and risk scores of MA entrants.

We tracked beneficiaries from the time they entered MA through their enrollment status in 2010. As

shown in the figure on slide 6, beneficiaries that remained in MA tended to be those that initially had greater favorable selection.

As you go down this chart, the longer a beneficiary remained in MA, the more likely it was that they were favorable to MA plans when they were in fee-for-service, as indicated by the green bars, getting further away from 100 percent of the expected fee-for-service costs prior to MA enrollment.

For example, let's start with the top two rows corresponding with beneficiaries that entered MA in 2018. The original cohort of MA entrants in 2018, indicated by the dashed line, had spending that was 96 percent a fee-for-service in the year prior to enrolling an MA. By 2019, only a small share of these beneficiaries were no longer an MA. However, enrollees that either disenrolled from MA or died were unfavorable to MA plans, and those that remained in MA were relatively favorable. Thus, when we restricted the MA entrants to those that remained in MA for two years, the top green bar, this sub-cohort of beneficiaries had spending that was 94 percent of fee-for-service.

Now let's look at the bottom row in figure. The

original cohort of MA entrants in 2012, indicated by the dashed line, had spending that was nearly 90 percent of fee-for-service in the year before MA enrollment. This includes beneficiaries that either died or disenrolled from MA. When we restricted the MA entrants to those that remained an MA from 2012 to 2019, this sub-cohort of beneficiaries had spending that was 74 percent of fee-for-service. Thus, enrollee that are most favorable to MA plans tend to remain in MA.

The substantial favorable selection in the year before MA enrollment coincides with historical data that suggests favorable selection continues through all years in MA. When examining the historical 2008-to-2019 fee-for-service experience of 2020 MA entrants, we found favorable selection that persisted, even for beneficiaries with at least 13 years of MA eligibility.

Overall, we found approximately 11 percentage points of MA favorable selection in 2019. Thus, even assuming no coding differences, if the average MA bid was 89 percent of fee-for-service spending in 2019, after accounting for favorable selection, the average MA bid would be nearly equivalent to fee-for-service spending.

Because of favorable selection alone, Medicare payments to plans for the Part A and B benefit should have been about 11 percent lower in 2019, and this overpayment would be even greater if we accounted for plan coding intensity.

These findings raise concerns about the appropriateness of basing MA benchmarks exclusively on fee-for-service spending data. Future options for benchmarks should consider the extent to which MA favorable selection is addressed.

Now Eric will summarize the potential challenges of declining fee-for-service enrollment.

MR. ROLLINS: Another concern about MA benchmarks is that the share of Medicare beneficiaries enrolled in fee-for-service is decreasing as more beneficiaries enroll in MA. In absolute terms, total fee-for-service enrollment peaked in 2017 at 38 million beneficiaries and has since declined to about 34 million.

The fee-for-service spending for a county can become unstable if the number of fee-for-service enrollees becomes too small, and CMS now makes what's known as a "credibility adjustment" to stabilize the estimates for

counties with fewer than 1,000 fee-for-service beneficiaries. The number of counties that need this adjustment will likely increase in the future as fee-for-service enrollment declines.

In addition, we have observed that some population characteristics, such as the share of beneficiaries who are eligible for full Medicaid benefits or the share who qualified for Medicare due to disability, are higher in counties with low fee-for-service enrollment, which raises concerns about the representativeness of the fee-for-service-based benchmarks.

To be clear, apart from favorable selection, we have not identified a problem with the way fee-for-service spending data are used to calculate benchmarks at this point in time, but problems could arise in the future if fee-for-service enrollment continues to decline.

Given the potential weaknesses of using fee-for-service spending data to set MA benchmarks, we're now going to switch gears and look at three alternate ways of setting benchmarks. Each option either reduces or eliminates the use of fee-for-service spending data. The first option would use plan bids to calculate benchmarks, also known as

"competitive bidding." The second option would use both fee-for-service and MA spending data to calculate benchmarks, and the third option would set benchmarks and then update them using a fixed growth rate instead of fee-for-service spending growth rates.

Under the first option, competitive bidding, the MA benchmarks would be based on plan bids instead of fee-for-service spending data. Over the years, there have been several proposals to use competitive bidding in MA, and the concept received serious consideration during the development of the Affordable Care Act.

One thing I'd like to highlight is that "competitive bidding," as we use the term, would differ from premium support because it would only be used to determine MA payment rates and would have no direct effect on the fee-for-service program or fee-for-service premiums. The use of bidding is appealing because it could potentially generate more accurate payment rates relative to MA costs and more program savings.

Here's an illustrative example of how MA plan payments could change under competitive bidding. The current benchmark system is shown in the three bars on the

left. Note that the vertical access has been truncated to show more detail. Based on its per capita fee-for-service spending of $1,000, this county has a benchmark of $1,075, which CMS calculates before plans submit their bids.

Three MA plans submit bids ranging from $900 to $800, shown in the purple bars. Remember that bids include plan administrative costs and profits. Each plan gets a rebate equal to 65 percent of the difference between its bid and the benchmark, shown in the yellow bars. When rebates are included, total Medicare payments to the plans range from $1,014 for Plan A to $979 for Plan C.

With competitive bidding, shown in the three bars on the right, the benchmark would be determined by plan bids and would not be tied to the county's fee-for-service costs. There are several ways you could use plan bids to determine benchmarks, but the most common proposal has been to use the enrollment-weighted average bid as the benchmark.

In this illustrative example, the average bid is $850. As under the current system, plans that bid above the benchmark must charge a premium equal to the difference between the two. So Plan A's enrollees have a $50 premium,

which is shown in blue. Plans that bid below the benchmark receive rebates that are used to either lower enroll enrollee premiums or provide extra benefits.

In many proposals, plans receive the full difference between the benchmark and the bid, instead of just part of the difference, to give them stronger incentives to bid lower. So Plan C receives $50 in rebates. Since Plans B's bid happens to equal the benchmark, the plan would not charge a premium or receive rebates. As a result, unlike the current system, Medicare would pay each plan the same amount, the $850 benchmark amount.

There are some design issues that policymakers may want to consider for a competitive bidding system. First, plans could be required to have standardized benefits, which is an issue that the Commission examined in some depth last fall.

The use of standardized plans would make it easier to compare plans on an apples-to-apples basis and promote price competition, because any differences in plan bids would be reflected in plan premiums. The standardized MA benefit package could also include a specific amount of

extra benefits to help ensure that MA remains an attractive option relative to fee-for-service, even if competitive bidding reduces payment rates.

Second, you would need to consider how to calculate the benchmark. As I said, many bidding proposals would use the enrollment-weighted average bid as the benchmark, but other approaches, like using the median bid or the second lowest bid, are also possible. Using the average bid would give large insurers more influence over the benchmark but could also be more stable over time, since enrollment patterns tend to change slowly.

Third, the MA market is relatively concentrated, which raises concerns that plans in some areas might use their market power to generate benchmarks that are higher than the ones we have now. Policymakers could address this concern by putting caps on benchmarks that are based on current benchmarks or plan payment rates, which would help ensure that bidding generates program savings.

Fourth, one advantage of competitive bidding is that it would reduce the impact of favorable selection and coding intensity on program spending. Under a bidding system, benchmarks would be based on standardized bids,

which is the plan's bid divided by its projected risk score. Favorable selection and coding intensity push up a plan's risk score, and as a result, they would decrease its standardized bid and put downward pressure on benchmarks and payment rates.

Finally, based on previous experience with other MA payment changes, we anticipate that plans would change their bidding behavior under a new system. So there is some uncertainty about the overall impact of bidding on payment rates and program spending.

DR. JOHNSON: A second option is to base benchmarks on spending for the entire Medicare population. This option would keep current bidding and benchmark structure, but the benchmarks will be based on a blend of spending for fee-for-service and MA enrollees in each local area. If the fee-for-service population declines in a local area, the benchmark would rely more on the spending for the MA population in that area.

Similar to current policy, benchmarks based on all Medicare spending would be empirically based, meaning that they would automatically adjust for changes in prices of services, new technologies and coverage decisions, or

fluctuations in care-seeking behavior.

Finally, the influence of favorable selection in MA would be reduced because, as the share of MA enrollment grows in the local area, the benchmark would rely less on fee-for-service spending.

Under this option, spending for the fee-for-service population in a local area would be calculated as it is under current policy but would include adjustments to reflect prior MedPAC recommendations to establish benchmarks using beneficiaries who have both Parts A and B and to use payment areas that are larger than counties.

Spending for the MA population in a local area could be based on MA encounter data in the future. However, we have found that encounter data do not include records of all services provided to MA enrollees, and encounter data do not currently contain complete spending information.

For this presentation, MA spending is instead estimated using plan bids. The MA spending estimate would include spending for Part A and B services plus an add-on to allow for plan rebates. This rebate add-on should be large enough so that plans can attract beneficiaries but

low enough to produce savings for the program. One possibility is an add-on of 10 percent of the national average plan bid.

Finally, MA and fee-for-service spending estimates would be projected forward to the payment year using local fee-for-service growth rates and then combined using the MA and fee-for-service share of enrollment in each local area as weights.

Using the method described above -- on the previous slide, we simulated benchmarks for 2022. The top figure shows that simulated benchmarks would be very similar to fee-for-service spending in many areas with about half of areas between 99 and 101 percent of local area fee-for-service spending.

Similar to benchmarks under current policy, the simulated benchmarks are somewhat higher in areas with lower fee-for-service spending, allowing for greater plan participation, and lower in areas with higher fee-for-service spending to generate some savings. Overall, the simulated benchmarks are about 8 percentage points lower than the benchmarks were under current policy for 2022.

Therefore, in the bottom figure, we calculated

actual plan bids as a percentage of the simulated benchmarks for 2022. The average plan bid was 86 percent of the simulated benchmarks, meaning that the average plan had a relatively high rebate amount.

In the local areas, the enrollment-weighted average plan bid in 2022 was lower than the simulated benchmark for all areas, noted as 100 percent in the figure.

These results indicate that benchmarks based on all Medicare spending would likely provide a viable alternative for Medicare for establishing benchmarks, and more plans are likely to bid below their benchmark under this approach.

One potential concern is that fee-for-service spending is used to some extent to establish the benchmarks, and therefore, these benchmarks would reflect some favorable selection into MA. The fee-for-service spending estimates could be based -- could be adjusted to eliminate the effects of differential selection between fee-for-service and MA.

On the other hand, highly concentrated local areas are also a concern. An MA organization that

dominates in the local area could have a large influence on the benchmark. Such concentration could be addressed by capping the weight of an individual MA organization in a market or by creating a minimum fee-for-service weight.

Alternatively, an overall cap on benchmarks could be set using the Commission's June, 2021 recommendation to rebalance MA benchmarks.

Finally, the amount of the rebate add-on to the MA portion of the benchmark may need to be adjusted to balance policy goals of plan access and program savings.

And now we turn to the third option, which would use a fixed growth rate to set MA benchmarks. Under current policy, benchmarks are updated each year based on national fee-for-service spending growth rate. The national growth rate can vary based on changes in fee-for-service spending trends. Over the past six years, the national growth rate has varied between 2.7 and 5.6 percent.

Under option 3, the current growth rate would be replaced with a fixed rate. To do this, policymakers would establish benchmarks in the initial year. These initial benchmarks could be set using MedPAC's recommendation for

revised benchmarks from June 2021. However, these fee-for-service spending-based benchmarks would need to be adjusted to eliminate the effective favorable selection in MA.

The second step is to determine the fixed growth rate, which we discuss on the next slide. The primary benefit of determining benchmarks with a fixed growth rate is that it establishes predictability in plan payment rates several years in advance. Predictable benchmarks may reduce a plan's effort to construct annual bids or negotiate with providers and may help plans budget for long-term projects.

One method to define the fixed growth rate is to use the CMS Office of the Actuary's projected growth rates for Medicare prices, volume and intensity, and demographic mix. Considering prices, MA plan payments track fee-for-service rates for most provider types, although there are a few exceptions. So this method would incorporate the full Medicare price growth rate.

MA plans are more likely to control volume and intensity growth relative to fee-for-service. So this growth rate could be reduced by a discount factor. A fixed growth rate with a 50 percent discount on volume and

intensity would equate to a 3.5 percent growth rate annually.

A second fixed growth rate method would be to use the growth rate for the Medicare prices plus a growth rate based on real U.S. gross domestic product. Real GDP is the inflation-adjusted growth rate of the value of all goods and services produced in the country over a specified period of time. A fixed growth rate using Medicare prices and real GDP growth minus an adjustment of 0.5 percentage points would equate to a 2.9 percent growth rate annually.

Under current policy, benchmarks are empirically based and automatically adjust for fluctuations in spending trends. However, a preset fixed rate that is independent of actual Medicare spending would require a method to assess the adequacy of plan payments and determine whether an adjustment to the fixed rate would be necessary.

MedPAC assesses fee-for-service Medicare's empirically-based rate updates by considering provider financial performance, the number of providers participating in Medicare, providers' access to capital, and other factors. Applying these metrics to MA may be possible, but evaluating MA plan margins could be

particularly difficult due to the increasing number of vertically integrated arrangements with providers. And the Commission has concluded we do not have meaningful information about plan quality and service use.

If indicators of payment adequacy are unclear, policymakers' assessment of adequacy and any adjustments to the rate could be vulnerable to stakeholder influence.

That brings us to the discussion. We'd like to get your feedback about the implications of favorable risk selection in MA and on the three alternative options for setting MA benchmarks, competitive bidding, benchmarks based on both fee-for-service and MA spending, and updating benchmarks using a fixed growth rate.

To the extent that you have other ideas on benchmark setting, you should also discuss those potential alternatives.

We're going to include this material in an informal chapter in June, and I'll turn it back to Mike.

DR. CHERNEW: So that was terrific. Every fiber of my being wants to talk for the next half-hour, but I'm going to not do that, as best I can, and instead we will go to Round 1. And I think Round 1 questions are going to

start with Jaewon.

DR. RYU: Yeah, thanks. In the reading you talk a little bit about the migration between MA and then, as people might get sicker, a migration into something like MedSupp. I may be remembering this wrong, but I thought there were limitations or some sort of penalty around when someone enters MedSupp. I may be totally wrong, but if you could just clarify that, that would be helpful.

MR. SERNA: Yeah, that is correct. So there's only four states where beneficiaries have guaranteed issue if they've been in MA for longer than a year, I believe. So if they wanted to go back to fee-for-service and then purchase a Medigap supplemental insurance plan, then they would not have guaranteed issue rights. Consequently, their premiums would be much higher relative to if they had stayed in fee-for-service.

MS. KELLEY: Amol?

DR. NAVATHE: Thanks. Great work, guys. I have several questions that are generally truly intended to be clarifying questions.

The first is something I've asked before, but I'm sadly having a senior moment, and I can't remember the

answer exactly. But we talk about how the rebate can be used largely for supplemental benefits, but then a portion of it can be used for administrative costs and for profits. I was wondering if you could remind us what that ratio is that can be used for administrative costs and profits, and in future versions of this, if we could just add a footnote there and clarify that so people like me don't keep forgetting it.

MR. SERNA: That is something we are reporting in the March chapter, which is coming out in a couple weeks. To my knowledge, there is no limitation on the amount that is allocated towards administrative expenses and profit. But typically, it's going to be generally 5 percent profit on average, 10 percent administrative costs, similar to the AB benefit.

DR. NAVATHE: By definition, then, or by arithmetic, 85 percent ends up going to supplemental benefits or premium reductions for Part B?

MR. SERNA: More or less, correct.

DR. CHERNEW: Depending on what you believe in all the actuarial -- like, the enforcement of the -- there's like what is written is happening, and then what

you think is actually happening, and it's really hard to tell. That's a Kenny question.

DR. NAVATHE: Right, so I'm just asking about --

MS. BARR: Hang on one second. I thought the Affordable Care Act mandated a 15 percent maximum profit, and the problem is there's a 15 percent mandate, but then what that 15 percent contains is very squishy. Right? So that's the problem -- right? -- is that the 15 percent includes -- you know, you can get around that. Is that right?

MR. SERNA: Right. There's some differences between the medical loss ratio for the ACA requirement, and we're talking about here there's some puts and takes for quality improvement, for audit enforcement activities, but that's correct. In general, medical expenses are supposed to be 85 percent.

DR. NAVATHE: Great. So the second question I have is a bit of a broad question, but the way that we're looking at favorable selection -- and the next set of questions I have are kind of about that analysis -- we're looking at individuals, beneficiaries, who are first enrolled in fee-for-service and then switch into MA. So we

have enough claims experience to understand something about them. I was just wondering if you could remind us what percent of enrollees are directly going into MA and if you have any directional sense of whether we think the favorable selection, if you will, is similar or different for that cohort of individuals who are going right into MA.

MR. SERNA: Sure. So the proportion that had at least two years of prior fee-for-service experience was 47 percent in 2019, so roughly half. The ones that are going directly into MA, we have limited insight into their data, but when we looked at those that had at least one year of fee-for-service experience, our assumption based on looking at that data for 2017, '18, and '19 is that the favorable selection would have been a little bit bigger, at least in that initial year, if that answers your question.

DR. NAVATHE: Okay, thanks. So with that being said, obviously we don't know exactly how that would extrapolate to the immediate [inaudible.]

MR. SERNA: That's correct. That's an assumption of the analysis.

DR. NAVATHE: Okay, great. The next question I have is: So now diving more deeply into the analysis that

we actually do, it sounds like we are risk-adjusting based on what the HCC risk score, but that being said, there could be distributional differences between those that are joining -- switching into MA versus those that remain in fee-for-service, and those distributional differences could also relate not just to the quantitative risk score but also -- and you guys hint at this in the context of the networks for cancer centers and stuff, but also the composition of the conditions that actually exist in those beneficiaries, again, between those who decide to switch into MA versus stay in fee-for-service.

So my two-parter question here is: One, if we just think about this simply in the context of the quantitative risk score, where do we have -- or I guess the binary question would be: Do we have perfect overlap in the risk score distributions? Or do we actually not have perfect overlap in the sense that there may be greater weighting, if you will, of fee-for-service enrollment amongst those switching amongst those who have high risk scores relative to MA? Is that question clear?

DR. JOHNSON: I think you're asking in the individual cohorts where we compare an MA and fee-for-

service population are the distributions of the MA risk scores overlapping with the distribution of fee-for-service risk scores, or are we comparing two different distributions?

DR. NAVATHE: Yeah. I guess the question is to what extent are they overlapping, right.

DR. CHERNEW: Can I try another version that may or may not be what you're saying, and if it's not, I apologize.

DR. NAVATHE: Sure.

DR. CHERNEW: There's selection on observable and unobservable things. In other words, you could look to see -- if you just looked at the risk scores, are people with more severe risk scores moving into MA versus people with -- just observably what's the selection. And then there's selection within the -- so two people with the exact same risk scores, but you think more of them are moving into MA, which you're basing off of spending and a switching analysis.

One would expect that those two types of selection would move together, that you would see -- if you thought there was selection within risk score categories,

which is unobservable, you would also see selection just in the risk score distributions. And I think Amol was asking -- so if you look at just the -- ignore the unobservable part -- just the observable part, you see huge amounts of selection going on. I don't know if that --

DR. NAVATHE: Well, in other words, exactly as you were saying, Andy. If you plotted the distribution of risk scores for MA and if you plotted the distribution of risk scores for fee-for-service amongst those in our analysis, how much overlap is there under distribution and is there -- are there areas where there's not overlap?

DR. JOHNSON: I don't think we looked at the observed level of risk score differences, but I think in general, these populations are large enough that there is a lot of overlap. There might be small differences in the average MA risk score over fee-for-service, but it is not going to be a bimodal distribution or something.

DR. CHERNEW: If I understand a lot of what's going on in this analysis, an enormous amount of what you're talking about is selection on unobservables.

DR. JOHNSON: Yes.

DR. CHERNEW: Selection at the risk score is

simply not capturing, and you're inferring that based on the spending of the people before they join.

DR. JOHNSON: Yeah.

DR. CHERNEW: Right? So essential risk score adjusted, the people joining MA are healthier is basically what you're saying.

DR. JOHNSON: Right.

MR. ROLLINS: Correct.

DR. CHERNEW: And the issue -- did I mention I was going to talk for half an hour? I just -- the issue, I think, that arises in this analysis is the serial correlation people assume in spending and switching analysis. It's not -- this is true of all switching analysis. You look at people -- I could write down a model, which I promise I won't, in which you get huge amounts of selection based on the year before they join, but if there's enough independence over time and spending, it turns out there's no effect of it by the time you get a few years out. It's all based on a strong assumption of serial correlation, which is the way switching analysis works.

I was hoping to get through MedPAC without

mentioning switching analysis issues, but I failed. So keep going, Amol. I'm sorry.

DR. NAVATHE: Okay. The point that I was trying to make was -- so I was going to kind of get to Mike's point, but he jumped ahead. The point I was trying to get at was a little bit more for the fiscal econometric nerds in the audience and in the group here, kind of like common support and propensity matching, right? So if we're making these extrapolations and the distributions don't overlap perfectly, essentially, then we are extrapolating a relationship outside of -- and this usually happens at the extremes of the risk scores. So that's why I think it would actually just be helpful for us if we could see those distributions. I totally suspect you're right, Andy, that the vast majority of the density of these distributions is overlapping. But if there are areas that are not overlapping, just for the credibility of our analysis, it might help to truncate on those ends where there's not overlap, because then we are fully supported, if you will, by the distribution. So that's kind of where I was...

DR. CHERNEW: I'm sorry. Keep going.

DR. NAVATHE: Okay.

DR. CHERNEW: I feel like we're in step.

DR. NAVATHE: Sorry, yes. The next question I had is related to these potential conditions that interact with things like the networks. In particular, I was curious about cancer diagnoses, and I was curious to hear if you could give us a little bit of -- so there's many -- just to elaborate a little bit, there's many different aspects of how the MA program is currently designed, the lack of a hospice benefit, for example, or having hospice paid under MA is another one that's kind of tilting this way.

So what I was curious about is have we done any sensitivity checks just to look at how the distribution of cancer -- members with cancer or beneficiaries with cancer diagnoses might be shifting around this. And I think I'm broadly aware of some literature around this, but I was just curious. One, have we done some sensitivity checks or have we looked at this issue? And if we hold out certain groups where we do see a lot of this switching, it's -- I don't want to say that it's not relevant to include them because it's not irrelevant to include them, but I'm just curious what would happen if there are these kind of

incomparable groups that people who always stay in fee-for-service and kind of would never switch into MA, then they may not be the perfect comparison group, but it might be good to just see how much our estimates are sensitive to that group. If they're not, then that would be double confirming.

DR. JOHNSON: We haven't done that type of analysis, and I think we might also be concerned about the differences in coding of conditions of MA and fee-for-service. So think about that, and I'm trying to assess whether we can come up with a reliable analysis of that, individual conditions and the types of facilities or specialties that are more common in the network. That might be beyond the scope of the June report, I think.

DR. NAVATHE: Okay. Fair point. And just to be very clear, it's not that I don't find our analysis credible. I do. I'm just trying to think about what are the different dimensions so we can explore the contours and be as confident as we can.

I have one question that is about the mailing material itself. So we have -- this is switching gears a little bit. On page 10 and 11, we have a point here that

says, "A plan's network can also contribute to favorable selection by including clinicians whose practice patterns tend to have lower overall medical spending." And I was a little confused by that statement because if the clinicians actually have more efficient practice patterns, is that -- I'm trying to understand why that would -- assuming that that clinician is also taking fee-for-service patients, why that would contribute to favorable selection specifically in this way.

MR. SERNA: So I think the analog here is when we talked about TIN selection for ACOs. If you have a group that consistently have lower risk-adjusted spending, that is one potential method of having favorable selection.

I think going back a little bit, one important thing about it, before we parse out individual HCCs, is that this analysis is meant to see what is assumed in benchmarks. So we're not really trying to look at certain HCCs or exclude certain HCCs. What is the overall effect for benchmarks? And what are benchmarks assuming between the fee-for-service and MA populations? And the reason why we looked at what happened to MA entrants before they enter MA, years before they enter MA, is to see how would their

favorable selection change in a world where they stayed in fee-for-service? The short answer is it wouldn't change very much.

DR. NAVATHE: Great. Okay. I think the remaining questions I can -- they're trivial. Thanks.

MS. KELLEY: Scott?

DR. SARRAN: You mentioned that during the run-up to the ACA there was consideration for incorporation of a bidding process for MA. Any insights into why that didn't make it into the final draft in terms of what were the reasons that people backed off from it?

MR. ROLLINS: To be honest, I don't know specifically why. We note this in the chapter. Historically plans have very much preferred to have a payment system where they have preset benchmarks, so I'm sure -- I'm not sure, but I would suspect that there was some discomfort in the plan community as well with moving to this system. But, you know, I don't have a full answer for you on that question.

DR. CHERNEW: One of the issues, Scott, that arose was the role that fee-for-service was going to play in the balance between fee-for-service. That was mentioned

in your talk about would you charge people more if they stayed in fee-for-service, how would fee-for-service be treated as a bid, and what would the actual out-of-pocket have to be in the way the system was designed. There are a lot of design issues -- actually, MedPAC spent a lot of time on a version of this back in the day if Jim wants to comment on it. Yes, on a version -- I don't know what we called it. What were we calling it?

DR. MATHEWS: We called it "competitively determined plan contributions," one of our less elegant formulations.

DR. CHERNEW: As an aside, I actually prefer a different term, which is "bidding-based benchmarks," because that's what's really going on here. The real question is: To what extent do the bids feed into the benchmarks versus not. That's the core philosophical question.

MS. KELLEY: Larry?

DR. CASALINO: I have three questions that I think are quite quick. One is: Do you have a sense over any time period you want to name of the percentage of people in MA who switch back to -- who switch to fee-for-

service?

MR. SERNA: So we referenced one study that looked at everyone who switched between 2011 and 2019, and those who had been alive for at least five years during that period. So among those who had switched from MA to -- from fee-for-service to MA, 23 percent of those had switched back to fee-for-service at some point during the five years.

DR. CASALINO: But do we have a sense -- that's helpful, but do we have a sense of people who start off in MA, what percentage switch back within - or not switch back, but what percent start in MA and then switch to fee-for-service within two years or five years?

MR. SERNA: We haven't looked at that, but that's something we could look at.

DR. CASALINO: Yeah, I think to me that would be really important to know.

The second question is: Is there any data on the percentage of beneficiaries who are in MA who don't understand the penalty if they try to switch to fee-for-service? That's something that actually I don't think there's tremendous awareness of, even in academia, and yet

it's pretty important.

MR. SERNA: I'm not aware of any survey data, which I think is where that would need to come from, that actually looks at that specific question.

DR. JOHNSON: It is something we've encountered in the focus groups we do with beneficiaries, though, that it continues to be an issue that people don't understand.

DR. CASALINO: It is an issue in the focus groups?

DR. JOHNSON: Yeah.

DR. CASALINO: I don't know if a question or two could be added to our own survey of beneficiaries, but this would be an interesting thing to know, seems like an important data point.

Then the last question is -- could we go to Slide 14? The second big bullet point, empirically based benchmarks adjust for changes in prices, technology, blah, blah, blah. So this is for the second alternative, using both fee-for-service and MA spending to set benchmarks. But could you say that -- wouldn't this bullet also be true in, just for shorthand, the competitive bidding alternatives? Presumably plan bids are going to -- there

are many things that could factor into what plans bid, but presumably they would be considering changes in prices, technologies, coverage, and behavior. So is this advantage unique to Alternative 2, or would it also be true for Alternative 1 and -- well, I guess not for Alternative 3, right?

MR. ROLLINS: I think that's the way to think about it. It would also be -- that feature would also be in our competitive bidding system. It's more of a concern for the third option where you have sort of this fixed growth rate over time.

DR. CASALINO: Good. Thanks. That's it.

MS. KELLEY: Marge.

MS. GINSBURG: My question is very much linked to what Larry just said and that is the ability of people in MAs to switch to OM. And it seems to me this is a gigantic issue that has to affect the distribution of clients between MA and OM, since it is my understanding that after the first year that to get a Medigap plan you will likely have to go through medical underwriting, and how often do people do that and are rejected.

So as we are concerned with the greater number of

people moving into MA, but we know so little about those who are trying to scamper back, if you will, to OM but are unable to succeed, that, to me, is a gigantic issue. And if, in fact, it exists -- and this is a topic for the future -- is there anything we can do to squelch the ability of Medigap plans to reject people?

So I don't know, and I don't remember that, perhaps we have, looked more in depth about how often Medigap plans reject applicants. That is, to me, a really big part of all this, and I wonder whether you know a little bit more about this than I am aware of or whether this is something that we might look into further.

MR. ROLLINS: So I think some of what you're talking about sort of requires data that we don't have, and frankly, I'm not sure exists. I mean, you can use administrative data to see how many people at MA do migrate to fee-for-service over various periods of time, and I think also there's probably data you could use to see how many of those people do have a Medigap policy at some point after they do go back to fee-for-service. But if you want to look at how many people got back to fee-for-service and then applied for Medigap but got rejected, I think that's a

group that we don't have data on specifically.

To your larger policy questions, we haven't done -- and Jim can jump in; his memory goes back farther than mine -- the specific rules about sort of Medigap and when it's a guaranteed issue or when it's not is not something that I think the Commission has looked at, at least for a long time and possibly ever. Jim can provide more.

DR. CHERNEW: Yeah. To some extent I think -- go ahead, Jim. No?

To some extent these issues are common across actually all three of it. So there is a separate issue. You join MA for whatever reason and now you don't like your plan. In fact, your plan changes, that your doctor was in a network and now your doctor is not in a network, and you want out.

MS. GINSBURG: [Off microphone.]

DR. CHERNEW: Okay. All right. But the point is there could be a whole bunch of other things that happen, your condition changes or something, whatever. And that's probably true in a whole bunch. Independent of how we set up the bidding system or not, I think that issue is a somewhat separate issue of the question about what extent

do we rely on bids to set the benchmarks. Because you're always going to have the situation about the rules of going back and forth and locking in selection, and they increased the lock-in to avoid a lot of other broad -- there was this notion where there could be a lot of adverse selection, where originally you could just jump out whenever you wanted, with no penalty. And they found the selection was a lot worse. So by locking it in they've reduced some of the selection.

Go on, Betty.

DR. RAMBUR: Briefly on this point, I'm curious if anyone has looked at, is it possible, is it valuable to look at the four states that do have guaranteed issue, and is there anything that can be learned about similarities and differences. Thanks.

MS. KELLEY: Scott, did you have another question.

DR. SARRAN: A procedural one. Are we wanting to or trying to firmly put our thumb on the scale and recommend one of the three options or rank them?

DR. CHERNEW: So the answer is certainly at this stage absolutely not. I'm not sure I'll call that a

clarifying question, but it is what I was about to say, because I think Scott is the last one in Round 1. Dana, right? So we're about to go to Round 2. So let me say a little bit more about where we are.

There is an arc of work. There have been some problems that have been identified. We have to decide two things: to what extent do we want to continue along this path or not -- so this is just a broad path we should keep exploring in a bunch of ways -- and then if so, how we feel about specific things.

And I'll tell you what I think the specific issue that's most important to get -- if you have a view, if you don't I understand -- is to what extent should we rely on bids, or could we rely on bids, and the reason why that comes up is in a world where MA is 70 percent, 80 percent, 90 percent, you have to rely more and more on these credibility adjustments to make things work. You have to deal with geographic variation and stuff. There's a whole bunch of other things.

And so there was, since the beginning of when we were doing this work, as was pointed out, there's been a lot of interest in using bids. And I think for us to think

about work going forward, getting a sense of how people feel about bids matters. So I am just going to make a very hopefully quick comment on this.

If you go to Slide 12 -- you don't need to, but if you did -- you would see there's a specific kind of equilibrium that's implied of what happens. But, in fact, if you asked a separate question, if there was a monopolist plan and you let them bid, what would their equilibrium be, recognizing that bid would enter. And what you would find is, well, that's not good, and then you would see, as the slide said, well, that could be a problem, as again the staff said, and you might need some other system of capping or doing a whole bunch of other things to guard against that competitive issue.

And what matters intently is how people switch. So even if there are five plans, but no one switches amongst the plans, for whatever reason, any one plan has a lot of inframarginal beneficiaries that they know are not going to switch. And they can raise their bid, get a higher benchmark, depending on the system that's set up, and not lose beneficiaries in particular ways.

The other problem, which is almost the exact

opposite problem, which arises more in the mailing materials, is imagine competition works perfectly. And then if you look at Slide 12 you would see where that works. You would see now they will compete away a lot of the benefits, and so that's where the chapter outlines a mechanism of how you might address that in a policy sense. We are going to give you a certain amount of money to just add on extra benefits, and, of course, depending on what that costs the government depends a lot on how competitive the bidding system is.

So there's a lot of underlying dynamics of how this plays out, and I think the question on the table as we go around broadly, in my mind, really hinges on how worried are you about the selection issues as MA gets bigger and bigger and bigger. How do we think about Medicare program where MA is the dominant source of enrollment versus not, and should we address that through the status quo approach -- because we have a bunch of recommendations, cut at least 2 percent, et cetera -- or should we think about designing a program that's more reflective of a dominant MA world, and if we do, to what extent do we want to trust a bidding system to set where the benchmarks are, which works great

in some models of competition and not so good in others, or to what extent do we worry about a government version, which says, all right, we're moving to a world where it's just a much more kind of budgeted sort of world but make the plans responsible. But, of course, in that world the government can get it wrong, in a whole bunch of ways.

And so getting a sense of how people feel about that tradeoff will, I think, be useful in how we think about moving the work forward.

MS. BARR: Michael, can I just -- I'm confused, because I thought we were given three options to consider and we're asked to weigh in on the three options. Are you saying that's not the case?

DR. CHERNEW: No. You can weigh in on the three options, but we are a long way away from even having a vote.

MS. BARR: I thought that was Scott's question, though, is do you want us to weigh in on these options.

DR. CHERNEW: That's right. Yes. But there's really two options, even though there's three. The first two are versions of bidding. One of them is just pure bidding. One of them is bidding but it dilutes it a little

bit by adding in fee-for-service, but it's still basically a bidding thing. so the one is bidding matters, and it's just a question of how much, and then third one is no, bidding doesn't matter.

So when you weigh in on those three options you are effectively going to be answering the question about how you feel about biding in the MA program for setting benchmarks.

MS. BARR: Or how you feel about the government setting the benchmarks. I just want to make clear that there are two options here. I feel like we're being a little bit driven, and so I just want to make sure.

DR. CHERNEW: No, actually not at all. In fact, you could also say, "I don't think we should take this on yet because we don't know." That's another reasonable view.

What I was trying to say in response to Scott's question is you are not being asked to weigh in on these options the way we are on other things we've done. When April comes there's going to be a bunch of votes. You're going to see a chapter about wage index, a chapter about Part D, where we're weighing in on things, that is really

coming close to a vote.

Here we are at a much, much, much, much earlier stage. So you're being asked to weigh in on the broad ideas about where we're going. The specific options are much, much less tied down than they would be a year or two down the road.

Oh, Jim is going to add another thing.

DR. MATHEWS: Yeah. Just to layer onto Mike's comments here, first one minor clarification. The second option does indeed invoke MA bids as a potential source of spending for the MA population under that scenario, but I think the chapter alludes to a potential future world where MA encounter data might also be a source for estimating Medicare Advantage spending. So there's a little bit of a toggle there.

The second thing I want to say is very consistent with what Mike said regarding where we are in the development process of this work. So again, nowhere close to recommendations, but it would be useful for the Commissioners to signal where they think some additional analytic work from the staff would be useful to help us start to zero in on which, if any of these, policy options

will move towards recommendations in the next cycle.

MS. GINSBURG: May I ask a clarifying question about the concept of the options for bidding? Maybe we said it and maybe I missed it. Are we proposing or suggesting, offering the idea that if MA plans are bidding against each other that some will be rejected?

DR. CHERNEW: No one gets rejected in that sense. Think of it more that the bids are being used to set the benchmarks. So the benchmarks now, based on fee-for-service spending, and you bid whatever you bid. So they're bidding against each other already, but the rebate amount is based on that. In this world, the benchmark would go up if all the plans bid more. It would go down if all the plans bid less. So the material shows if there was no change in bidding behavior, with bids 15 percent below fee-for-service, the bid would just drop a ton because the benchmark would just be set where the bids are, not where fee-for-service is, and the current bids are well below fee-for-service.

MS. GINSBURG: And have we ever talked about the option of, in fact, not approving every MA plan as a player in the area, and is that off the table?

MR. KAN: No. I think that's too prescriptive, Marge. I think the best way to think about it, for me anyway, is on page 12. If you look at page 12, look at Plan A. Plan A, currently under the current payment system, the cost is $1,014. In a competitive bidding scenario, you know, basically the average of all the bids is $850. So then any member that's in Plan A will have to pay $50. So in the past the member did not have to pay anything, but now they pay $50. So this is where then that member would have disruption. Then you may have to switch back to fee-for-service. So that's where all the disruption and switching analysis comes in.

DR. CHERNEW: That's right, but we have not considered a situation where a plan bids and we decide there's something wrong with that plan, "I'm sorry, no, you can't serve." Right? It's almost like the exchanges. Plans can be on the exchanges if they want to be on the exchange. They can set the premiums they want. But we are not doing a Department of Insurance oversight on rejecting of a plan.

MR. ROLLINS: If I can add just one thing, Mike. I agree that there's never been the discussion of limiting

the number of sort of insurers that can participate in the MA market. I think one idea that was sort of, at least in the background in our discussions of standardization in the fall, was that you might not limit the number of insurers that can participate in the MA market but you might limit the number and types of plans that they could offer.

DR. MATHEWS: And there is also, Marge, an analog for the idea that you've mentioned in durable medical equipment competitive bidding, where DME suppliers or manufacturers submit bids and then CMS estimates the ability of a group of suppliers to serve a market and will establish a cutoff point above which plans with bids higher than that cutoff are not able to participate.

DR. CHERNEW: I hope it's clear the type of things -- we don't need to go into a lot of detail, I think, about this specifically or that specifically, or how would you actually do the cap. It's really a bigger-picture question of what role do you see bidding, or for that matter MA encounter data, in the setting of benchmarks versus not. That's the big-picture question, and if you have a view on that. Some people may not.

Anyway, go on.

MS. KELLEY: Okay. I have Jonathan first.

DR. JAFFERY: Thanks, Dana. I'm not sure we haven't been in Round 2 for about a half hour, but that's okay.

[Laughter.]

DR. JAFFERY: So first off, this is great. Thank you all so much for the chapter, the presentation. I think it's really enlightening about some of the selection, which is a bit different than some of the other issues we've talked about in terms of how MA overall cost and performance is or isn't compared to traditional Medicare.

You know, I do think it's crucial that this work goes on. Kaiser Family Foundation had an article they published, an analysis, just the other day, looking at gross margins that big plans have across the country, and they're $650 or so or $700 for Medicaid managed care group and individual market, which, not incidentally, is a lot more -- the people who are providing the actual care are not making a lot of money off of Medicaid managed care, for example. But in MA it was $1,750. I mean, it's 2.5 times what it is in these other markets. So there's a lot of opportunity here.

Thinking about these three options, the middle one, the second one, I definitely have concerns given what we continue to see with the trends. I mean, you mentioned a couple of problems about the encounter data that continues to be an issue for a number of reasons, but certainly the fact that more and more we're seeing Medicare Advantage be the dominant, and in some markets very dominant. It's hard to understand how this would work in every market even today. Puerto Rico comes to mind. That's a place where it's almost all Medicare Advantage. So that could be tricky.

But of the other two, when I think about competitive bidding, Mike mentioned how if you had a monopolistic plan, they could drive prices up. I also think that you could get the situation where a large plan actually drives prices down as they enter a market to try and eliminate the competition and the ability of small plans to compete and drive them out of the market and then subsequently raise benchmarks.

I think if we do have a competitive bidding process, I agree that a standardized plan, which I know we've already started to talk about a little bit this

cycle, would be very important.

And I do wonder, actually, if there's an opportunity to pilot something like competitive bidding, so it would have to be a program that rolls out across the country.

And then finally, talking about the third option, using a fixed growth rate, I mean, you certainly talked about all the different things appropriately that we'd have to think through and the policy questions. You know, I guess I worried less about is the government going to get it right setting those rates, because, you know, certainly they're not going to get it exactly right and we'll have to adjust. I worry more about the political influence that folks might have on impacting those things.

But that said, it feels like there's an opportunity to explore policies in something, and forget about a fixed growth rate language and thinking about it in terms of an administratively set benchmark that gets it closer to what we've been proposing for population-based payments in traditional fee-for-service and ACOs.

And so to me the more we align how those programs work in areas like this, where you're talking about how we

set benchmarks and not make it difficult to continue to propagate either program and allow them to actually compete in individual markets I think is appealing.

So again, it's pretty early, I know, but to me that third option has some potential to think about administratively set benchmarks in a similar way that could be very appealing. So thanks so much.

DR. JOHNSON: If I could add, on the encounter data since it's come up a couple of times, we say that there are issues now. I think this future world, envisioning, where I would say that benchmarks are going to be set on encounter data and that plans would then have, by far, the biggest incentive to submit anything bigger than currently now to submit complete and accurate encounter data. So we're assuming that issue would resolve itself as the incentives were increased.

DR. JAFFERY: Yeah, that's a great addition. I mean, obviously, as you know, that would help with all sorts of other things. So to the degree that that would be a strong lever for us is a nice idea.

MS. KELLEY: Kenny.

MR. KAN: Thank you very much for a very thought-

provoking analysis.

Regarding the three alternate benchmark options, my comments for future cycle analysis are as follows. Option 1. competitive bidding. In addition to the administrative complexity, I'm not supportive of this, as I believe that it will result in a race to the bottom, which will likely result in greater MA consolidation and significant beneficiary access disruption. Currently, the top three MA national players hold 55 percent. Under competitive bidding scenario, maybe that could be 80 percent like Part B.

Option 2, a plan of fee-for-service in MA. This may have some merit and would suggest that we spend the next one or two cycles understanding the various dynamics and scenarios with a few key assumptions, possibly being, number one, what is the ultimate level of MA penetration, say, 10 years from now?

Number two, how do we get comfortable with the credibility adjustment of fee-for-service benchmarks when we reach that level of MA penetration, similar to what Mike mentioned earlier?

Number three, how do we think about competitive

game theory behavior of MA players under those equilibrium scenarios, and what are guardrails against undesirable behaviors?

Number four, potential beneficiary access issues, and is this a technical term, switching analysis in counties with low, medium, and high MA penetration.

And after we are able to think through these various assumptions and scenarios and after we have a better understanding of these issues, I would suggest then we look at the totality of it. How do we evaluate the pros and cons of an alternate benchmark redesign and overhaul versus incremental tweaking at the edges? So that would be my comments for Option 2.

Option 30 a fixed growth rate benchmark. I don't favor this, as I believe that such a benchmark is more susceptible to political intervention and governed by politics, potentially leading to unsustainable and actually unsound benchmarks. I understand that such a fixed growth rate benchmark may have worked for Medicaid rates in perhaps a fiscally responsible state like Utah. I believe those fiscally responsible states are a small percentage of the union and would suggest that we be very careful about

extrapolating that to the broader Medicare program, given the $32 trillion federal debt.

Thank you.

MS. KELLEY: Greg.

MR. POULSEN: Thanks.

So leaping from the fiscally responsible but unusual state of Utah --

[Laughter.]

MR. POULSEN: I guess just to get this out of the way, because I actually lean a little bit towards the three different approaches may not be our highest and most important focus right now. But because I think that is what we're bringing up, I am biased towards a combination of 2 and 3. I think there's a way to do that in a way that would be clever to prevent what Kenny just talked about and yet would be less amenable to gamesmanship than I think competitive bidding currently is and is likely to be. But I really wouldn't like to jump into that for the focus of my brief remarks.

What I would like to say is that there's MA, the way it basically exists today, broadly speaking, which I think is way, way, way under what it ought to be. And then

there's MA, the way it was envisioned back when Medicare+Choice was brought into being a couple of decades ago, more than three decades ago-ish.

And there are examples of real achievement in that area, both historical and current, and it seems to me that the ideal situation would be to come up with a mechanism that makes those rare examples common examples.

Something that is true in the chapter as well as the slides is the perception, which is today accurate, that favorable selection exists whenever MA costs are lower than the risk scores would predict. That's probably true today, by and large. On the other hand, that is really what we should achieve. What we'd like to do is to say here's a population that has this level of underlying illness burden and other situations, and here's what we would expect, but oh, by the way, what we'd love is to find ways to keep those people healthier than they're expected to be, spending less money than they are expected to spend. And that's what we should aspire to in MA. Anything else than that, then all we're really doing is transferring the administrative burden from CMS to private organizations, and CMS has demonstrated it's very capable of doing

administrative stuff. I think if that's our -- if that's all we hope for from MA, there's no reason to pursue it.

But I think there is a reason to pursue it. I think we have some really good evidence from organizations both that exist today and have existed historically that it's not -- it's not silly to expect that we can change the trajectory of people's health, that we can help them to live healthier and happier lives at less expense to the government and to themselves.

I do agree that the current risk scoring is deeply flawed, and I know you all have heard me say this, but I feel like it can't be repeated too much. No other insurance mechanism uses this basic approach, not large or small group commercial plans, not individual coverage, not the ACA exchange plans. None of them use the kind of risk scoring that we use in MA, and I think it's deeply flawed because it leads plans to put their primary focus -- the easiest way to be successful in MA is to maximize your risk scoring, and we see that if we compare -- it's in the chapter -- if we look at a population and the risk scoring in traditional Medicare versus their scoring when they're in MA. They don't bear a strong resemblance to each other,

and it always goes one direction, no surprise.

So I think that to come up with a different and better way of scoring risk or identifying what the risk of a population of Medicare Advantage enrollees is is job one, and I think it's doable. And we've got examples in the other insurance mechanisms that already exist in the United States today and including in some government programs.

If we look at other ways of identifying risk profiles in a group, we can follow the principles that are already in place, as I mentioned. I would point that when -- that there's good reason to be optimistic that this can really be -- achieve
great results. I think that there's demonstrations over the years of places where populations of the same people have been cared for in a way that reduces spending by meaningful and -- meaningful amounts, enough that would really catch people's attention, while simultaneously having enrollees that are both happier and healthier. And isn't that the ideal that we're really after?

I would just one point to one thing. I know we all agree -- I think we all do at least that stars ratings are far from perfect, but they're not also completely

without some validity in terms of mentioning some difference between the way plans are meeting the needs of their enrollees. If we accept that as even true to an even minimal extent, I think it's just really interesting.

If you go back to 2019 -- and I'm just going pre-pandemic because it's clean and you don't have a whole bunch of other chaff in the air. So the last year that was pre-pandemic, the roughly 3,500 MA plans in the country, 20 of those, just 20, or five-star rated in that year. That's a pretty small percent. Duh. But if you look at those, 13 of those 20 were in plans that had prepaid or provided value-based incentives to their providers, 13 of the 20, and yet there were only 221 plans that were -- that we're paying that way. So 13 out of 221 versus the remaining 7 out of 3,350, that's roughly 30 times more likely to get a five-star rating for those plans that incentivized correctly the providers that they were working with.

Why isn't everybody doing that? Because that's not what's rewarded today. You can make more money by doing the easy lift of increasing the risk score than you can by doing the hard lift of actually getting providers to

change the way care is delivered and put more -- give them the incentive so that they're rewarded when people are healthier.

Today everybody in almost every aspect except those 220 plans, everywhere else everybody makes more money when people are sicker. And those 221 people make more money when people are healthier, and it makes a huge difference. And I think if we could move down that pathway, we would be enormously benefitted.

I commend you all for your chapter because I think the points you make are right on, and I think that we have a pathway out of this if we will pursue it. It will take some hard work on our part, though.

MS. KELLEY: Stacie.

DR. DUSETZINA: Thank you so much, and then thank you for a great chapter.

I guess I'm a little bit torn here. One of the things that I think Amol brought up really nicely was this issue of the analysis presented of those switchers, and I'm not exactly sure how to get to the right spot with that. But I do worry that there is some bias in there for the people who aren't moving versus who are moving between

traditional to MA. And I guess the way I would think about this is kind of a "don't rock the boat" if you are healthy and doing fine. Well -- or if you're healthy and doing fine, you may actually be willing to rock the boat because you're like, you know, maybe I can save more money or I want to go and get some vision or dental benefits or something like that. But if you're not well and you're interacting with the health care system, you might just be like I know what my plan is, and I don't want to move. So I just worry a little bit about that analysis and who's represented and who's not.

So I think the comments early on about trying to get a little bit more of a big picture, who's in which plan from the start and who's moving around would be really helpful just contextually. I know that's hard to get, and I know you can't replicate the same analysis that you did because of the lack of the same data on the MA population in the pre-period.

I guess for the options, Kenny has made me second guess my actually liking the cap -- or the competitive bidding with the cap. I really appreciated the way that you all described the potential for gaming there, and I

completely agree. I think that sounds like why Kenny also doesn't really like this is that there's so much consolidation within the MA market that you could imagine gaming in either direction, like gaming it to get all the way back up to the same fee-for-service level or gaming it to race down to the bottom. So I guess that was conceptually the one I liked the most, but I also appreciated the additional comments from Greg about -- and Kenny about the fee-for-service and MA and trying to use all of that information.

So I guess I'd say least interested in No. 3, but I would like the idea of exploring a little bit more the competitive bidding, and going all the way back to Scott's Round 1, that was the first thing I wrote down is like, "What was the fatal flaw of this for the ACA?" Is there something, some sort of landmine we don't -- we want to avoid around the competitive bidding to not go too far down that path because maybe it's really contentious in a way that would make it unproductive for us to spend a lot of time trying to go down that route?

But excellent work, and thank you all very much.

DR. CHERNEW: I just want to say one thing. I

wouldn't characterize what Kenny described or what you described as "gaming." That's just the way competition works. So if you looked at the prices that are set in consolidated markets for hospital services and they're charging high prices, right, that's not gaming. It's that they have -- you've set up a system where they get to set the price, and they compete with other hospitals that set the price. And if there aren't a lot of other hospitals, the price goes up.

So you've fundamentally set a model where you have created a competitive dynamic to set the price. If The competition isn't working, the prices are really high, and if you set the prices in the government system like you do in, say, Medicare, the prices turn out to be substantially lower. Are the prices too low? I don't know. We had a whole chapter that's going to come out on whether the prices are too low, but at least you don't have to worry about the competitive model that's working for setting hospital prices.

So, again, this conversation can go on. My only point is if you think of the -- if we were having this exact same analysis, should we have competitively bid

hospital prices or should the government set fee schedules for hospital prices, this discussion would probably go something like, well, it really works well for competition for setting hospital prices if competition works, but if competition doesn't work, we get commercial prices that are extraordinarily higher. And the government actually sets a better rate, albeit too low in some -- potentially too low; hence, what we do. And so I'm not arguing which is right, but I think that's the analogy. If you were thinking about this exact same question, do you want competition to set hospital prices or do you want the government to set hospital prices, and you ask how that plays out, you have to work through the equilibrium of what you think will happen.

And that' where I think this core tension is, and so the competitive bidding models, if you were to write them down on how they work and you believe people switch, say, in most hospitals, you would get really low hospital prices. It would be very competitive, and it -- so that's not how competition in the hospital sector, for example, has largely been working.

Boy, I'm waiting for -- you can reach us at

meetingcomments@MedPAC.com or via Twitter to complain. But I think that's --

UNIDENTIFIED SPEAKER: It's dot-gov.

DR. CHERNEW: Dot-gov, whatever.

Anyway, sorry. I think that's -- my only comment -- I'm sorry for being so ranty -- is I think fundamentally it's not a gaming issue. It's fundamentally an equilibrium issue when you're allowing different organizations to basically determine through competition what they're paid and how well you think that will or will not lead to the outcomes that you want, and again, I both am relatively speaking pro-market and then relatively concerned that it doesn't work well in health care. And that's the tension.

Anyway, that was also --

MR. SERNA: I wanted to respond to Stacie's --

DR. CHERNEW: Oh, please.

MR. SERNA: -- concern about people who weren't included the analysis. So the available data that we had on the people that we weren't able to include suggests that favorable selection would actually be greater, and those in the sensitivity analysis that we did, they're actually in the footnotes. So we looked at those who were nearly newly

eligible, right? And so their initial favorable selection was actually greater. It was when they initially would have entered MA. It would have been 85 percent as opposed to 95 percent for the cohort that we were actually able to include. So just -- I just wanted to set that straight.

MS. KELLEY: Amol.

DR. NAVATHE: Andy, Luis, Eric, this is really terrific work and I think really fundamentally important and really commend and thank you for it.

I have a few high-level comments and then kind of a hit list of nice features, features to worry about as we can go forward.

So my first comment is kind of very generally about framing. I think I have a decent sense of what we're empirically trying to uncover here with the favorable selection analysis, and I think we then use that as kind of a launching pad to go into why we might consider alternative ways to set benchmarks.

My concern here is that I think there's a lot of complexity in this market. There's a lot of complexity in terms of what plans are doing, in terms of what beneficiaries are doing, et cetera, et cetera. And I think

while your analysis obviously contributes to what we understand of what's happening, I don't know that we necessarily need to, quote/unquote, prove the point on exactly specifying the level of favorable selection and generalize it. Of course, we want to do as credible analysis as possible, because I think there's a whole number of other reasons that we might think that there's opportunities to put some -- or gain some efficiencies in the MA program.

We know there's a number of program design issues. There's stars. There's how the quality program works and adding dollars. There's the way that plans that work -- national plans that work in multiple markets have some advantages in terms of how they group sub-plans or counties and states and such together. So I think there's a whole number of reasons, including where we see the bids currently are, relative to the benchmarks that suggest that there is great opportunity here for the federal government, the Medicare program, taxpayers, and beneficiaries to get some more efficiency while accomplishing the types of aims that Greg is pointing out in terms of better value, better quality, changing the trajectory of clinical care.

And so I feel to some extent that we should broaden our motivation here and include this selection analysis as part of it, but I think take some pressure off of it, to some extent, because I don't think we need it as much as -- currently, I think it's sort of implied in the paper, and I think that will actually help a lot.

Second thing I wanted to say is that I won't restate all the empirical suggestions that I made in Round 1, but I think those would be generally helpful to do because I think it will help us understand the contours of what's happening here on the observables. Of course, on un-observables, it's harder to know.

Andy, I think it was either you or Luis. I can't remember. I think it was you, Andy, who mentioned something about differential coding as being a challenge in looking at things like cancer diagnosis. I think, if I understand correctly, we're using fee-for-service data to identify diagnoses. I don't think differential coding specifically is confounding that type of analysis, although I understand your general point about differential coding. So I just wanted to make sure to make that point.

Okay. Now moving to the kind of transition of

the policy option pieces. So I'm struck here that there's a tremendous amount of complexity. Mike has alluded to it in many of his comments. Ken, you brought it up. I would find it helpful -- and I think MedPAC has done this. We did it as part of our APM work. I think we've done it as part of other work, the prescription drug space -- otherwise, where we've outlined some principles that we're trying to get at in terms of how we can make the MA program work better and more efficiently. And I think without that as kind of a scaffolding from which to jump, it's hard, to some extent, to understand where we might be making tradeoffs. Inherently, we're going to be making tradeoffs, and the question is, are those tradeoffs worth it? Is what we're giving smaller than what we're getting? And I think it's hard to know that unless we have some kind of organizing frame.

So if I take a step into that, for example -- Mike has outlined that, you know, how competition works may vary. It may vary it may well. It may well vary tremendously geographically, because we know that MA penetration, MA competition in markets, also in terms of number of plans available, varies a lot.

But I think if we take a step back and say what are we trying to accomplish, I think we're trying to accomplish a more efficient MA program.

I think, generally speaking, this notion of an empirical-based benchmark where using what is actually happening in terms of prices, technology utilization, as a way to inform a system that is kind of able to adjust itself over time relative to something like an administrative benchmark, where we would need policymakers to come together and decide what that growth rate is or something like that, I think that's a tension. We could identify some kind of principle around that, that would help guide our ideas.

I think the standardized benefit is something that I strongly support. I think it would help beneficiaries a lot. Again, we could define whether that's something that the Commission supports in terms of our principle going forward and how that would then fit into the system as we think about it going forward.

Another element is supplementary benefits and how we want the supplementary benefits to work. So a concern around a competitive bidding type solution would be

potentially that you could compete away all the supplemental benefits. And we as a Commission and certainly the beneficiaries as they seem to be voting may suggest that that's not really what the beneficiaries want. That may not be actually what's right for our system. And so preserving some element, some degree of supplementary benefits, while also counterbalancing that with getting value out of those benefits. But right now I think there are concerns that we may be in a situation where the government is paying for supplementary benefits that either don't provide much value or in some cases may not even be used by many of the beneficiaries. And so having some rationalization, if you will, or some approach to get value out of those while preserving that might be another principle.

So I'm just stepping through several of these ideas because I think it might be helpful for us to codify them, particularly since we're not at the point where we're trying to vote on recommendations but really kind of lead us to the right policy options. I think this might be very -- particularly helpful.

The last point I'll make is I think to the extent

that we were to take on -- actually, sorry. One other principle to note was around the encounter data as well, so I think Jonathan brought that up. I think you all did that principle of creating incentives to get better encounter data, improve transparency of the program writ large.

The last point I wanted to make is I wanted to support Jonathan's idea, which is that to the extent that we were to suggest a larger shift where there might be a lot more in terms of unknowns of how plans might respond and how beneficiaries may be helped or harmed, the idea of potentially, to the extent that it would be possible, to do a pilot under CMMI or something like that might be a very attractive way to address some of the uncertainties that could then serve as a basis for more confident, if you will, policymaking.

Thanks. Great work.

MS. KELLEY: Lynn.

MS. BARR: Thank you, guys. Terrific chapter. You know, I'm going to counter Amol's comment about the favorable selection issue that you raised. I thought it drove the point home to me that things are actually worse than I think, and the more data we can put in front of

policymakers, you know, we've got to get them to move. And so I think it was very powerful data, so I certainly continue in the future.

And, you know, as a general comment about the whole program, we need to fix HCC coding because that is the fundamental issue that, you know, is underlying a lot of this craziness that we're dealing with.

As I looked at the options, I had -- my framework for looking at them were four things. One of them is accuracy. You know, what's going to give us the right answer. What's the fair price, you know, that we should pay for these services?

And when I think about the next three, I think about them across the stakeholders. So we have patients, providers, and plans -- right? -- and all of them need different -- you know, have needs that we need to address. And what I think about what they need is stability, simplicity, and trust -- right? -- and that we need to think about those three things for all three of the stakeholders and think how these different options fit in.

I feel like when we talk about stability, Option 1, you know, feels to me like a patient might have a co-pay

one year and not a co-pay the next year and might have a co-pay the -- you know, and they've got to stay in a plan. It feels like that's going to be a very unstable system for the patients, and I worry about that, and for the providers and plans as well.

When I think about simplicity, what I liked, what you mention in the paper as Option 2 is the most current -- similar to what we're doing today, you know, with the least amount of disruption. Isn't that right? And I think that disruption is important. We are disrupting everything for people, and the least we can disrupt and get a good outcome, we should lean towards that, you know, because of the burden that we put on both the plans and the providers, and the patients, to try to figure out what the heck we're doing now.

You know, and so simplicity is very important, I think, but also trust. And I don't know if we think enough about how much providers don't trust payers, right? And we're a payer. So if Medicare is setting the rates or if we are -- you know, in Option 3 we're doing administrative benchmarks, there's going to be a -- there is a huge trust issue, which is worse in some parts of the country than

others. I would say that, you know, in the rural parts of the country there's more of a trust issue. And it is very, very uncomfortable for them to be -- that these are numbers that could be potentially driven by politics.

So I strongly support looking -- hopefully getting the data and looking at a blend on Option 2, and in your analysis trying to understand, you know, stability and doing some modeling on stability and simplicity in terms of what is the burden that we're asking for with these different options.

Thank you.

MS. KELLEY: Betty?

DR. RAMBUR: Thank you very much. I really appreciate this work and the comments. I think it was at my very first MedPAC meeting I sort of slammed my fist down saying, "We need to do something about this," and, of course, I had no idea how complicated it was. So I just want to say how much I appreciate all the work you've done. It's really impressive.

So in reading the materials -- perhaps I'm channeling Stacie a little bit here -- my immediate instinct was that the comparative bidding with the caps was

the way to go. If Medicare Advantage is supposed to be putting some market forces into Medicare, that seems logical to me. And I understand, and, Kenny, you really have made me now rethink this, but is there a way the guardrails can be in there so that that can work. That was appealing to me.

I initially was very not excited about number 2 because keeping the fee-for-service benchmark as a part of it seems inherently flawed to me. But I also heard that that should be explored more. And I just wasn't excited at all about number 3 for whatever reason. But I think that there is -- you know, it's worthwhile to continue to look.

I think the last thing I want to say is, Greg, I really appreciate what you said about what are we really trying to do, so I agree with the what. What I don't see at all -- and probably somebody else can or we could craft it -- is the how. What is the how to that? What's the specific policy recommendation we could make?

So I agree with -- is there a way, you know, to really take this on so it really impacts people's health and well-being? But I can't trace that through these different options or other options. But thank you very

much for really excellent work. It will teach me not to pound my fist, right?

MS. KELLEY: Robert?

DR. CHERRY: First, I want to thank the staff for really a well-articulated document because it clearly tees up the problem and the robust discussion that we're currently having. To answer Mike's overriding question, I do favor continuing with this work.

Among the choices, I don't think there's any bad choices. They're probably all an improvement related to the current state. It's a series of compromises and what we're most comfortable with, and it's likely at the end of the day it will be a blended approach among these and maybe some other ideas as well.

So just, you know, looking at the three options, the first one, which is the bidding option, does seem rather straightforward, but there's no real, you know, pricing control here. I think there does need to be some sort of minimum floor to make sure that the plan operates safely in terms of the case that it's delivering and probably some sort of cap to make sure things don't really get out of control. So, you know, having that in place

would be helpful.

In terms of the second option, the idea of using MA and fee-for-service together intuitively makes sense, and it seems relatively straightforward. And so you start thinking about MA encounter data, and it seems like every meeting I've been here -- I'm a new Commissioner -- this comes up at every meeting in terms of data integrity with regards to MA encounter data and the limitations associated with that. So the idea of using that data does make me a little bit apprehensive in terms of the second option.

And then in terms of the third option, you know, with a fixed growth rate with administrative adjustments, may seem reasonable as well, but I'm concerned that the administrative adjustments are rather resource-intensive and it doesn't allow for long-term planning for the various MA plans that are out there. You know, if you don't know what next year is going to look like, it's hard to have a normal three-year business cycle and forward-looking planning.

I do agree that there should be some overriding principles that, you know, for me I did drop down, you know, a few of them. One is that I think some of these

plans do a good job of using their rebates and cost savings to invest in other services, like dental and vision and hearing, and I think probably some beneficiaries actually find that attractive.

I think also that there's probably other back-office operations that MA plans need to invest in for their beneficiaries, and that includes case management, navigators, patient educational materials, things that really provide for, you know, targeted care for complex patients, and that would avoid, you know, flights to fee-for-service, which has been articulated as a problem.

Then that translates into sort of a third principle, which is making sure that these MA plans in some ways are incentivized for population health and improving the overall health and quality of their beneficiaries.

So I'm looking forward to further discussions on this. I don't have any -- you know, right now any predetermined conclusions about, you know, which of these options is best, and am just waiting for more iterations to come in future discussions.

Thank you.

MS. KELLEY: David.

DR. GRABOWSKI: Thanks. So, first, I really appreciate the staff's work on this issue. I wanted to start, similar to Amol, with the issue of framing. The first part of the chapter really focuses on favorable selection in MA. There's a huge academic literature on this topic, and I'm a little bit concerned about how much value our work adds on top of this really well-developed -- I can't think of too many areas in the academic literature, in the health economics academic literature, that have been sort of more developed.

I'm not typically a big fan of the sort of switching analyses that are presented in the chapter. Given the amount of work that's been done on this, I just don't know how much value we're going to add on top of that. And I think the more important point that Amol made was that I don't know that it's necessary to sort of connect the dots and prove the point. We know that the MA benchmarks are flawed. We've been saying that since I came on the Commission in 2017. We have lots and lots of work on that issue. I don't think we -- to once again use Amol's great sort of phrase there, we don't need to prove that point. I think that's well established. And so I

really like Amol's point about reframing the chapter. We don't need to connect those two dots between, you know, that we have favorable -- or that we have selection issues in MA and that we need to reform the benchmarks.

Going to the second part of the chapter in terms of options for reform, I agree with Robert. All three of the options I think would be an improvement on the current system. I tend to favor, like Stacie and others, the competitive bidding. I appreciate Kenny's point. That's why you need those guardrails and caps that were put forward in the chapter. This is not unconstrained. There's going to be kind of checks and balances there. And if those are put in place, I'd love to see us kind of continue to work on that particular option.

Thanks.

MS. KELLEY: Scott?

DR. SARRAN: Four very brief points.

First, I'd reinforce the importance of continuing the work. The favorable selection issue, you know, is a huge one and the issue of being able to deal more effectively with high MA penetration counties as fee-for-service dwindles. So I think we, you know, just have to

keep going down this road.

Second, I would reinforce what Jonathan and Amol already did, which is we've got to have accurate and complete encounter data from MA plans. So I think anytime we have the ability or the opportunity to reinforce that in our public statements, we need to and should do that because more and more that's foundational.

Third, in terms of the three options that are laid out, in a much more gut-driven, less rigorous and quantitative way than Kenny and Michael and others did, I came up with fairly similar take-homes, which is the Option 1, the pure bidding option, whether you call it gaming or you just call it, Michael, an appropriate reaction in a compliant fashion of smart players in an imperfect market that will always be imperfect, it's just -- there's just too much chance that we race to the top or bottom and have unintended consequences. So I just -- I'm not sure there's value in continuing to develop that.

Option 3 -- and I'm a little bit like Goldilocks or Gandalf choosing the passageway in Moria, but just -- you know, the ability to be whipsawed year to year or administration to administration on political grounds just

feels wrong for something we are trying to get to behave like a market, to the extent possible. And so Option 2 just feels right, so I would like to see Option 2 to continue -- more work to be done to continue to develop that.

Fourth and last comment, I'd certainly reinforce Lynn and Greg's points about the HCC system. I more and more over time just believe it's fundamentally broken and should be replaced. Rather than, you know, trying to rehab a house, it just should be torn down.

And the last point of my last comment is that it's around Greg's -- your comment that we really need to try to hold MA to be what -- make MA be what we wanted it to be when Medicare+Choice was first put in place multiple years ago. And I'd suggest that the best marker of MA becoming what we want it to be may well be if we're sitting here, whatever, three years from now, looking at truly widespread documented adverse selection in MA, because if MA works the way we want it to work and beneficiaries behave reasonably rationally, which, you know, most beneficiaries reasonably do most of the time, then the sicker you are, the more you would want to be in an MA

plan, because you've got somebody who is helping you navigate, you've got a provider who's paid on a value-based mechanism, you've got a network that's appropriately curated, and you've got a plan that is chasing well-thought-out, outcomes-based incentives.

So, you know, at the end of the day, I think anything we can do to kind of keep that as -- you know, MA being what we want it to be as our North Star is very important.

MS. KELLEY: Larry?

DR. CASALINO: Yeah, I'm very glad that we're doing this work, and I hope we will move forward quickly. I don't want to lose sight of the big picture while talking about technical details. The big picture is that, you know, by MedPAC's own analysis, and other people's as well, we're giving right now I think about $20 to $30 billion extra a year to MA pans, and from 2007 to 2023 MedPAC's letter to CMS the other day, just for coding alone, $124 billion of extra money given to MA plans. This is really not the time to be doing that now with the Medicare budget and the federal budget more generally.

Also, you know, this money is being used to

reshape the health care system rapidly in ways that may or may not be desirable, but are probably not reversible. So we give $120 billion to large health insurers, basically, and they use it to buy medical groups around the country, and there's various ways that that can increase their profits.

So I do lean toward Option 1. It doesn't involve the government pretty strongly. It doesn't involve the government in setting prices or growth rates. I'll talk about Option 2 in a moment. It completely deals with favorable selection, which Option 2 doesn't really do very well at all, in my opinion. It keeps us from having to try to play Whac-A-Mole with HCC scoring, which CMS is trying to do a little bit right now.

I am worried about the impact of plan market power in a lot of markets with Option 1 and how the competitive dynamic might play out. I'm not an expert on this by any means. Mike has referred to it a few times. But I think there's pretty big literature on what happens when there's a potentially small number of bidders in a competitive situation. And I'd like to see more explicit attention to that, hopefully, you know, well-informed

attention.

There are ways to deal with possible undesirable effects in that situation, I think, and actually a couple are mentioned in the chapter, but very briefly. So I'd like to see a lot more on that.

One idea that wasn't mentioned -- and this is off the top of my head, it may be naive -- would be -- we're worried about market power -- not to weight bids by enrollment when we're using the bids to calculate a benchmark. So that's it for Option 1.

Option 2 I think is a non-starter. There's declining fee-for-service enrollment. The selection issues would still be huge. I think any option -- and Greg keeps talking about this. Any option that depends on HCC scores is fundamentally flawed, and it's just going to be forever a losing game of Whac-A-Mole.

Then the last point on Option 3, you know, I would have picked that myself over Option 2, but I think it's inferior to Option 1. It's just too hard to predict growth on this scale in any accurate way, and I think also setting the benchmark to start with would also be difficult politically, very fraught but also difficult to do well.

So I would lean toward Option 1. I hope we can, in any case, move the work forward as quickly as possible.

MS. KELLEY: Jaewon?

DR. RYU: Yeah, thanks. I agree with many of the comments that were already made, but I gravitate, actually, to Option 2 for some of the comments that Scott and Kenny and others have made. I think if you think about the two challenges that at least the chapter laid out, one being the declining fee-for-service enrollment and some of the challenges related to that or the credibility issues of the current approach related to that, and then also the favorable selection, the movement between MA and fee-for-service, that option actually seems to address both, the favorable selection being address because now you have both fee-for-service and MA in the pool of data that you're using to calculate the benchmark, and then the declining fee-for-service because, again, everybody is in the pool of what you're factoring in to assess the benchmark.

I think Option 1, I think the big thing that concerns me there is it seems to propagate and maybe even further reinforce a fairly concentrated market, and I think longer term if you play that out, I think it has the

potential to backfire, leading to less competition, not more, which is kind of ironic.

And then Option 3, I was just trying to play out in my mind what that would look like, and it seems administratively cumbersome, and it also seems like it would lead to even more kind of lagging dynamics to create these adjustments that have to factor in what's going on in the market.

So for those reasons I landed at number 2.

MS. KELLEY: That's all I have in Round 2 except for Cheryl.

DR. CHERNEW: I think Kenny wanted to say something.

MS. KELLEY: Okay.

MR. KAN: I understand the concern about HCCs. One thing to be mindful of is that in the latest CMS advanced notice, CMS, by updating the risk adjustment model, will help allay a lot of the comments on HCCs. So just one thing to be mindful of, so I just wanted to make sure I pointed that out.

And number 2, regarding competitive bidding, maybe we should take a look at situations outside of MA.

I'm a plus-one on Jaewon. I remember 10 to 20 years ago when generic drugs -- this was the game, basically, when a drug went generic a lot of competitors came in and they drove the price of generic drugs to under 10 cents on the dollar, even 5 cents on the dollar. Then all the small players get squeezed out, you have a few larger players left, and then it went back. And it's concentrated, and it's like 20 cents on the dollar.

So we just need to be mindful of that. So it's a similar dynamic as playing out right now in the EV space. Tesla has the first mobile advantage. I mean, we were just talking at dinner last night that they're dropping the prices. They hope to squeeze out a lot of players, and when the market gets bigger guess who wins?

So we may want to think about all of those dynamics and what [inaudible].

DR. CHERNEW: Cheryl, and then I'm going to make --

MS. KELLEY: Okay. Cheryl. She says, "This is a terrific chapter and I thank the team for the excellent work." She supports the Commission continuing to explore alternative approaches for setting benchmarks given the

continued growth in MA, if the current approach to setting benchmarks is not viable in the long run.

A key issue she continues to struggle with is the tension between achieving savings for the Medicare program versus continuing to make MA an attractive option via provision of supplemental benefits that are paid for by the taxpayers, which is problematic.

She favors continuing to play out the competitive bidding with some tweaks to deal with issues like market concentration. She likes the idea of standardizing benefits to promote competition and to make comparisons easier as this market is so difficult for any consumer to navigate, which hinders plan switching.

Mike?

DR. CHERNEW: I don't know. I need a drink, and for me that means soda.

Anyway, so this has been a great discussion. I have an enormous number of reactions that I think we're going to have to regroup on, so let me start by first thanking you all for your comments.

I am not sure where this is going to go. I'm going to make one big-picture comment. I hear the

enthusiasm for going forward and I share it. That's why we got here. I also understand there's a big opportunity cost in going forward, and I only want to go forward in some of these things if we can solve them.

I'll just lay my cards on the table and give my personal view. In most markets where we have relied on competition in a range of ways in health care, a whole series of dysfunctions have arose in ways that we then say, well, we've yet to find a tweak or a cap or a regulatory thing, and it goes back and forth, and you end up in something that is often -- Kenny gave one example. I think you could think about this.

Larry, so much of your work is around private equity and how competition works for health care services. The notion that if you let plans do the bidding you would not find situations where -- the first part of this chapter is on selection. Imagine a world in which they selected high SES or low demand patients. They'd lower or drove out other prices. Because you get it. You're serving a sick population, gets driven down. If a deep-pocketed plan or a plan that selected better than you bids lower than you.

And so we get put in this very complicated

dynamic of how that plays out. And so what I hear, I hear a lot of enthusiasm for going forward with competitive bidding, and again, just so you know, I was asked by Jim, should we have competitive bidding in this thing, and you can probably tell I'm skeptical of it. I said yes, because we should have this discussion. I'm glad we had this discussion.

But I will I think the reaction of, well, there are these problems but may be if we put guardrails we'll fix them, is kind of a level of optimism that's well beyond at least where I am. But I'm not opposed to trying to find what they are, so we will continue that process.

But what I hear is you really need to think through what you think the longer-run equilibrium of the process will be as opposed to not, and that is a -- I think it was where Scott was -- that's risky in a lot of settings, depending on how it plays out.

DR. CASALINO: If I may, we could really use help with this as Commissioners. I take what you're saying and what Kenny said and what Jaewon just said really seriously. But it's really a specialized area in which I think there is experience and literature. And it would help if we

could be more informed.

DR. CHERNEW: Myself too, by the way, and I think that's right. So I think that's the type of work we need to do.

The other problems which I think is just true -- and I'll just make a general comment -- I 100 percent appreciate the concern that if you give too much authority the government to set the rates you worry that they're going to be -- I don't know if words were used in the session -- whipsawed, you know, subject to political manipulation. I could think of a number of other words that all would capture a very legitimate concern that what happens if the government gets it wrong, and that is really, really, really, I think, an important thing to say in this meeting, and I think it is a really genuine concern.

On the other hand, almost every aspect of what we've done, even in the selection about how to get the right amount of benefits, you end up in a world of the government is now picking how much supplemental benefits there are. Because if the competitive bidding works the way it worked in the say Slide 12 shows, basically

supplemental benefits average zero, people have to switch around their plans, so that doesn't become problematic, so the government now has to pick how much supplemental benefits are getting in MA, which might be a better thing to pick. I'm not arguing. I'm just saying this is a really complicated area.

So, one, I will regroup with Jim, Amol, and the staff to decide what we take from this very rich and wide-ranging discussion. Once we have a course forward, I think it will be a reasonable -- there's a lot of competing things -- to have a discussion about this at the retreat, to try and do a little bit of what you've said, Larry. Because I think it is very hard to have this play out in, here's this bunch of materials. Okay, this isn't really what you guys don't study competition. Let's go around and say what you all say. That's a challenging thing to do. I agree completely.

So I think we will probably try and go there.

I actually have to say, in closing, as I said at the beginning, I'm really enthusiastic about this work and this topic. I do believe that the Medicare program was not designed for 70, 80 percent, some places more Medicare

Advantage, and giving some thought to that early. You don't want it to be 80 percent enrollment -- what do we do now? So getting ahead of that, I think, is actually a valuable thing for MedPAC to do.

On the other hand, I very much take the point that there are a lot of other issues going on in the Medicare Advantage program that we also have to pay attention to.

So we have a lot to chew on. The last thing I will say is this was an hour-and-a-half session, and Jim changed it to two hours on the theory that we might need the two hours. I said, "I don't know if we're going to need more than an hour and a half, but it's better to have it if we need it." So we're 5 minutes over, probably surely my fault.

But anyway, for those at home that haven't read the material that came out I will echo that the staff did an outstanding job of outlining a range of very complicated issues, both conceptually and empirically, and I really do appreciate it. I don't know if Jim conveyed to you what I said to him. I hope you did, Jim, but if you didn’t, I'll say it now in public.

What I like best is when I read the chapters and my opinion changes or I learn something, and that bar was met with this chapter. I'm not sure where I come down on it now, which I think is useful, but I do really appreciate, just personally, the opportunity to actually expand my thinking about important issues. So that's a thank-you to you three for what you've done. I really genuinely appreciate it and mean that.

So with that we're now going to take a five-minute break, and please let's keep it close to five minutes because we're going to finish up with our discussion of site neutral. So again, we'll be back in a minute.

[Recess.]

DR. CHERNEW: Welcome back. After that last session, I think we needed a little bit of a break. So now this is like a cleanse your pallet and jump in. This is a long-standing and really important topic that MedPAC is focused on, again, for over a decade, the issue of site neutral.

And so. Dan, why don't you take it away.

DR. ZABINSKI: All right. Thanks, Mike.

To start, the audience can download a PDF version of the slides for this presentation in the handout section of the control panel that's on the right-hand side of your screen.

All right. From 2012 to 2014, the Commission evaluated the effects of aligning payment rates for services provided in hospital outpatient departments with payment rates for services provided in freestanding physician offices.

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

At the November 2022 meeting, we discussed three options for the savings that occur under the aligned payment rate options. One option would be the current law requirement in which CMS would apply budget-neutral increases to the payment rates for the services for which payment rates would not be aligned. A second option was that Medicare would keep the savings from payment rate alignment, and finally, the final option was to use some of the savings to support safety-net providers that would have

been adversely affected. This option is no longer germane based on the Commissioners' vote in January on hospital safety-net policy.

Today we'll summarize the work that we've completed on payment rate alignment, and we'll also present a Chair's draft recommendation on aligning payment rates across ambulatory settings.

All right. In fee-for-service Medicare, there are distinct payment systems for the three ambulatory settings: physician offices; hospital outpatient apartments, or HOPDs; and ambulatory surgical centers, or ASCs.

Payment rates can often differ for the same service among these three settings. In particular, the outpatient prospective payment system, the OPPS, which is the payment system for most HOPD services, has higher payment rates than the physician fee schedule and the ASCE payment system for most services.

The primary concern about these differences in payment rates among the ambulatory settings is that they result in the providers in higher cost settings acquiring providers in lower cost settings, then billing at higher

rates. For example, hospitals can consolidate with physician practices and convert them to provider-based apartments. Hospitals can then bill for the physician services at the usually higher OPPS rates with little or no change in the site of care.

In recent years, hospital acquisition of physician practices has led to an increase in the share of office visits, echocardiography services, cardiac imaging services, and chemotherapy administration being billed under the OPPS with an analogous decrease in the shared billed under the physician fee schedule, and this shift of billing increased Medicare program outlays and beneficiary cost sharing.

On this table, we show how hospital acquisition of physician practices has led to the billing of two important services, shifting from the physician fee schedule to the OPPS. From 2012 to 2021, the share of office visits billed under the OPPS increased from 9.6 percent to 12.8 percent, and the share of chemotherapy administration services increased from 35.2 percent to 51.9 percent.

Note that these are just a subset of the services

that that have shifted from the physician fee schedule to the OPPS. Also, this shift of services illustrates the need to align payment rates across settings.

It would be easy to simply align all OPPS and ASC payment rates through the physician fee schedule rates. However, these sites of care have important differences that we first must consider. One issue is that some services that are provided in HOPDs can't be provided in offices or ASCs because they're not covered under the physician fee schedule or the ASC system. The most obvious of these are ED visits, but there's also relatively complex services, such as some joint replacement procedures, that are covered under only the OPPS. These services must continue to be paid at standard OPPS rates.

Another issue is that the OPPS and the ASC system have more packaging of ancillary items in their payment units than does the physician fee schedule. We must account for these differences in packaging when aligning payment rates.

Also, we should align payment rates across settings only if it's safe and reasonable to provide the service in the lower cost settings for most beneficiaries.

Now, you've seen this slide before. So I'll review it quickly. To identify the services for which it's reasonable to align the payment rates across settings, we collected services into ambulatory payment classifications, or APCs, which is the payment classification system in the OPPS. If offices had the highest volume for APC during the 2016 through 2021 period, we aligned the OPPS and the ASC rates with the physician fee schedule rates with an addition for greater packaging under the OPPS and the ASC payment system.

But if ASCs had the highest volume for an APC, we align the OPPS rates with the ASC payment rates, but we kept the physician fee schedule rates unchanged.

And finally, if HOPDs had the highest volume for an APC, we do not believe it would be reasonable to align the payment rates for those APC, and payment rates were unchanged in each setting in those situations.

And once again, you've seen this slide before, so I'll cover it relatively quickly. This table is an example of why Medicare payments are usually higher when a service is provided in an HOPD than in an office and how we align the payment rates across the ambulatory settings.

The service in this example is from the Level 2 nerve injection APC. The first column shows the payments that Medicare makes if the service is provided in office. When we sum the three components of the payment to the physician, we obtain a total Medicare payment of $256.

The second column shows the payment if the service is provided in an HOPD. In this case, the payment to the physician has three components plus Medicare makes a payment under the OPPS to the hospital. The total of the payments to the physician and the HOPD combined is $741.

And the third column is the same as the second column, except we apply our method of aligning payment rates between offices and HOPDs by adjusting the OPPS payment downward so that the total payment is equal across the two settings. That is, the total Medicare payment in the third column becomes $256, which is the same as a total payment in the first column when the service is provided in an office.

We used this method of aligning payment rates on this slide as a basis for aligning payment rates across the three ambulatory settings.

Right now, the OPPS has 169 APCs for services,

and we've determined that it's appropriate to align their payment rates for 66 of those APCs. Specifically, we identified 57 APCs for which we aligned OPPS and ASC rates with the physician fee schedule rates. We also identified nine APCs for which we align OPPS rates with ASC rates and left the physician fee schedule rates unchanged. And finally, we did not align payment rates for the 103 remaining service APCs.

And for the 57 APCs for which we align the OPPS and the ASC payment rates with the physician fee schedule rates, beneficiary cost sharing and program outlays would be lower for the services in those APCs. Under the OPPS, cost sharing in these APCs would be lowered by $1.2 billion, and program outlays would be lowered by $4.9 billion. Under the ASC payment system, cost sharing would be lower in these APCs by $50 million, and program outlays would be lowered by $200 million.

However, under current law, CMS would proceed by applying a budget neutrality adjustment by increasing the OPPS payment rates in the 103 APCs for which we have not aligned payment rates, which includes payment rates for ED visits to fully offset the lower payment rates in the 57

aligned APCs.

In the end, aggregate beneficiary cost sharing and program payments would not change, and because this policy would increase payment rates for ED visits, it would help hospitals maintain access to emergency care and standby capacity.

Then for the nine APCs for which we align OPPS payment rates with the ASC payment rates, all represent surgical procedures, including ophthalmologic, gastrointestinal, and musculoskeletal procedures. Aligning the OPPS payment rates with these APCs would reduce the cost sharing in these APCs by $300 million and program outlays by an even $1 billion. Once again, under current law, CMS would apply a budget neutrality adjustment by increasing the OPPS payment rates in the 103 APCs for which we have not aligned payment rates, which again includes ED visits to fully offset the lower payment rates in the nine aligned APCs. Therefore, aggregate OPPS spending would not change. However, the payment alignment policies coupled with the budget neutrality adjustment would shift Medicare payments among hospital categories.

On this table, we show the percent change in

total Medicare revenue for various hospital groups. By definition, the net effect on total Medicare revenue for all hospitals would be zero, as indicated in the top row, but rural hospitals would have to decrease in total revenue of 2.5 percent, while urban hospitals would experience a lower Medicare revenue of -- sorry -- more Medicare revenue of 0.2 percent.

Also, government hospitals would have a total revenue decrease of 0.8 percent, while for-profit hospitals would have an increase of 1 percent, and non-profit hospitals would have no change in their total Medicare revenue.

These decreases in revenue occur for the rural and government hospitals because the services in the 66 aligned APCs constitute a disproportionately high share of the total Medicare revenue for those hospitals.

And the concern raised by the Commissioners at the November meeting was whether to align -- was whether aligned payment rates should be adjusted for differences in health status between settings. We acknowledged that on average, HOPD patients do have slightly higher CMS-HCC risk scores than do office patients. However, we do not believe

that an adjustment for patient severity is needed, and we base this assertion on four points.

One is that the services in the aligned APCs are generally low complexity, like office visits and simple x-rays. For example, the average relative weight in the OPPS for the aligned services is 1.9, while the average OPPS relative weight for all APCs is 2.5 times higher at 5.0.

Also under the OPPS, providers can bill separately for additional services if a patient needs more intensive care. This contrasts with the inpatient PPS, which has a fixed rate for specific diagnoses.

Third, using regression analysis, we found that hospital charges for the services in the aligned APCs are largely unaffected by patient health status.

And fourth, in response to Commissioner concerns, we did an analysis of the risk scores for the patients treated in HOPDs and offices. We found that only 8 percent of the risk scores for the HOPD patients were above the 95th percentile of the distribution of office in HOPD patients combined.

I'll also note that the OPPS has a system of outlier payments that provides additional payments to

hospitals for unusually costly cases treated in HOPDs.

And for the Commission's consideration today, the Chairman has this draft recommendation: "The Congress should more closely align payment rates across ambulatory settings for selected services that are safe to provide in all settings." And note that CMS would select the specific services for site-neutral payments based on clinical input and existing utilization pattern.

In terms of implications, we expect that over the first year that the draft recommendation would have no effect on total Medicare spending, but we do expect lower spending over the longer term as hospitals would have less incentive to acquire physician practices, which will mitigate the shift of billing of services from the physician fee schedule to the OPPS.

For beneficiaries, they will have lower cost sharing, and we expect that under the draft recommendation, beneficiaries will maintain access to the services in the aligned APCs.

For providers, we have shown that payment alignment policies will have differing effects on Medicare revenue for different hospital categories, and to the

extent there is a concern about the effect of the recommendation on specific providers, we emphasize that these concerns should be addressed through policies targeted to those providers.

Finally, overall, this draft recommendation is not expected to affect providers' willingness or ability to furnish ambulatory services.

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

DR. CHERNEW: Dan, thank you tons for that. I'm looking forward to this discussion.

I will say that it's important to understand that the option of what we've done and what we've modeled, which has been very important, that is sort of an option of what's going on. The recommendation is kind of stepped back a little bit to be simply CMS should select services, and then there's some criteria in which they should pick. But the recommendation is not necessarily the specific services that we've outlined to do our policy option. We've picked ones that we think are reasonable, because obviously, the recommendation is not explicitly do these or don't do others or some version of that.

Anyway, that said, we should start with --

[Pause.]

UNIDENTIFIED SPEAKER: So please put the recommendation on the screen as opposed to the implication.

MS. KELLEY: I think Lynn has a first Round 1 question.

MS. BARR: Sorry, Larry. Got it. Thank you.

My concern is around obviously access, right? And so in your comment about that you didn't feel that this would harm access in, for example, rural settings, what was your thinking behind that?

DR. ZABINSKI: Generally that, number one, we have the new recommendation on safety-net hospitals from January, and also that rural hospitals as of right now, they have better financial status in terms of margins than do most other hospital categories.

MS. BARR: Okay. When the -- by the way, I think this is great work, and I think you're on to something here, and that there is a framework where we can look at services that are being offered and say should we or shouldn't we, you know, what should we pay for.

But when you're thinking about that, I just --

I'm curious as to how you thought about access, because what I believe you're saying here -- and I think is correct -- if you Medicare could get this service in a physician's office or a hospital, why should we pay? That's fair, right?

But what if there is no access other than the hospital in that local area? So it doesn't really consider that access piece. It seems like there's an assumption that access is a given.

DR. ZABINSKI: Well, just based on what you see in terms of what services are being applied, how they move around from the physician office to the hospital -- and it's clear, at least to me, that what the hospitals are doing when they -- they're moving a lot of these services into provider-based apartments, which are paid at physician fee schedule rates, and they don't seem to have an issue with providing more of them in that setting.

MS. BARR: In that setting.

Okay. But the assumption is this is a commodity, right? And you should be able to get it, and that there should be -- is there an assumption that you should be able to get this service in a physician office in order for this

formula to apply?

DR. CHERNEW: Can I try and take a -- do you want to take a stab, Dan, or otherwise --

DR. ZABINSKI: No, go ahead, Mike.

DR. CHERNEW: The assumption is not so much that you could go somewhere else to get it. The assumption is that the cost of it being provided in any setting is basically you're worried about commodities, that the cost is basically the same.

So the concern that you have, which is a completely legitimate concern, is that if there's no office setting and you lower the price to the hospital, even though we think that the hospital should be able to produce it at that lower price, because other places they can, that they really can't. And they will then drop it, and then there will be an access problem because there's not another place to go. That has to be taken into account in the selection of services.

I think what Dan would say is through some combination of what the marginal cost of producing the services are, the connection of the services to other things that are obviously going to happen in the hospital,

and then broader programs we've made to support those types of hospitals that might lose revenue in general, we are trying to cover those bases.

But the notion, I think, generally speaking, that you would pay dramatically different for very similar services, vastly, because you're just trying to -- because there's a few places where you can't -- is I think where we would push back.

MS. BARR: Okay. I just want to -- I don't want to dominate this, but just to clarify, that the services that you selected were services that you could get elsewhere, and that there was an assumption of access in that, in the selection of those services. And so I just don't think that that's a reasonable assumption.

DR. CHERNEW: It wasn't an assumption about access as much as an assumption about cost differentials.

MS. BARR: I thought it was an assumption that if you could safely do this here or there, right?

DR. CHERNEW: Yes, that's right, but --

MS. BARR: But that means access here or there.

DR. CHERNEW: No. That just means that if you could safely do it in the physician's office, even if there

was not -- that's loosely the cost of doing it. It's not about the --

MS. BARR: But you allow some things to stay in hospitals because it's more complex but not to stay in hospitals because it's the only access point. I'm just kind of clarifying that.

DR. CHERNEW: Okay.

DR. SARRAN: It's only the payment that's changing here.

DR. CHERNEW: Yeah.

DR. SARRAN: It's not where the procedures happen.

MS. BARR: I get it, but I'm just -- the criteria seemed to me around this is a commodity, and I'm not sure it's a commodity if there's no access, right?

At any rate, I'm not going to dominate the conversation, but that's my comment.

MS. KELLEY: Larry.

DR. CASALINO: So Dan and I have had, to me, a very satisfactory communication about this in this past week, but it is something I want the whole Commission to hear.

I think the idea of using volume as a criterion for which site's payment rate to use is a good one. In other words, if the volume is high in physician offices than the assumption is that it's safe enough to do in physician offices and therefore should be paid the physician office rate. I think that's good.

The problem is, as Dan readily acknowledged, that as hospitals acquire more practices this could become problematic. And so, for example, if you look at transthoracic echoes, which are discussed in the paper we were given, in 2012, 32 percent of them were done in hospital OPDs, and now with the acquisition of more practices it's 43 percent, and it probably won't be too long before it's about 50 percent, and you could imagine that that would happen with some other services as well. So that's a problem for the volume criterion.

I think there might be a solution to that, and Dan, I'm saying this partly because I think it is a Round 1 and people should hear it, but then I'd like your response. You could, for example, and Dan suggested this, set a point in time, like now, when you would decide which site to use for the payment rate and then that would be true forever

after. Otherwise, every year you could get more and more services in an ASC or in a physician office now being dominated in volume in a hospital and then you'd be paying hospital rates.

So Dan, your comments?

DR. ZABINSKI: Yeah. I mean, that's clearly an issue. I think one idea would be to, okay, you set some group that you think are viable candidates and you don't allow any to be taken out over time, and if any come up that seem to be viable candidates in the future you can add to them. That's one possibility.

DR. CHERNEW: I think the recommendation is trying to get to more of a multifactorial selection process. But to deal with that issue, for example, you could treat freestanding hospital outpatient departments like they were offices to pick the services. In other words, you could differentiate between how CMS would do it.

But again, there is a level of detail about how CMS would go through the process of selecting that's a little bit beyond this. That's why we've moved it to, you know, how clinical input matters. Volume is just a way of identifying sort of a quick way of getting candidate

services, I think to use a Dan phrase, to say what are things that we think could be produced at the cost that we're currently seeing outside of the hospital. And then once you get this, so it might be you have to go through a whole bunch of other screens, somewhat related to Lynn's concern, would hospitals drop and would we lose access, and related things.

DR. CASALINO: I'm sorry. I just would like to see this specifically mentioned in the chapter, the potential problems with the volume criterion and how to deal with it. Transthoracic echo is not a dangerous procedure, to put it mildly. It's safer than getting your blood drawn really, and probably doesn't need to be done in an HOPD to be safe.

MS. KELLEY: Robert.

DR. CHERRY: Yes, thank you. I was wondering if you can clarify for me how we're defining physician offices. And to provide some context, increasingly physician offices are in atypical locations these days. So you have health plans buying physician practices. You have retail pharmacies, big box stores, telehealth companies, et cetera. And so how broad is this in terms of how we're

defining physician offices in this context?

DR. ZABINSKI: It's defined in the sense of how it's billed more than anything. Kind of why I emphasized that's probably the better way to think about it is how it's billed. It might look like a physician office but if it's billed under the OPPS, it's not. If it's billed under the physician fee schedule then it's classified as a physician office. It's more a billing technique rather than a location type thing.

DR. CHERRY: Okay. So that's clear. Thank you.

MS. KELLEY: Kenny.

MR. KAN: Great work, Dan, on the site neutral analysis. I'm very supportive of the Chair's draft recommendation.

On page 13, I found the finding that hospital charges for the services in the aligned APCs are largely unaffected by patient health status reviewing, and having done this in a prior commercial setting, because in trying to implement something like that the one complaint or pushback is that hospitals will say that they have the higher acuity patients.

So I'm curious as to what do you think drove that

finding on this slide?

DR. ZABINSKI: Yeah, that's a good question. I think it's sort of a combination of two things. One key factor here is just the type of services that we're including. They're generally pretty basic, like I said, office visit, x-rays, that type of thing.

The second is the nature of the OPPS. You have a patient, one who is in really very good health and one that is in very poor health, and under the OPPS if the patient in very poor health needs some additional things that the one in very good health doesn't, they can bill separately for additional things under the OPPS. It's not like the inpatient PPS, where you have kind of a set rate or whatever the patient is in the hospital for, where you don't get additional payment for doing more, but under the OPPS you can.

MS. KELLEY: Amol.

DR. NAVATHE: Dan, great work. I just had a very quick question of clarification, which is that with respect to the rural hospitals, critical access hospitals would not be affected by this because they're not paid by OPPS. Is that correct?

DR. ZABINSKI: That's correct. Yes.

DR. NAVATHE: Thanks.

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

DR. CHERNEW: Let's go to Round 2.

MS. KELLEY: All right. I have Jonathan first.

DR. JAFFERY: Thanks. Yeah, Dan, this is great, and I really appreciate how you've sort of continued to give this more nuanced, sort of elegant, targeted approach to this concept. And I think it's very timely and commercial payers are starting to push on this concept more. So the more that we can get ahead of that, to add that nuance, I think is important.

With that said I think there are two or three things I want to mention where I think there still may be some disconnect between the analysis, the policy proposals and goals, and sort of what happens on the ground.

The first one may have some similarities to what Lynn was saying, but I'm thinking more specifically about the ASCs and the nine APCs that are done most commonly there. So while conceptually I agree that if it's done most commonly there it's safe to do there, and effective.

But the analysis around it is really national level, right, and as you know, ASCs are not available everywhere. And even if they are, they may not provide all those services because some of them are very specialized.

So I think that's a potential concern, and I wonder if there's an opportunity to think about incorporating something like what we had proposed in the past around isolated dialysis centers, if there's some sort of modifier if they're some distance from the nearest ASC that provides those services. So that's one thing.

You talk about some categories, trauma and emergency medicine, that might have some modifiers and I think that makes sense. I wonder if there are some other things, other categories that are things that beneficiaries might need or choose to go to a place where there are more services readily available, and that might be based on some other characteristics like transplant, cancer, some other immunocompromised state.

And I guess that sort of gets into my last thought. This gets into the complexity, and I appreciate that that complexity doesn't necessarily translate to whether or not something could be done safely, needs to be

done in a hospital safely all the time. But I'm not sure that always totally captures the complexity and what that means for beneficiary choice or provider preference or advice around where somebody gets something done.

So even if the presence of diabetes or a history of transplant or whatnot does not change the outcome whether it's in the hospital or in a physician office, and even if you don't end up needing additional services or needing additional things, as you said, that there may be some subjectivity to where something needs to be done. And that's important because, I mean, I think that's what we're getting at with some of the basics is that the hospitals need to have greater capabilities to do things in certain circumstances, and that's very costly to maintain that kind of capacity and capability.

And so it may be a very appropriate decision for a beneficiary to go one place versus another, even if they don't end up needing those services. So I think that's a potential distortion that we should think about that goes beyond just what their HCC scores or diagnosis codes include.

Thank you.

MS. KELLEY: Greg.

MR. POULSEN: Thanks very much. I'm really piggybacking very much on what Jonathan just said, so thank you. I'm grateful for the hard work that's gone into this, Dan, and I realize this is an incredibly difficult and challenging topic in some meaningful ways.

I've really, really wrestled with this, this last week, and I'm supportive of the way this is phrased, and I understand that that's likely to go with wording that essentially mentions that these services are those that could be effectively treated in freestanding settings except for an occasional emergency situation, something like that.

And the reason I think that it's really important that we understand that is that there are often things that end up looking exactly the same in terms of the way you bill it and code it and so forth, and yet are very, very different.

Let me just give you an example. I'm going to pick one that I intentionally didn't determine whether it was on our list of possible examples or not because it is irrelevant whether it is or not. Examples like this could

be used for a whole bunch of things, including transthoracic echocardiograms. And I got real examples from real people that happened in the last week.

Consider one that's a 76-year-old who has developed difficulty swallowing, occasionally feels like her airway is partially blocked. This trouble is gradually growing, and after an examination her internist decides that an MRI of the neck and thorax is appropriate to look for what's going on and see if there's a tumor or something else.

So it's scheduled at the imaging center within the same clinic. She shows up. She goes to the changing room. She gets changed. She goes in, sits down on the table, lies down on the table, they give her a headset, and say, "Okay. This is going to make some loud thumps and so forth. Don't be concerned. Relax."

So she's zoomed into the MRI machine. She's asked to breathe deeply and then hold still. Boom, boom, boom. This happens three times. Out she comes. She sits up and she goes back and gets changed and leaves. End of story.

Okay. Now imagine an 82-year-old living in a

care center, moderate dementia, losing some cognitive skills. And Sunday morning this actually happened. Sunday morning this gentleman throws up. They're worried that something is going on. There is a little concern that he may have swallowed something that's lodged but there are other concerns too. They decide that an MRI would be very helpful. And so they call the hospital because, by the way, that's where patients from these centers go. They don't go to the freestanding imaging centers, even if it wasn't a Sunday.

So off he comes there. He's disoriented. He's now in a place he's not used to. Two technicians assist him in getting changed. They have to call back to the care center to make sure that he doesn't have any metal implants that would be dangerous in an MRI setting. They double-check his mouth.

Also, because he's disoriented, they really have two choices. They can either basically knock him out or they can sedate him a little bit and provide assistance in the MRI. Doing the latter requires an open MRI as opposed to the normal closed tube MRI that some of us are familiar with. And it's a more expensive machine, by the way.

So on he goes to that. Because it's an open MRI it doesn't have the strength of magnetic fields for the patient so they need to have him hold still longer than he would in the closed tube, which, oh, by the way, is very difficult because he doesn't understand the hold still parts of this. So they go in, they try it out, and they can't get a sharp image because her keeps moving around, especially when the loud bangs start. It startles him -- no surprise.

So they move in with a second tech, so you're going to have two techs in holding each hand and reassuring him, trying to help him to be calm, which they ultimately do. They ultimately get the images that they need. At this point the two techs now go and help him to dress, and off he goes back to the care center. Elapsed time, about four times as long as the first patient took in the freestanding center. And oh, by the way, rather than having one technician they had three technicians involved during that time.

So at the end of the day it's still coded the same procedure. And there really aren't additional services. There's not additional things that happened to

that patient. They didn't suture him. They didn't give him anesthesia and so forth. So this ends up being really expensive.

Now that's a rare example in the scope of all the MRIs. It's not a rare example in a tertiary referral center hospital. That's not uncommon at all, because people who can go in, lie down, get the exam, get up, and go out are going to go to the freestanding center. So the costs are significantly higher at those hospitals, historically, when those have happened.

Let me just give a quick example that you'll all recognize. OB ultrasounds, which we don't do a whole lot of for Medicare patients, I get that, but nevertheless those are basically not done in most hospitals anymore as an independent service because they're so readily available elsewhere, and by the way, they cost a lot more in the hospital. We all know that.

So if you want an OB ultrasound the only way that you get it in a hospital is through the emergency department, if you show up with pain that requires that. My concern is if we start to have patients like our second one that really only get access to the hospital setting via

the emergency department that's a huge challenge because the clinicians in here know you'll never have a patient show up at the emergency department and say, "We need an MRI of the upper chest." Ain't going to happen. The ED physicians are going to say, "Well, we've got something in the upper chest. Let's take a look and see what's going on."

They may go straight to the MRI but they may determine that an endoscope would be the appropriate way to approach this, at which point you've got general anesthesia, you've got endoscopy, you've got minutes in the OR, and suddenly what started out as an imaging test just became a full-blown intervention that could become incredibly expensive, and spending many, many thousands of dollars.

So I think the downside if we don't limit this to the appropriate cases -- and I think the wording here does that, so I am supportive. But I really want it on the record that we need to be very careful that what we don't do is unintentionally push this into something where people who are, for their own situation, able to get this service in a freestanding center and those who don't, end up going

down an emergency room pathway. Because a lot of hospitals already are in this situation. My hospitals are in this situation because we have freestanding imaging centers, and the people who should go there do go there. And I'm proud to say they're not licensed as hospital outpatient departments. They are freestanding centers.

But for those people who actually need the hospital service, the payments that they are getting to date don't cover their costs, and to push them further, I think, is likely to see some institutions simply unwilling to take those as an independent outpatient service. It rather would be, "Great. Call the emergency department. We'll get him in and we'll take care of it." And they'll do a good job but it's going to cost multiples of what this outpatient service --

DR. CASALINO: Greg, do you have a proposed solution?

MR. POULSEN: Yeah, absolutely. I have two proposed solutions. The one is part of this, which is let's make sure that we constrain this to those services which really can be done in a freestanding setting, with only occasional ones that go through the ED, which a lot

these are. I mean, we've got a huge number here in the list that are things like chemotherapy. That's appropriate to be done --

DR. CASALINO: But you wouldn't include MRIs.

MR. POULSEN: I would be thoughtful about which MRIs I did include.

DR. CHERNEW: Just to make sure that we move along -- I don't mean to belabor this point --

MR. POULSEN: No, I understand.

DR. CHERNEW: The actual details -- and Greg knows this because he's talked about it a lot. The actual details of what will be chosen and the exceptions or not or whatever happens is the recommendation assigns that to CMS. I think the way that I read or listen to Greg's comment is getting on the record the notion for the text to make sure that CMS does that thoughtfully.

MR. POULSEN: That's it. That's the entire point.

DR. CHERNEW: Right.

MR. POULSEN: And the other point is the one that Jonathan made, which is I don't think it would also be unreasonable to contemplate -- although I don't think this

is in the recommendation. I'm supportive of the recommendation irrespective of this -- is were there an additional code that allowed you to have some sort of a multiplier for cases that justified a differential level of care without necessarily getting some different procedure. It would be the same procedure. So I think there are a couple of mechanisms that could be used and either one of which, I think, or in combination.

So, again, sorry, long way to say I appreciate what's been done. I know there's been a lot of work here, and I just wanted it to be on the record that CMS has a responsibility to be thoughtful about this or there could be adverse consequences.

MS. KELLEY: Okay. Lynn has -- oh, sorry, did someone want to jump in?

[No response.]

MS. KELLEY: Yeah, Lynn had a Round 2 comment that she sent before she had to leave. She thinks this is important work and supports the approach of identifying instances where beneficiaries can get a similar service in alternative settings and reducing pricing in those instances. Her concern is that the current formula assumes

that access is equal in urban versus rural areas. In rural settings, the only reasonable access to these services may be the hospital. She thinks the formula needs to be modified so that areas that do not have access to alternatives should not have a reduction in payment.

Rural and sole community hospitals may reduce or eliminate unprofitable services and access under this policy like they have eliminated maternity services due to poor Medicaid reimbursement. This doesn't seem like a good policy if it only punishes rural and government hospitals, threatens access for the underserved, and doesn't actually save Medicare any money.

I have Robert next.

DR. CHERRY: Thank you. I appreciate all the hard work that has been done around this. I have to say I'm very much on the fence regarding this proposal, mainly because there are several potential, you know, unintended consequences associated with this.

One is the fact that, you know, hospital outpatient departments are licensed facilities associated with their hospital, and I'm a little concerned that it might drive the de-licensing of these outpatient areas.

Now, there are pros and cons to doing that, but there are also, you know, significant cons as well, and I don't think that's really been considered. So it may drive behaviors among hospitals that have not really been fully considered.

The other thing I was concerned about -- and Greg articulated this very nicely -- is the level of difficulty in using coded data and trying to figure out how to select services across all settings, and particularly among academic health systems or health systems that deal with a lot of tertiary and quaternary patients because of the complexity of care, the co-morbidities that they have, and the clinical judgment that's necessary to determine which is the most appropriate setting. And so I'm a bit concerned that there could be unintended consequences that Greg mentioned in terms of providing an optimal location that coded data may not be able to fully adjudicate for.

Then, finally, the other concern is just the unintended consequences or optics around, you know, rural hospitals, you know, losing 2.5 percent under this model and for-profit hospitals gaining 1 percent. I'm not quite sure that that is what we're trying to drive here in terms

of equitable care and access to services.

So these three concerns are major concerns for me, and there would be a lot more work involved, I think, to make this a viable solution, at least in my opinion.

Thank you.

MS. KELLEY: Stacie.

DR. DUSETZINA: Thank you. Dan, I think the lucky socks maybe are working, hopefully. So I am very much in spirit in favor of this recommendation and getting payments to align more closely. Could you go to Slide 8? I think it's where you demonstrate the breakdown of the payments and how this would shift.

[Pause.]

DR. DUSETZINA: Okay. Yeah, that's the one. So I guess one of the overarching things when I look at this and when I'm thinking back through the issue of, you know, that savings here mean that we just repay for services within the OPPS at higher amounts, so there's not like a huge savings.

The other thing that seemed glaring to me is: Is this the right amount for those services in the office setting? And part of this, I think, goes to the issues,

you know, looking at the list of proposed services, you know, in the top, a lot of drug administration codes, and some of the work we're talking about separately on the payment redesign changes how much, you know, the drug payment is, but the administration codes and fees are different.

So I guess I'm just kind of thinking about those two separate work streams and this concept of is the office setting -- is that the right price there before you do that adjustment to match them and then redistribute that money across other OPPS services.

So I realize that that's probably not something we could specifically do, but it's just maybe a point of Jaewon's dreaming yesterday, like if I could think about are these the right amounts, then match the prices, and then, you know, reshuffle the dollars within the OPPS for the other services because of the neutrality.

That is probably dreaming, but it did strike me as something that even if we're not saying what services necessarily will be included, those seem like low-hanging fruit, especially given the amount of spending on those services, the frequency of spending for those services,

and, you know, that they can be safely provided in both settings.

Also to Robert's point, I completely agree the redistribution that looks like the government hospitals and rural hospitals are harmed is really concerning. And I really appreciate Lynn's comment about like what do you do when that's your only site of care, like the hospital is your only site of care to get those services. Do you pay them more? But then I worry that would also reward like an incredibly consolidated area where, you know, maybe you don't have systems because everything is under the hospital outpatient umbrella, so then we're accidentally overpaying both the places that are treating patients who have no other real options, and we're also maybe accidentally rewarding consolidation, which I think we don't want to do.

So I am in spirit very much in favor of this, and I also really appreciate the analytic approach and all the detailed work that you've done there. I think it makes a lot of sense from a logical perspective of how to select services this way. So I very much applaud the work, but do think there are some of these big-picture considerations that I'm still wrestling with.

MS. KELLEY: Okay. Now I have a comment from Cheryl. She is very supportive of the approach outlined in this chapter and the Chair's draft recommendation. She's concerned, given budget neutrality under current law, that there are no net savings in the near term when ideally the Medicare program and taxpayers would be able to benefit from the proposed changes.

She does wonder how much will be accrued in savings over a longer time period as a function of reduced incentives for provider consolidation. While this may tamp down on future consolidation, a great deal of provider consolidation has already occurred, which will limit the potential savings.

And now I have Betty.

DR. RAMBUR: Thank you very much. Just to start off by saying I'm a very big supporter of site-neutral. I can tell you that perhaps as a nurse I have somewhat of a different experience, but it's very, very hard to respond and feel like it's honorable to a patient who says, "I had this done in this setting just this little bit ago, and now again the exact same thing, the exact same office, and this was more expensive. Why?"

It is very hard to feel like it's an honorable response, so I'm very supportive of the language.

A couple of things about specific things that were raised. The issue of government and rural I think, you know, gives me pause. At the same time, I'd be reluctant for us to pay more to rural, for example, because I've seen a lot of mission drift in rural hospitals who actually figure out how they can get the revenue. So they start doing, you know, complicated surgeries when there's a place not that far away. So I don't have a solution to that, but I think we should pay attention.

I was questioning on page 16, 15, it says there wouldn't be any cost savings in the short run. I wasn't clear on that because the example I gave of Person X who now has this much bigger bill, isn't their savings in their cost sharing, you know, even in the short run?

DR. ZABINSKI: Well, yeah, you know, on specific services, yeah. What we're talking about is, okay, you have the savings on the services for which we align payment rates, there's savings there. But then they do -- CMS would step in. This is in law, in statute, that they'd have to increase the payment rates for all the non-aligned

services.

I'm finding myself that there is potential eventually for some pretty big savings as the consolidation -- to the extent it -- it all depends on how much the consolidation slows down.

DR. CASALINO: And the budget neutrality rule for this could be changed as well, potentially.

DR. RAMBUR: But we'd want that to go in the right direction.

DR. ZABINSKI: Right.

DR. RAMBUR: Anyway, it seems to me that individual people would feel a difference in their cost sharing.

And then the last thing, the issue of using volume as one of the drivers, I'm not able to critique that, so I really have to, you know, look to some of you in terms of getting that right. So I appreciated the comments on that. But I am very supportive of this overall direction.

MS. KELLEY: Mike, before we end, I wanted to note that before he had to leave, Scott said he was extremely supportive of the recommendation and he thinks

this is solid and important work.

DR. CHERNEW: Great.

MS. KELLEY: Amol has something as well.

DR. NAVATHE: [Off microphone.]

DR. CHERNEW: I'm going to go around. Say your piece, I guess Larry and then Amol, and then I will say my piece, and then we'll go around quickly.

DR. CASALINO: Really my piece is just go around saying --

DR. CHERNEW: Okay. Amol.

DR. NAVATHE: [Off microphone.]

DR. CHERNEW: Okay. So, first of all, this is a very helpful discussion, and I mean it when I say I've heard a lot of the concerns. I think one of the challenges that we face in general -- and I would say this is a broad problem with fee-for-service, writ large -- is we just don't get the prices right in a gazillion different ways. And so I have to say personally I'm very skeptical of using site of care as a proxy for illness or severity, but I also am quite aware that in some ways site of care is a proxy for severity. And certainly when we get our post-acute stuff, we struggle with exactly that issue of how to play

out.

I think we need to separate out our desire to support organizations like rural or government, or whatever it is, in ways that don't involve mispricing services. And so there's a balance in how this is played out. This is intentionally crafted in a way that the recommendation does not explicitly say, you know, this is what the volume criteria should be for when you're doing it. The volume is being used mostly to identify services -- if there was a service that was always done in one site or 90 percent done in one site, you wouldn't want to worry about should we -- you wouldn't really worry about exactly how to manage it when you see services that are done broadly across different sites, you would then look at them, to Greg's point. That is just -- you have to look at them, right? And then CMS is going to have to make decisions about what service is going to be paid where, as they do for a whole bunch of other things, and sometimes the services are right and sometimes they're not. And we had a lot of discussions on that.

So that's sort broadly where I am on thinking about how to implement our principles of paying similar for

similar care, understanding that you can never say the same and they're going to get it wrong in some cases, and you have to worry to the point about if some -- you're the only provider in an area and you drop the services, that's clearly a problem in a range of ways, so that has to be taken into account. But it has to be taken account, in my view, by CMS in the selection of the services and what they do as opposed to the principle that we're recommending.

But that's my view, and so now maybe we'll go around, and I guess we'll start -- we started with Jonathan last time, so we'll start with Kenny, if you want, and we'll just go around just quickly.

MR. KAN: I'm supportive.

DR. DUSETZINA: I'm also supportive.

DR. RILEY: I'm on the fence. I'm with Robert. I'm really worries about the effect on governmental hospitals and rural hospitals.

DR. GRABOWSKI: I'm supportive.

DR. NAVATHE: I'm supportive as well. I want to make a couple of really quick comments.

One, I agree with Mike that the implementation pieces are really important, and that what we're doing here

I take to be illustrative, and so CMS would put a lot of effort hopefully in trying to implement this appropriately.

Second, I think Greg made a number of fantastic points. I think importantly we have to differentiate whether something costs more to deliver versus a lot of these services, like having MRI, open MRI, are not created for the purpose of this OPPS service. They're for a much bigger issue, and so what is the marginal difference, in economist-speak, you know, that little difference. And we're not stopping to pay for these services. We're just paying an increment less. And so I think they're -- this is something to think about there.

The third point, Betty pointed out the cost-sharing piece. I think that's really important. Essentially, as part of this, we're saying a lot of people who are getting the identical service in a different site are paying more cost sharing, which seems unfair.

And the fourth point is I agree with concerns that Wayne and others are raising. I think we have to also keep in mind that we did do the safety-net work that I think is in part really just to try to help some of these issues.

Thanks.

DR. RAMBUR: I will say again I'm very supportive and consider it to be a matter of fairness and ethics as well. Thank you.

DR. CASALINO: And I am very supportive. Look, I'm a clinician, and I get what Greg described, real-life cases, and Robert in a more abstract way also brought up some problems. But I just want to put things in perspective here.

I think that -- what's the most common thing where this is a problem? It's office visits, right? So by way, way, way overpaying hospital-based physicians for office visits, we've driven consolidation. We've cost CMS a lot of money. So I don't want to let the exceptions drive the policy. If we just did exactly what's in this report, nothing else, I think the country would be so much better off now than it is if we don't do anything.

That doesn't mean that CMS, as Mike keeps saying, couldn't try to do something to deal with exceptional cases. You know, rural is so often a problem, but there would be ways of dealing with that. I don't want to let the exceptions drive the recommendation here. So I think

it would be great, and then CMS would have to try to deal with some of the concerns that have been brought up, and I think they could be dealt with. But, again, these are not -- as Greg said, these are not necessarily rare, but they're very uncommon in relation to high-volume things like office visits, which we are way overpaying for now in hospitals.

MS. GINSBURG: I'm with Larry.

DR. CHERRY: I'm on the fence, but, you know, less supportive in the current format.

MR. POULSEN: And as I said, I'm supportive as written, with an understanding that the text will identify that there are services -- that CMS should examine the services to make sure that we're not doing harm and driving things to the ED, which I think is an absolute possibility -- not for office visits. I agree with that. Not for the services that I think have inappropriately been created by the definition of a hospital outpatient department when, in fact, it is a freestanding area. I agree with all those points. I just want to make sure that we don't take what I think could become a major, major inflator of costs by driving people to the emergency department as the only way

for people with distinctive illnesses to end up getting their car. Ditto kind of for the rural issue.

DR. JAFFERY: It strikes me that sometimes when we drive towards fairness in everything, you get unintended consequences. So, Mike, you were very thoughtful to say let's start over there because we started here, but now I get the first and last word.

[Laughter.]

DR. JAFFERY: So, you know, I think I said most of what I've said, and as Greg just said, I'm very supportive of this overall approach of trying to align payments so they're safe to provide in the appropriate settings, and, you know, just with some of those same caveats. You know, Larry, totally agree, if the bulk of these are office visits, you know, office visits absolutely should be on that list. It sort of gets down to what's on what list, and I'm not sure we -- there may be still some nuances to work out. I mentioned the thing about the availability of ASCs and so how do we modify for that. But there may be some things that are on the biggest list now, on physician offices, that maybe we need to think about and if there are other modifiers. That may be a select few,

and I think, Greg, you had made this point earlier. There may be -- even if those -- though those things may be in the scheme of things very rare for individual institutions, they may be relatively common.

Thank you.

DR. CHERNEW: Apart from my microphone, I also don't know if anyone can see me, but that's besides the point. I am here, just so you know.

Thank you all for these comments. It really was a good discussion. It was a rich discussion. I think it shows the level of deliberations that we can do, so we will regroup and think about all of this and make sure that the text reflects these concerns, and then we'll ponder where we are, and I'll be continuing to work with Amol, Jim, and the staff on this.

So, with that, it concludes our March meeting. For those of you at home, thank you for joining us. Please don't hesitate to reach out at meetingcomments@medpac.gov. We do want to hear what you say. Or you can go to the website and leave us comments there.

But, again, Dan, terrific job. We really do appreciate it. There's a lot of analytic work and thought

that goes behind this, and I think it's really quite a good job. So, again, thank you. Thanks to all the other staff for their presentations today and yesterday, and we will see all of you again in April.

Everybody, travel safe.

[Whereupon, at 11:42 a.m., the meeting was adjourned.]