Washington State Health Care Authority
Prescription Drug Affordability Board
Meeting Transcription
July 16, 2024

MaryAnne Lindeblad: Small group today. So good morning.

Eileen Cody: It's summer.

MaryAnne Lindeblad: Yeah, it's summer. So I just want to go ahead and welcome everyone for those that are online and the small group in the room, and let's go ahead and get started with some introductions.

Eileen Cody: Eileen Cody.

MaryAnne Lindeblad: Mike? Oh, let's get Hung and Doug. Please introduce yourselves.

Douglas Barthold: Hello, I'm Douglas Barthold, Board Member. It says that the video is disabled for me right now. It won't let me turn my camera on.

MaryAnne Lindeblad: Oh, Okay.

Hung Truong: Me, too.

MaryAnne Lindeblad: And get that fixed. There we go.

Hung Truong: There we go.

Douglas Barthold: Great.

MaryAnne Lindeblad: Hello there. Welcome. It's nice to see you both.

Hung Truong: Hi, Hung Truong, Board Member. I had a late start this morning, and I couldn't make it down there on time, so I went straight to my office.

MaryAnne Lindeblad: Doug.

Douglas Barthold: Hi. Doug Barthold. Board Member. Hi, everybody.

MaryAnne Lindeblad: Great. So let's quickly do staff.

Mike Neuenschwander: Yeah. So Mike Neuenschwander, director for the program here from HCA.

Simon Borumand: Simon Borumand, Policy Analyst.

MaryAnne Lindeblad: And then staff that are online.

Ryan Pistoresi: Good morning. This is Ryan Pistoresi. I am the Assistant Chief Pharmacy Officer here at Health Care Authority.

MaryAnne Lindeblad: Expecting anyone else?

Dana Beuhler: This is Dana Beuhler from the Attorney General's Office.

MaryAnne Lindeblad: Dana, okay. Welcome.

Mike Neuenschwander: Is Kelly online?

MaryAnne Lindeblad: Kelly?

Kelly Wu: Oh. Hi, I'm Kelly, and I'm the PDAB Data Analyst.

MaryAnne Lindeblad: Anyone that you're expecting?

Kelly Wu: Nope.

MaryAnne Lindeblad: That's good. All right. Well, then let's go ahead and get started. So again, welcome. It's great to see you all, and I hope you're having a wonderful summer. And should we go ahead and start with Mike's report?

Mike Neuenschwander: Yeah. So just a director update. Let me pull up my list. So we are still looking for that elusive fifth Board member. We've had a few names that have been sent to the Governor's office, and so we've been waiting for them to go work [cross-talk] on the next steps for that. So there still has been interest in that, and hopefully, we will get that resolved in the near future. And then let's take it over to Simon, who has updates on the Advisory Report.

MaryAnne Lindeblad: Oh, great.

Simon Borumand: So, as you know, we opened up an application for members of the Advisory Group. There are two phases of that. The first stage is finding a core Advisory Group, and there are up to nine slots available for that and a range of expertise that they could fall into, and I can share my screen just to make it easier to see what those available are and what we've received so far. So these are the potential expertise that we're looking for and, so far, we've received five applications -- Jim Freeberg, Ronnie Shure, Laura Berry, Tim Lynch, and Dharia McGrew -- and across the five of them, they hit all of the different buckets, except for one, which is clinical and health services research. So we're leaving the application open and accepting applications on a rolling basis just to get that filled up. But I think at this point we can move forward with getting these folks on Board, and I have sent over the applications to you all to review.

MaryAnne Lindeblad: So timing wise, what do you think it will be?

Simon Borumand: So I think the goal is by -- I need to look back at the schedule -- but I do see [cross-talk] --

Mike Neuenschwander: Let's have a little bit of a timeline here.

Simon Borumand: Okay.

Mike Neuenschwander: So for this summer, the Board Members take a look at those applications, and then in September we can go ahead and appoint the Advisory Group members we would like, and then along with that for our September meeting, hopefully, looking at a draft dashboard for some of the drug selection metrics that we're going to be looking at today. And then also review any draft drug review outline that MaryAnne has been -- working on, so what our drug review is going to look like probably collect the data from that. And so, yeah, those are the next steps here for the summer and all for our next meeting.

MaryAnne Lindeblad: Great. Thank you. Douglas or Hung, any questions about that? All right. So, anything else?

Eileen Cody: That's it for your [cross-talk] --

Mike Neuenschwander: [Cross-talk] I see your point.

MaryAnne Lindeblad: All right. So we'll go ahead, and on this item, we actually do have to take a vote to approve the eligible Drug List Identification Policy. So Mike and Kelly.

Mike Neuenschwander: Yeah. So that is the policy that we were reviewing last time. We talked about it for the last [indistinct] this is the policy that we will be using in order to create that drug list as required by the Legislation with the drugs under those different categories over $60,000 per year with a 15% or 50% increase, etc. So yep, I think [cross-talk] --

MaryAnne Lindeblad: Gone through it?

Mike Neuenschwander: Yeah. We've gone through it a couple of times here, so I think we are ready to go.

MaryAnne Lindeblad: Okay, that sounds great. [Cross-talk] Oh, a question.

Douglas Barthold: Yeah, thanks. Sorry to -- that I didn't raise this earlier, but I actually do have an issue with one of the items in the policy, and so [audio cuts out] from PhRMA, and they have a pretty good point in there on the seven-year market requirement. And essentially if you look at item 1 (d) -- sorry, it's 2 (1) (d), where we say a prescription drug on the market for at least seven years means the drug ingredient has been on the market for seven years, and that actually is -- like sort of contradictory to what it says in the statute about identifying prescription drugs that have been in the market for at least seven years, and so the way that we define prescription drugs is sort of in line with the statute says is not then by drug ingredient being market for seven years, which is what we then have in item 2 (1) (d), and so that seems like something we should either correct or clarify, just because it does seem to be contradictory.

MaryAnne Lindeblad: So what would you suggest in terms of language change?

Douglas Barthold: So there are a couple of options. One, so do you see that just above that in item 2 (1) (d), we do define a prescription drug. And so if in the next item in 2 (1) (d), we said that the prescription drug has been on the market, I mean, I guess, it [cross-talk] seems redundant. But right now the way it's worded with the drug ingredient being the market for the seven years, just seems to be -- yeah, sort of contradictory to our definition of prescription drug.

Mike Neuenschwander: And Ryan, I think, has a comment.

Ryan Pistoresi: Yeah, so the reason that we made this determination for it to be the drug ingredient is really around the biosimilars, right? So if we're looking at the requirement for looking at a biosimilar and trying to determine if it's an affordability review, if that biosimilar had to be on the market for seven years, you would be looking at the launch price from over seven or eight years ago. So we were looking at that and felt that the Legislature did not want you in let's say 2025 to be looking at the launch price of a drug in 2018 and say that it was unaffordable in 2018 and have a new requirement for an upper payment limit and an affordability review in 2028. So really, we felt that if it were not the drug ingredient, there would never be an opportunity to look at a biosimilar with how it was written, and that would just invalidate really any biosimilar review that you could do because you would be looking at the prices from seven years ago when it launched versus all of the other drugs, which would be within that last year. So in order to accommodate for that, we used the drug ingredient.

Douglas Barthold: Okay, thanks. That makes sense for the biosimilars, but what about for brands and generics and those criteria which make up, I think, the vast majority of our eligible drug list. Is there -- I guess like my -- the reason I'm concerned is just like because of the -- I guess I worry about if this was challenged, if there is any issue with the legality of defining the seven years by drug ingredient rather than by -- rather than with our own definition of prescription drugs.

Ryan Pistoresi: Well, I think one of the challenges is that we do see the line entries and new generics, and so we do see some drugs that may be on the market, and then the manufacturer may pull it and then introduce a new NDC associated with it, so that could essentially get around this seven-year mark. So even though the drug has been approved and is able to be marketed because of that product availability, there could be games played in which a drug could be pulled from the market and then a new one entered, and that would reset that clock, and we wouldn't be able to do the [cross-talk] --

Douglas Barthold: [Cross-talk] Sure.

Ryan Pistoresi: -- affordability review for it.

Douglas Barthold: So yeah, I agree on the justification. I think it does a good job of doing what we are trying to do. I just -- obviously, I am not a lawyer, so I just won -- the

reason I ask about it is because it does see -- like, it's just the language that we are using seems to not match the statute, and so I wonder if we are going to have any problems with that. Is that something we should be concerned about?

Ryan Pistoresi: And so maybe we can ask Dana, who is our AAG on the call today. I know that she hasn't been part of a lot of the discussions that we've had, Michael Tunick, but she might be able to talk about how we went through our rulemaking and defining it in WAC and some of the ways that we try to address it with some of the rulemaking.

Dana Gigler: Yeah. Thanks. Let's see, my Zoom won't let me turn my camera on either, but I am here. And you're right, I have not been part of any of these discussions for about nine months. I advised on some of this very early on, so I haven't had a chance to look at any of these substantive issues or questions, so I'm not really in a position to give you a good answer today. But if you -- if that's something you would like a deeper look at, then we can take the question back, and Michael or I can look at it and get back to you with a more thorough legal analysis.

Douglas Barthold: I mean, is that [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] that is probably what we need to do. Yeah, it sounds like that's what we need to do would be my suggestion, and just let's put this one on hold and have it ready for next time. Does that? Does that work for everybody?

Unknown male: Yep.

MaryAnne Lindeblad: Okay, then let's just go ahead then.

Douglas Barthold: That's fine with me, too.

Hung Truong: Hey, Doug, just a comment. Actually, I like to keep talking about that with you for a little bit on -- so are we worried that when we call a drug ingredient -- because a drug ingredient can come out anytime. It's just when it becomes a drug, I mean that's really when you actually can start using it, right? And so a lot of the ingredients have been around for a while, so when we define it this way -- and I think we were alluding to it, it hasn't been out in use long enough

to be eligible. That's -- I think that's when -- we need to interpret the drug ingredient a bit further.

Douglas Barthold: Yeah, I agree with that. I mean, I think Ryan's point was spot on about the potential gaining that could exist if we just did it at the NDC level [cross-talk] --

Hung Truong: [Cross-talk] Yep, okay.

Douglas Barthold: And so, yeah, I completely agree on this justification. I just wanted to make sure that we are in line with the statute.

Hung Truong: Yeah. No, that's a great question. I was trying to think through, like, Okay, how -- but I can see the issues with it.

Unknown male: Oh.

MaryAnne Lindeblad: Right. Well, I think at this point, then, we'll go ahead and put that on hold and work on some language over the next few weeks and have something to propose next meeting. So let's go ahead, Simon, reviewing the annual report.

Simon Borumand: I'll pull that up there as well.

MaryAnne Lindeblad: Thanks.

Simon Borumand: So each year we are tasked with submitting an annual report to the Legislature. Last year's was fairly short. It was just we appointed a Board [indistinct]. This year, it is also fairly short but a little bit more going on. And if you're wondering why we're doing this in July, the review process takes so long before it can be submitted that we basically start drafting it in the summer, but in what we've done up until now leave placeholders for what we expect to come over the rest of the year and then submit it to the Legislature [indistinct], and so the key areas here at the beginning of the year, we selected a Board Chair and Vice Chair. We ratified policies and procedures. Over the course of this year, we'll be creating a PDAB Advisory Group. We have developed an initial drug list, and that's part of the [audio cuts out] actually, and you know we contracted with PORTAL, so this section is fairly short, just kind of going over those key points. This is posted on the PDAB website, and it's been shared with Board members. So it goes through it in more detail later on in the [audio cuts out], but you can see the draft. So

we still have things to fill in over the course of the year, but it just gives a brief description of each of these milestones that we hit. [Indistinct] --

MaryAnne Lindeblad: It's due December 15th [audio cuts out] and we've got a little more time for folks to review, and if they have any questions or concerns, and then whatever you add to it.

Mike Neuenschwander: [Cross-talk] Well, and there are a number of levels of internal review [cross-talk] we're going to send it all, and you're well aware.

Eileen Cody: Yes. [laughter]

MaryAnne Lindeblad: Multiple levels.

Mike Neuenschwander: Yes. So it's got [cross-talk] --

Eileen Cody: We're both laughing at this from different viewpoints.

Mike Neuenschwander: Yeah. Yeah, so--

Eileen Cody: So like the fill in the blank, yeah.

MaryAnne Lindeblad: Yeah. [Cross-talk] --

Multiple Speakers: [Laughter].

Mike Neuenschwander: Yeah. So if you do have comments or questions or things you want to edit, sooner rather than later is better. And I think we'll have time to bring this back to take a look at it again in September for our September Board Meeting before it goes for its final [cross-talk] review through the whole system. And we will be able during our November meeting to look at what final products could look like, but, at that point, it won't really be edits because they need to submit by in December so the Legislature can look at it at it the start of the next year.

MaryAnne Lindeblad: Of course [cross-talk] --

Eileen Cody: We would have to read to every [audio cuts out], so.

MaryAnne Lindeblad: And so just reminding folks then to go ahead, and if you have comments, we want to have those by the September meeting [cross-talk] so we can get this wrapped up on time.

Mike Neuenschwander: And knowing we are doing this six months in advance, so we are forecasting a little bit of stuff that hasn't [cross-talk] even been done yet, right? [Cross-talk] but in order to meet [cross-talk] in order to meet the timelines since it's the process we have.

Eileen Cody: But they changed the date, right? [Cross-talk] Wasn't it earlier that you had to report last year? I thought [cross-talk] --

Mike Neuenschwander: So December 15th, I believe, is the date that it's supposed to be in. Well, it's like officially [cross-talk] done, done, but to get to that mark [cross-talk] --

Eileen Cody: [Cross-talk] I know, you start [cross-talk] --

Mike Neuenschwander: [Cross-talk] So it's got to be [cross-talk] --

Eileen Cody: [Cross-talk] got to be here in, like, September, right?

Mike Neuenschwander: Well, probably -- I think it's at the end of this month we send out our first draft, right?

MaryAnne Lindeblad: Yeah, the first. Yeah. It sounds about timing, right?

Eileen Cody: Sounds about right.

Mike Neuenschwander: Yeah.

MaryAnne Lindeblad: Yeah.

Mike Neuenschwander: So.

MaryAnne Lindeblad: All right. Just a reminder for everyone, make sure you have a chance to review [cross-talk] all the way.

Mike Neuenschwander: Yeah, read it. Got comments? Get it back to us ASAP.

MaryAnne Lindeblad: Yep. All right. Well, Mike wanted to talk about the updates to the WAC.

Mike Neuenschwander: Yes. So for WAC, again, another process that takes a little bit of time and has to go through a number of levels of review. There were two bills that added some language concerning the PDABs, where we have to make some tweaks. Bill 1508 was talking about sharing data between the PDAB and Health Care Cost Transparency Boards (HCCT), and so we're working to figure out how -- what the wording is to be able to do that. Additionally, there is Bill 1105 that requires the Board -- so we already had the 30-day requirement public comment when we set upper payment limits. This just simply specifies that we need to have a start and end date for those 30-days, so we need to have that publicly available so that way people know exactly when it opens and closes for that 30-day comment, so that's something else we're putting in the WAC. So those are the two things we need to look at, according to other Legislation that has been passed. And if the Board has anything that you want to change in the WAC, again, due to the timeline of how long it takes, again, speak now. I know Simon sent out some requests if you have any things or ideas to have those ready. Yeah. So any others? Doug?

Douglas Barthold: Uh, I don't have any suggestions, but I just wondering, can you tell us which sections of the WAC -- you said it's two things that you want to change?

Mike Neuenschwander: Correct.

Douglas Barthold: And yeah, I mean --

Mike Neuenschwander: So the first one goes under the data confidentiality section is where we're looking to put that because it has to do with sharing data with HCCT.

Douglas Barthold: Okay.

Mike Neuenschwander: The other one we were just going to create a new section. We aren't at the point where we need to do upper payment limits yet. That's still a couple of years out, obviously, but because it's pertaining to that, we were just going to create that initial upper payment limits section, so a whole new section that we tack on at the end of the current WAC.

Douglas Barthold: All right, that sounds good. And so then are we reviewing those today? Or what possessed you to just telling us that that's the plan?

Mike Neuenschwander: Yeah, we -- I still haven't gotten this, like, officially in the document, but this is what we need to do, so we're working in terms of what would have to happen with drafting, and I can show that during our next Board meeting in September.

MaryAnne Lindeblad: So be prepared for the next Board meeting for any comments.

Mike Neuenschwander: Yeah.

MaryAnne Lindeblad: And then you'll want to vote then or the meeting [cross-talk] --

Mike Neuenschwander: So the WAC isn't -- that's something we [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] Don't have to vote on, okay [cross-talk] --

Mike Neuenschwander: [Cross-talk] vote on because this is kind of its own separate [cross-talk] process outside?

MaryAnne Lindeblad: Okay.

Mike Neuenschwander: But if you do have anything else that you want to add to the WAC, now is the time to say so, so that way we can work on writing it in.

Eileen Cody: [Cross-talk] Yeah. I'm just curious. Staff doesn't have anymore things that they think that we need to do WACs on [cross-talk] as we move forward?

Mike Neuenschwander: Right now, no, because the other stuff in terms of like the drug reviews and upper payment limits, but we are going to want more of that. We haven't completed that yet. And so -- and then two, just because of the timing of what we need, submitting this stuff now to get it done by December 31st. Again, unless we do it right now and have it all ready, it won't get done in time, so that stuff would be for the next year.

MaryAnne Lindeblad: So you're saying this is really an additive process?

Mike Neuenschwander: Yeah. Oh, yeah. No. The WAC as our program goes as we are adding these Our program goes as we are adding these different sections and building the program, yeah. You know, it was the upper payment limits section there will be [cross-talk] --

MaryAnne Lindeblad: We get them [cross-talk] sadly, it is the long process that it takes to write a WAC rule into WAC. So you'll be in that kind of [indistinct] probably on an ongoing basis for a while.

Mike Neuenschwander: Yeah. [Cross-talk] So I now I foresee in the next couple of years we are going to be adding stuff, and next year is where potentially at more meaty stuff, as where this is more smaller edits on specific things related to our program.

MaryAnne Lindeblad: Great. Any other comments? Questions? Well, I think we're doing really well with time.

Mike Neuenschwander: Yeah.

MaryAnne Lindeblad: So let's go ahead and let Kelly and Ryan and PORTAL talk about the current eligible drug list.

Mike Neuenschwander: Yeah. So maybe -- because PORTAL is not going to hop on until 9:15, [cross-talk] when we talk about the drug selection methodology, but I guess Kelly, Ryan, anything you want to talk about in terms of our list, and does the Board have any questions specifically on the list that we generated?

MaryAnne Lindeblad: [Indistinct].

Mike Neuenschwander: That whole list is [cross-talk] in the back.

Eileen Cody: [Cross-talk] Oh. Look in the back. Oh, my God! [Cross-talk] --

MaryAnne Lindeblad: [Cross-talk] Oh, it's that teeny tiny [cross-talk] bill.

Eileen Cody: Okay.

MaryAnne Lindeblad: It comes with a negative [indistinct].

Eileen Cody: But it doesn't have just the 14, right? You've got -- this is everything.

Mike Neuenschwander: Yeah.

MaryAnne Lindeblad: That met criteria.

Eileen Cody: The ones that had the two. I was intrigued by the nitroglycerin one.

MaryAnne Lindeblad: There was some on there that really surprised me. I was like, that's been around forever, yeah. Yeah. However, they made the list kind of thing.

Eileen Cody: [Cross-talk] Yeah, right.

MaryAnne Lindeblad: [Cross-talk] Yeah. So that was surprising. Most not, though.

Eileen Cody: Yeah. Well, yeah.

Douglas Barthold: So it looks like our distribution, when I look at like how the categories of how you get onto the list. It kind of matches what we saw in Colorado, right? Where it's mostly a course of treatment over $60,000, although, there's just a different threshold. And then there's a good chunk of biologic with greater than or equal to 15%, and then -- is there only two generics that made it? Am I reading that right?

Ryan Pistoresi: Yep. You're right about the two generics. And yeah, the Colorado threshold I think was $30,000 [cross-talk], and ours is $60,000. So you know their list will be larger than ours. But for the upper ones on their list, it should be the same.

Douglas Barthold: Well, that's good. I mean, I think it's encouraging that the distribution of categories matches theirs and also -- the number of drugs that made it in match what our intuition suggested it would be given the differences in the rules. And so it suggests that we apply the rules correctly, which is good. Yeah, I think this spreadsheet looks great. It's very helpful, well-organized.

MaryAnne Lindeblad: Any other comments or questions?

Hung Truong: Hey Ryan, I'm looking at the list, and the category for some of these non-specialties. And, I mean, I didn't fact-check any of that, but just to see some of them. And it says the course of treatment is over $60,000, it doesn't seem correct. I mean Lamictal, as an example, is it truly over $60,000?

Ryan Pistoresi: I think the way that it met that threshold is it was looking at that high dose. And so if a patient were to be taking that Lamictal at that dose, they'd be taking more tablets per day. So I think in the real world someone that would be taking that higher dose would like to be on a higher strength, and that

higher strength I don't think appeared on that list. So based off of how we ran the calculations and the data set, that's how some of these drugs appeared. But to you, as the Board, you may look at that drug and say we don't think that necessarily is one of the drugs that is causing affordability challenges to Washingtonians, and you may not prioritize it, but still based off of the way that we calculated it, it does make the list. But I think to your point and to the points of the other Board members that some of these other drugs are ones that you do recognize as causing affordability challenges and, likely, those are the ones that would make it to the next step, whereas this example, the Lamictal probably won't.

Hung Truong: Yeah. And I think there's opportunity just for the team to clean it up because the Board might -- we might not know, right? I've seen it before just because of practice, but for others, they might not. And so. Yes. Yeah, I'm sure there's a lot more work into this that we need to do. But thanks, Ryan, for explaining, clarifying.

Mike Neuenschwander: And part of that, too, will be as we go through these next steps of the process where we're trying to prioritize the data that we specifically want to see, that we'll be talking about here shortly. And that will help refine those drugs down more specifically to0 measures and things that we feel are -- or that the Board feels is important to be looking at as we take this list of 400-some odd drugs and try and get it down to a handful, right? So this -- I think the purpose of this first go around is just getting that list, meeting the initial legislative demands, and creating a list that is done in a way that we can make sure we get a good showing of what could be out there to meet the legislative intent, but then our filters will help bring that down and eliminate some of these other drugs, if we're like, oh, yeah, maybe that's not really the kind of thing that we want to look at, right? So.

Douglas Barthold: Yeah. The high-dose could be super rare, and also the rebates may actually bring -- could effectively bring the price way down if the use of the drug in general could be super rare. But I think I like this first poll as sort of just like this is the most you could possibly be, and then and then we filter from there.

Mike Neuenschwander: Exactly. Yeah, that way we're not missing stuff, right? So it gives us a good broad net. Okay, other questions, thoughts on this list when we take our initial look at it?

Eileen Cody: Well, I've got a question because I don't remember how the Legislation like with the NDCs that are on multiple lists, and there's what, one, two, three -- it's all the patch on the nitroglycerin. So if we do the review, does it count as one drug doing a review when it's the same drug that is just a different strength? Or would each one have to have a review?

MaryAnne Lindeblad: That's a good question. I mean, I hadn't thought about that.

Eileen Cody: Because it would seem like it would be the same one review for all [cross-talk] of them, but I'm just -- this may be one of those things that we have to figure out whether we need clarification on the Legislative level or whether we can do it in a WAC. I mean, those are.

Mike Neuenschwander: Ryan?

Ryan Pistoresi: You know, that is a good question and one that I haven't thought of. So we might need to take that back and think about what that intent was and what we might be able to do with it in WAC. But that is I think something that we'll have to take back.

Eileen Cody: No, it just impressed me that the nitroglycerin patch was, obviously -- I thought that was great technology.

Douglas Barthold: I mean, ultimately, it's going to depend on the level at which we apply the upper payment limit, right? That's where the sort of where it meets the road. And so we would want it -- that is something we will specify in the section of the WAC about the upper payment limit, right? The unwritten, non-existent future section of the WAC about the upper payment limit?

Multiple Speakers: [Laughter]

Douglas Barthold: Is that right? Is that? That's where we will say the UPL will apply at some level. We'll define that level, and that level could be NDC, or it could be all of the -- whatever the six rows of nitroglycerin, all of them get looped into one.

Ryan Pistoresi: Right. Because I think you know one of the things that we had thought about, but, again, we need to go through the details is that manufacturer's version of that drug. So to Hung's point earlier that Lamictal, if we were to choose that, then would we only apply it to that low-strength NDC, like the, whatever, 2 mg, but the 20 mg don't, and so then would everyone then switch to the 2 mg

and begin taking 10 tablets instead of one of the 20s? So I think there are some things that we would need to think about operationally and what we would want to have as the intended effect of these upper payment limits, so that way we don't necessarily have a situation like that.

Hung Truong: And then we run into different makers with different prices. And so going back to the point of are we looking at NDC or drug ingredient? I'm assuming there are quite a few makers of nitro patches, right? And so this one happens to hit that threshold to be on the list, whereas the other four or five might not. And so what do we do? Is it worth putting in a UPL on it?

Douglas Barthold: Then in multiple indications will matter, too, because that -- they were these -- you know, this -- the course of treatment we're defining kind of -- we're defining a way that gives us the maximum possible catch to see how much these things could possibly be, but the -- if there are multiple indications where the course of treatment varies widely -- you know, big differences in course of treatment or big differences in doses, we would only want to apply an upper payment limit to the indications that actually do have the dosage and course of treatment that meet that threshold of unaffordability, which could be a rare indication, or it could be a common one. So I think it's important that as we get down -- as we filter this drug this down, we have to have a way of incorporating indication. Relatedly, one idea that I think could be helpful for that is if, when possible, grouping could be at the NDA level, the new drug application level because I think it's something -- correct me if I'm wrong -- but every new -- every NDA is for a new indication. And so that could potentially be helpful for us to separate -- whatever -- the same ingredient used for two different indications.

Ryan Pistoresi: You mean SNDA, the supplemental for new indication.

Douglas Barthold: Yes.

Ryan Pistoresi: Okay, thanks.

MaryAnne Lindeblad: Are there comments, questions?

Douglas Barthold: Actually, Ryan, I have a question. Would it be -- like, how hard is it to link -- so our current eligible drug list with its -- um, how many rows do we have here? 470 rows. How hard is it to link each of those NDCs to a specific NDA or SNDA? Or I guess it would be in ANDA for the two, but yeah.

Ryan Pistoresi: I think there is a field in the database that we use that does have a table with NDA information? If not, there might be a table that we could download from the FDA that might have that information. So I have a few ideas on how we might be able to link the list that we provided with a list that finds those NDAs or SNDAs or other application numbers, but we don't have that necessarily readily available right now. But I have a few ideas on how we might be able to make that list.

Douglas Barthold: Great. That's awesome. Yeah, I mean, that's kind of like, to me, I consider that, like, as a possible option for how we can easily separate by indication, but if there's another way to get to do that, then we can do that, too. But this just seems like one possible strategy.

Mike Neuenschwander: Anything else?

MaryAnne Lindeblad: So we've got about five minutes before we expect.

Mike Neuenschwander: Yeah, 5 minutes. All right. See you in five. [Indistinct] --

[break]

MaryAnne Lindeblad: Thank you. A nice little break. So the PORTAL folks have arrived. Is that? Okay. And we started out and had a bit of a conversation about the list, and I think we just want to go ahead and continue that. So --

Mike Neuenschwander: Kelly.

MaryAnne Lindeblad: Kelly or Ryan.

Mike Neuenschwander: Kelly is up as the presentation.

MaryAnne Lindeblad: Is she up for presentation?

Mike Neuenschwander: [Indistinct].

Kelly Wu: Sorry, are you starting the presentation?

MaryAnne Lindeblad: Yeah, if we could go ahead, Kelly.

Kelly Wu: Okay.

Mike Neuenschwander: Okay.

MaryAnne Lindeblad: There we are.

Kelly Wu: Okay. I'm sorry. For some reason I don't have permission to share my videos, so you'll just have to listen to my voice. Since the last meeting, we've been able to touch base with each Board member to get a sense of what their priorities are and what data measures they're interested in. So when it comes to selecting drugs for affordability reviews, so I'll be presenting the information that we gathered from these meetings, and I'll also go into a little more detail about whether the various data measures proposed are feasible or not. Um, oh, okay. So before I jump into those data measures, I'll go over again what the Board is required to consider when selecting drugs for affordability review, then I'll go over the proposed data measures and discussion points to think about, and then we can have some more time for discussion and questions. So this is a reminder of where we are in the process. So right now we're at the selecting drugs for affordability review stage. Okay. So a reminder before we jump into the proposed data measures. The bill says that the Board must look at three data measures, and that's the prescription drugs and availability -- sorry, the class of prescription drugs and the availability of therapeutic equivalents, input from relevant Advisory Groups, and the average patient's out-of-pocket drug cost -- the out-of-pocket cost for the drug. And then also the Board can choose up to 24 drugs a year to review. All right. So let's jump into the data measures that the Board proposed. So just an illustration, here, basically where I said in the last slide. So when deciding whether to select a drug for affordability review, we have these three, required data measures, and the Board can also look at other data measures that aren't in the [audio cuts out]. So I would categorize the data measures brought up by the Board into these four main categories. So we have drugs on multiple lists, drug costs, utilization, and treatment options. So feel free to stop me as I go into more detail, and let me know if I missed anything, or if you have any other data measures you thought of and want to add. And I'm anticipating that there will be lots of discussions, so feel free to speak up as we move through the slides. So first we have drugs on multiple lists. So when selecting drugs for review, the Board could consider whether a drug meets multiple review thresholds and is, therefore, on multiple lists. For example, a drug increased in price by both 15% in the last 12 months and 50% in the last three years, and another consideration could

be whether other states have identified the drug for review. So even though Washington may have different review thresholds than other states, if the drug happens to be on another state's affordability review list, this could be useful to know because perhaps there may be some information sharing if another state already did a lot of work on pulling the data for that drug. And the Board could also consider, for example, whether they want to review the same drug as another state. Another category is drug costs. So there are lots of proposed data measures for this category. So we have the total drug costs, the out-of-pocket cost, which is one of the required data measures in the bill. We have member paid amounts, cost per member per month, rebate amount in manufacturer assistance programs and coupons. So later on I have a slide on data measure, so we might need clarification or definitions for. Like, for example, what are the costs that should be considered when calculating the total drug cost? And like what is the difference between out-of-pocket cost and member-paid amount? And something to keep in mind that I'll mention later is whether you want to whittle down the amount of data measures we are going to use to select drugs, or are you just going to look at all the data measures available? For utilization, their proposals of looking at the percentage of the population using the prescription drug, the number of people using the prescription drug, the utilization by disease state, and the utilization by specialty and non-specialty drugs. So I think these were getting at the idea of does the Board want to review perhaps the drugs that are used by a lot of people but are not as expensive or drugs that are really expensive but not used by a lot of people. And, of course, these two scenarios aren't mutually exclusive, there could be a drug that is both expensive and used by a lot of people, but these are some scenarios that come to mind for these data measures. And, finally, the Board members proposed considering treatment options, for example, whether the drug has therapeutic equivalents, therapeutic alternatives, or generics available. So, basically, are there other options instead of taking this drug? And another consideration is step therapy or utilization management. So does the health plan require patients to take alternative drugs that are less expensive before they can access the more expensive drug. So just to go back to the previous graphic that I showed, now that we went through the proposed data measures, we hit two of the three required, and I have a slide later talking about how we anticipate input from Advisory Groups. So I showed this during our last meeting, but I want to get everyone reacquainted with the data sources again before I jump into my next few slides. So a very important data source is our Washington All Payer Claims Database, which is where we will get our utilization and out-of-pocket cost-related data, and I have a few slides coming up going into

more detail about this data source. And we also have potential manufacturer and PBM data, and I'll talk about why I'm using the word potential here and in some slides coming up later as well. And then we have our commercial drug price databases, First Data Bank and MEDISPAN, which is where we'll get our drug price data. So a little background on the Washington APCD. So it contains claims dating back to 2014 for about 70% of the total Washington state population, and all health carriers in Washington state are required to report their data as well as state Medicaid plans, PEBB, SEBB, third-party administrators in the Washington State Labor and Industries Program, and self-funded plans are not required to submit, but they can do so on a voluntary basis. So as with any data sources, there are some strengths and limitations to the APCD data. So the APCD is great because it captures data from a very large portion of the Washington state population because it contains data from most public and commercial payers in the state. And the PDAB team also has access to the APCD data, which is important if you want to use it, and there's also some great Technical Support provided to us. Some cons of using the APCD are that it does not capture the entire state population, particularly the uninsured people or self-funded plans that choose not to report and also other types of claims such as claims paid by auto insurance. So on a similar note, other missing data would be like manufacturer rebates or coupons provided to patients. And then also another limitation of the APCD is data quality. So, for example, there could be a lack of consistency with regards to data quality across different submitters.

MaryAnne Lindeblad: Doug? Doug. Doug has a question.

Douglas Barthold: Yeah, thanks. Um, just a question about the All Payer Claims Database. What amount of detail do we have about the plan or the payer for each colesevelam? Can we link? Is there like a plan ID that you can like to? I'm thinking about the UPL coverage guide that we are working on now that was just sent around. Is it possible to know if each claim is covered by a plan that would be where the UPL would apply if it was a UPL?

Kelly Wu: So no. The APCD just has like the planned type, like HMO or Medicaid or Medicare, so it doesn't go into that amount of detail.

Douglas Barthold: Do any of our data sources have a plan ID or anything like that that we can link to? Then we can then know whether or not a UPL would apply?

Kelly Wu: At our moment, I believe our only claim source -- like source of claims data is the APCD.

Douglas Barthold: Okay. Um, well, I definitely keep that in mind. And I think we've spoken about this a bit before, but, yeah, I just want to emphasize that ideally, these criteria that we were using for selecting drugs for affordability review, especially the cost and utilization, we would want to measure those in plans for the UPL can apply because we could potentially let -- I mean you can imagine -- you said so it doesn't cover the entirety of population, you can imagine a situation where like most of the claims are driven by plans where the UPL wouldn't apply, and then we would have measures of cost and utilization for people whom we will never affect with any of our policies, and so that would not be the best way [indistinct] -- it's an extreme example, but that's what we want to avoid. And so we should keep that in mind as we measure cost and utilization because we want to make sure to try to be aware if we're measuring it for people that -- where we don't have any policy leverage.

Hung Truong: Kelly, you mentioned 70% -- it covers 70% of the state lives, right? Okay. So it looks like 30% are probably for the self-funded, I'm assuming.

Kelly Wu: I did not look up the statistics for what other that make up the other 30% is but, yeah, probably uninsured/self-funded, and then, like I said, some like miscellaneous types of claims like paid by your auto insurance or something.

Douglas Barthold: Hm. So that's good then -- if the self-funded is the bulk of what we're missing because we can't affect them that they're not subject to the UPL anyway. So that's encouraging.

Eileen Cody: And that -- it would have to be mostly the self-funded that's not included in the uninsured. I mean, and what? We're at, like, 4% uninsured in the state, so we're 4 to 5 where we're at lately. So yeah, actually, I'm encouraged that there are that many of the self-funded that are kicking in their data to the APCD.

MaryAnne Lindeblad: [Indistinct] 70%.

Eileen Cody: Yeah.

MaryAnne Lindeblad: That's better than what I would have expected.

Eileen Cody: Yeah.

Douglas Barthold: And then I have one other question, just as we calculate cost and utilization. Is there any way in the APCD to know the indication?

Ryan Pistoresi: No. I don't believe there is a way to look in the APCD and know what the indication is because I think it's just the pharmacy claims. And because ICD-10s are not on pharmacy claims, there's no way to actually link that. We would have to go into the EHR [cross-talk] --

Douglas Barthold: [Cross-talk] Yeah, we [cross-talk] --

Ryan Pistoresi: -- to get that level of data.

Douglas Barthold: Huh, okay. And [Cross-talk] --

Ben Rome: [Cross-talk] And I can't speak to specifically the Washington APCD but, in general, for claims data. All right? Like you link medical and pharmacy data to make those determinations, so it does get complicated. I mean there -- assuming there is a unique patient identifier where you can identify -- you know, even in studies where people do this, where you sort of look for indication, we've done this in some studies. Like, you look for indications, like how much of a drug is being used for different indications, and there's always this sort of number of claims that, like, you can't find the indication. Like, there's no ICD code that sort of matches. And there's also the concern that the ICD codes don't match the FDA labeling so often, like there might be some very granular FDA labeling distinctions that there's just no way to tease apart based on even if you are able to link to medical claims. So I would say that, like, in some cases, claims data, more generally in APCD data, can be used to identify. It's a more complicated task, but it cannot work in all circumstances, and it's imperfect.

Douglas Barthold: Okay, thanks. So yeah, as we move forward, we want to keep that in mind, like, for all the same reasons I mentioned before about the importance of indications when we're grouping or when we're defining the level of drugs that we're analyzing. Maybe there's some way we can just -- and I apologize -- this is a bit of a digression to going back to sort of this level of drug conversation, and maybe there's some way that we can flag NDCs or ingredients or generic names that are commonly used for multiple

indications as sort of just like -- as something that we might want to consider as we're selecting drugs.

Ben Rome: I'll just say, Doug, I wasn't -- I know I was -- I got an update from Matt on your first part of the meeting. I apologize I couldn't have -- I wasn't here -- but, in general, no country that does a new process -- and I've never -- and I don't know of any sort of contracts around pricing that do like differential pricing by indication. And because it's challenging, how do you actually know, like, when [cross-talk] there is no requirement to submit unless a PBM or a health plan requires a prior authorization, so then they sort of do know because it's a checked box by [cross-talk] the doctor of like what indication the patients using it for, and again, because defining an indication is hard. In cancer, for example, like there might be two indications. One is first-line therapy and one second-line therapy. Are they all lung cancer? Or are those two separate indications? From the FDA standpoint, there was a separate review process. It might be separate regulatory processes for determining whether or not the drugs were safe and effective in those two different uses. From a common perception standpoint, it's all lung cancer, right? I'm just like giving it a broad example. So it's not -- so, you know, it's not very easy. Or kids are another example, like an antibiotic that treats a particular infection, and then it's studied also in kids. Are those two different indications, or is it just like one indication? So defining an indication is not super straightforward either. And again, like, especially when you go to claims, like, those things aren't going to line up.

Douglas Barthold: Yeah.

Ben Rome: They are not required to. There's no, like -- there's no, you know, there's nothing. There are no, like -- you know, there's nothing that's binding the FDA to think about ICD codes when it's thinking about how to write label [cross-talk] or approve labeling for drugs.

Douglas Barthold: Yeah. I mean, so one of these were talking before, it's just like you could end up with vastly different costs for a course of treatment for two different indications just because, obviously, the length can vary, and the dose can vary so much. And so what we did in our first step of defining the eligible drug list was we sort of took what the max of what -- you know, the max values to just get like the max it could possibly be for a course of treatment. But as we, you know, for evaluating whether or not that drug should have an affordability review or whether it should have an upper payment limit, even

if we can't know -- even if we can't calculate the cost of treatment at an indication-specific level, which I think would be ideal, but if we can't do that, then I think we at least want to try to know which drugs are commonly used for multiple indications just as an additional criterion on which we have make our decisions. Does that make sense?

Ben Rome: It does. Although, I don't think it fully gets at your max question. I mean, I think, right, I mean I agree with you, but I think that [cross-talk] --

Douglas Barthold: Yeah. The max is -- that is sort of just to get, you know, the biggest list of drugs as possible. We want -- like, we have, you know, a very broad inclusion criteria at this -- at the first eligible drug list, and then as we refine, you know, some of those, maybe they won't make it because -- uh [cross-talk] --

Ben Rome: [Cross-talk] Right. So to your point, though, the APCD can be used to look at, like, the average amount paid per patient, right? Like that, or per over the course of the year, right? So for just, like, if you just line up every patient who used the drug and figure out how much they spent on the drug that year, or how much them plus their insurer spent, that can be done. That's data that Colorado -- the Colorado PDAB has presented to its Board in the last five cost, you know, affordably reviews that it did. So that is how they sort of -- and it was -- that was how, you know, that was how they thought about sort of defining the course of treatment was based on basically just real life use. They did not [cross-talk] stratify it by indication, so it's built in that if a drug is used 50/50 for indications, which would be sort of weighted. If it's 90% for one indication and 10% for the other, it's going to be weighted heavily towards the one indication. It matters because they're sort of looking at all patients. So each -- it's weighted by the number of pa --, you know, by [cross-talk], so just kind of waiting was sort of built-in.

Douglas Barthold: Yeah. And I like that. I just worry about that bimodal of this if there is like a bimodal indication where, like, it happens to be, you know, cheap and short in the real world for one indication, and then long and expensive in another, and then we have -- then we [cross-talk] --

Ben Rome: [Cross-talk] So to your point, that's not -- right. So a flag saying that a drug is used for multiple indications doesn't tell you whether there's going to be a bimodal distribution. So there are some drugs, like, I know of where the price does vary because it's either weight-based dosing, or the dosing is different for different indications. But oftentimes even for drugs with multiple

indications, the price for a course of treatment is very similar. Right? So I think that your question is, are there different prices for different indications? And if your question is are there multiple indications on the label? That won't get you all the way there. And that would be -- I mean, most drugs would have multiple indications on a label, or many drugs would [cross-talk] and not give you an answer to your question of, is there [cross-talk] by different [cross-talk] by different [cross-talk] --

Douglas Barthold: [Cross-talk] I was thinking that it is like [cross-talk] --

Ben Rome: [Cross-talk] really what you're trying to drive at.

Douglas Barthold: Yeah. That could be -- I was thinking of that as like a flag to trigger, sort of, like, either further investigation or, like, you know, just, you know, something else to keep in our minds as we are making a decision about that drug. Yeah. We can -- I mean I think we can move on, and we'll consider that as we think about these things.

Kelly Wu: All right. So, the next data source would be manufactured PBM data. So in the bill, Manufacturer is defined as a person, corporation, or entity engaged in the manufacture of prescription drugs sold in or into Washington state. And the bill stipulates that the manufacturers must comply with PDAB's request for data when conducting an affordability review, but there isn't anything in there about needing to comply if PDAB asked for the data at the drug selection stage, but PDAB can use manufacturing PBM data that is presently collected by HCA's Drug Price Transparency Program. So for those of you who don't know what that is, it's a program created by the state Legislature, and the goal of this program is to develop a better understanding of the drivers and impacts of drug costs. And this program collects data submitted by health carriers, PBMs, drug manufacturers, and pharmacy services, and administrative -- organizations, so I copied the part of the RCW that states that. Okay, so back in a previous slide, I checked off two of the three required data measures that the bill requires the Board to consider when selecting drugs for affordability review, and the remaining unchecked data measure is Advisory Group input. So these are some of the ways that we think the Advisory Group input could be incorporated. So a question to think about is, where in the drug selection process does the Board want to incorporate Advisory Group feedback? So should it be when the Board is selecting data measures? Or should the Board let the Advisory Group give feedback after it has the proposed list of drugs selected for review? Or should the Board

incorporate Advisory Group feedback every step of the way? So once we create a dashboard like similar to the one that the Colorado PDAB has that can be shared with the Advisory Groups, so the Advisory Group would have access to the data measures. So yeah, the question is, like, where in the process do you want Advisory Group feedback to be incorporated? And I'm going to address feasibility of pulling these data measures with this table, so we can see whether we have the data sources available to pull each data measure. So you can see that most of the data measures have check marks, and at the bottom you will notice two data measures that have exclamation mark icons, so I put these to indicate that these measures are probably not feasible at this time -- this point in time. For example, for rebate amount, theoretically, manufacturers and PBMs would have that data, but we don't know if we can get it from them, and the TPT Program does not have that data, so we can't get it from them either. And then same goes for patient assistance programs and coupons. This is also data that the TPT Program is not collecting at the moment, and we don't know if we can get that from the manufacturers. And then continuing on to more data measures, just directing your attention to the exclamation point icons once again. So we have it for therapeutic alternative availability and step therapy and utilization management. So therapeutic alternatives are not that straightforward to pull, so, Ryan, feel free to chime in here because sometimes there could be other drugs treating the same condition that are not -- that are in a different therapeutic class, so this would require some researching to determine, so that we get, like, all of the therapeutic alternatives available. And then for step therapy and utilization management, technically the PBMs would have this data but, again, there is no guarantee that we would be able to get it from them at this stage. And then finally, we have the proposed data measure of whether other states have selected the drug for review. So this is definitely more accessible than the manufacturer or PBM data, but it would also require, like, manual research because not only would we have to research what drugs that other states selected, we would also have to look at their statue and what their thresholds are to determine if they are different from ours. Okay, so now that we have established the proposed data measures for selecting drugs for review, I do have some questions for the Board Members who proposed some of the data measures. So, first, what costs are we talking about when we talk about the total costs of a prescription drug? Um, second is, what is the difference between out-of-pocket costs versus member paid amount? I know a Board member mentioned, like, including premiums [audio cuts out] paid amount. And then another question is if we wanted to look at utilization regarding specialty versus non-specialty drugs, what

criteria would be used to classify drugs as specialty versus non-specialty. So I don't know if you all remembered, like, if you proposed the measure or not, but, yeah, feel free to chime in.

Douglas Barthold: Yeah. Can you tell us about the out-of-pocket versus member-paid options?

Kelly Wu: Well my question was more like what is the difference between the two? And I know the person who proposed member-paid amount did mention, like, including premiums in the member-paid amount, and so I wonder if that's what they're thinking, or are there other things that make it member-paid amount different from out-of-pocket costs?

Eileen Cody: I mean, you wouldn't need it -- I don't think you'd include mem -- premiums. That's really stretching.

Ben Rome: Is it -- I mean, premiums can't be attributed to a single drug, right? They're [cross-talk] --

MaryAnne Lindeblad: Exactly.

Ben Rome: So I think when you're doing a specific -- like, I don't know how you would assign premiums -- to a specific drug. I mean, every drug has an impact on premiums, but there's no way to quickly assess that part.

Douglas Barthold: Yes, I'm not familiar with the member-paid amount figure. Does anyone have a definition of that?

Hung Truong: Is that a copay? I mean, it's just [cross-talk] --

Ryan Pistoresi: Yeah. So an out-of-pocket cost could be in addition to other things related to what a person could pay, and I think that's kind of where that premium may be. A member-paid amount is a field that we have in our drug database that just shows what the member paid at that pharmacy, which could include, like, copay coupons and not necessarily reflect what the patient actually paid. So, for example, because you know the claim on the insurance runs first, we see that member-paid amount as maybe, like, $100, but then a co-pay coupon may come in on the back and reduce it to $5.00, so then the actual out-of-pocket cost is $5.00, but the member-paid amount is reflected to be $100.

Ben Rome: Yeah, I don't think out-of-pocket cost has a specific -- I mean, out-of-pocket costs, Ryan, to your point, I mean, like, doesn't have a specific definition. I think it's a broader term. It includes copayments, coinsurance, and deductibles that patients pay usually at the point of sale. I mean, again, usually we're not talking about premiums and thinking about out-of-pocket cost for drugs just colloquially, but, obviously, the term just means how much the patient spent. I think, Ryan, your point is member-paid is just how payers are tracking, how much they -- how much the patient is responsible for -- the member. In their eyes, it's not patients, it's where members are responsible for, but it doesn't tell you how much they actually paid at the point of sale. That number would be known by the pharmacy but not by the payer. The payer just knows how much they -- the patient is responsible for, and if the patient finds out their means, like a coupon card or something to pay off that, that wouldn't be reflected in APCD data.

Mike Neuenschwander: And one thing I would maybe say just as we're thinking about all of these measures generally, right? So we're trying to use these as a filter to take a list of 400-some odd down to much more manageable. So in terms of what we're looking at in super detail or the difficulty of obtaining the data, I think that's important to consider at this stage. So like if we're doing a specific drug review on a specific drug, that's where we can dig down more and kind of get maybe into more of the weeds with the nitty gritty of how does this work on this one? But in terms of, for example, collecting difficult-to-find data on a mass amount of drugs, I would suggest avoiding that at this point because, again, we're just trying to use this to filter down, right? We don't want to do an entire drug review on 400 drugs and the associated work of finding all of that detailed data on that. Right? So as we're trying to define stuff and pick stuff like, can we easily access this data? If we can't access it without a ton of extra work like having to go out to all of the manufacturers to collect [indistinct] data, I don't know if we want to do that at this point, right? And this is just me thinking out loud, right? Or, you know, obviously, feel free to chime in. Yeah, we're trying to determine what are our insurance premiums for each of these drugs, and how can we try and assess that out to fit towards this, right? That could be hard.

Ben Rome: Right. So, I mean, just to be clear, you can -- I mean, like, I think with the APC data availability, assuming that you can get individual member-paid amounts, I think there is -- still something to determine in terms of how you want that data presented or sort of aggregated at the drug level for you. So, I mean, for example, like, it may not be sort of [indistinct] attributed, so do you

want to look at the mean or average? Do you want to look at a median amount? Do you want to look at how many patients pay over a certain threshold, right? So there are many -- there are different ways to assess the sort of aggregated data that the Board could consider in terms of, like, how its thinking about sort of we want to look at drugs where at least 20% of patients are paying more than X dollars, right? So those are decisions that you all could make. I think it's -- and instruct your data team to sort of provide you with that type of information. But you know you probably don't want to have, like, 18 different ways of slicing the data because it's not going to be -- it's going to be challenging for you at that point to, like, look through those different 18 data points and try to come up with a coherent story across many different drugs. So you do want to be -- to that point, you want to be sort of somewhat judicious, and just, you know, you're trying to get an idea of which drugs you want to do further investigation of.

Mike Neuenschwander: Yeah. What are your most important data points that will help us sort this stuff out ? [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] Exactly. It's not perfect.

Mike Neuenschwander: [Cross-talk] great point then.

MaryAnne Lindeblad: Doug.

Douglas Barthold: Yeah, I completely agree that I don't think premiums should be involved or accounted for. But yeah, going back to this out-of-pocket cost measure, like, I actually, I think I heard some conflicting information on whether or not that would account for coupons. I think I thought Ryan said it did, but I was -- I didn't know that that was [cross-talk] --

Ben Rome: The All Payer Claims won't. All Payer Claims won't.

Douglas Barthold: Okay. And so, I mean, obviously, we would want to see that, but I don't think it's visible anywhere, right? Does that -- is it possible to observe coupon amount?

Ben Rome: It's possible to observe it from datasets that collect information from the pharmacy level because pharmacies, obviously, know who is paying them, so there are datasets out there, like commercial datasets that aggregate and collect that information. So I will leave it to your team to decide whether you

have access to those datasets, those commercial datasets to do it, so I don't think it's impossible to find out that information. But you're right, it's not readily available in claims data, which is [cross-talk] the component source and sort of the internal source that you have at your disposal.

Douglas Barthold: So, Kelly, we don't have -- any of those options that would tell us the coupons. Is that correct?

Kelly Wu: Yeah, that's correct.

Douglas Barthold: Okay. Um. Yeah, well -- so then from my perspective, the out-of-pocket costs that they report all in the APCD is kind of -- is what we have. And I agree with Mike that at this stage working with what we have is, obviously, important and expeditious. So yeah, my -- certainly my -- for me, the most important criteria that we've discussed so far would be the distribution of out-of-pocket costs. And so in addition to the mean, I would want to see, like, maybe the 5th percentile and 95th percentile, maybe 5th, 25th, 75th, 95th, and I'm already at 5 data points, but that's kind of -- that distribution, to me, I think it's very important, the most important thing on this of any other criteria we've talked about.

Eileen Cody: I don't understand what you're saying. Could you percentage -- get [cross-talk] --

Douglas Barthold: [Cross-talk] Yeah. So like the 5th percentile, the out-of-pocket cost would mean that -- so there's a value. Let's say it's $20. That would mean that 5% of people paid less -- or 5% of claims are less than $20, and then 95% of claims are greater than $20.

Eileen Cody: On that particular drug or compared to the other drugs?

Douglas Barthold: On that drug. So it would be like if you had a data set of all of the claims for one drug, and then you sorted them by how much the out-of-pocket cost was, and then you basically just cut it up at these specific percentiles. And so that's how focused like, you know, -- the mean can be weighted by if there are a few really high-cost observations that pull the mean higher if the vast majority of observations are low and cheap. But by having -- by getting those percentages as well, you can get a better picture of if there are tails of the distribution that are meaningful in either their inexpensiveness or their expensiveness.

Eileen Cody: So -- and you're talking about on that out-of-pocket, wouldn't that vary depending -- there would be a big variation, then, on the coverage, like, how much a plan -- like, if somebody buys a cheap plan that has a high deductible, they're going to have a lot bigger out-of-pocket. Ah. That doesn't seem like it's an even playing field for the drugs then [cross-talk] --

MaryAnne Lindeblad: And copay, you know, the copay versus a percent of -- you know, so some plans you pay 20% [cross-talk] of the cost, [cross-talk] and then others, you might have a $10 copay. So you've [cross-talk] got that creation.

Douglas Barthold: [Cross-talk] I completely agree all of those things will affect out-of-pocket costs, but if we want to get a picture of what out-of-pocket costs are among the users of these drugs in Washington state, then I don't think that we should -- I don't think we necessarily want to equalize, or I should say adjust, for the planned generosity. We want to see what people are spending. That -- to me, that's the measure of affordability that I care most about. And even if they have -- let's say that you have whatever, you know, non-generous insurance or bad insurance and you have to pay more, that doesn't mean that I care less about that high payment. To me, that's still potentially an affordability problem.

MaryAnne Lindeblad: Sure, sure.

Eileen Cody: Right. What I guess I'm just thinking that the total cost of the prescription drug, what the carrier pays, and what the patient pays is probably more.

Douglas Barthold: I agree. Yeah, I think total cost is my second most important criteria. But I agree it is also important. And, actually, I do think that Kelly wants us to talk about how we define that as well, so maybe we should get to that. But I think they are both important and, like, to me, affordability to consumers or to patients is, like, the where I see the most direct measure of cost for [indistinct] patients is from was out-of-pocket costs, and so that is kind of -- that's why it's the most important to me, yeah.

Mike Neuenschwander: Jingping Xing, do you have a comment, question?

Jingping Xing: Sorry, I correct the wrong button.

Douglas Barthold: So, Kelly, does that -- I mean, is my request for out-of-pocket costs distribution reasonable? And I guess I should ask the rest of the Board if they have other thoughts on, like, how they would be -- how they might be interested in measuring out-of-pocket costs? Like Ben was saying, you could potentially say, like, number of users who pay more than $50, or something like that.

Douglas Barthold: Yeah. I'll just point out, Doug, that, like, I mean, again, I'm basing this in part on experience looking at the public Colorado dashboard. So you need to count -- so you need to decide how you're going to -- and their sort of methodology document. You need to decide how you're going to create a bucket of patients so the patient -- it might be that all patients with at least one claim for a drug or one, you know, paid claim within the year or something like that might be your definition. But you have to remember that includes patients who started the drug midway through the year, patients who were not adherent because of high costs. It includes a lot of things, right? So it tends to underestimate [cross-talk] like actual total spend and out-of-pocket spend because you're going to have a mix of patients who have one claim and patients who took the drug a whole year for drug. Some drugs are not taken chronically, right? So like if it's a hepatitis C antiviral, like, most people will have claims for -- they might have like three months worth of claims, and then that's it. And so anyway, just to point out, like, how you define that population. But, in general, yeah. I mean it's like easy to get the number of people who took the drug in that year. It's easy to sort of sum up a bunch of measures around sort of both member and total pay. And then again, you just have to sort of decide as a Board how you want those presented to you -- how you want those data points presented to you.

Douglas Barthold: So, yeah, I totally agree defining the sample is critical. My gut first stab would be among patients with at least one claim in the year, I would want to see what the sort of mean cost per month was, I guess. You know? I mean, whatever. You could do per year, too, but I certainly would want to restrict to those with at least one plan.

Hung Truong: Well, I think tooling will make a big difference, too, on where it's placed in the formulary, right? And so where it's generic, you could have lower out-of-pocket costs, and if it's a two to three brand nonpreferred, I don't know if there's a way if that information shows up, but you can make a guesstimate based on that. So for the question of specialty versus non-specialty, well for

specialty, you are probably paying 20% of drug cost or the highest copay level, so --

Douglas Barthold: Yeah. And that's what we want to -- that's what we want to capture, right? As we're [cross-talk] --

Hung Truong: Yeah.

Douglas Barthold: -- with whatever measures we're using for out-of-pocket costs. It can be because it had high coinsurance rates, it was high -- in a higher tier. It can be maybe it's used by people who tend to have high-deductible plans, and so then -- they're spending a lot more out-of-pocket for it. In either case, it's something that can push it into unaffordability, and so that's what I want to capture.

MaryAnne Lindeblad: Any other comments or questions on this slide?

Douglas Barthold: Kelly [indistinct] I guess there's the bullet point one and three. So Kelly, did you want to talk about how to define total cost for the drug?

Kelly Wu: Yeah. I just like clarification on, like, what costs would go into that calculation.

Douglas Barthold: So for me, that would be, like, patient paid amount or out-of-pocket plus plan paid amount, uh, minus rebate, and ideally minus rebate, minus coupon. I know we can't observe that, so I'm willing to. We don't -- it doesn't have to be in there at this stage. Do we have rebate information on any of our data sources?

Hung Truong: No. It would be [cross-talk] --

Eileen Cody: [Cross-talk] No.

Hung Truong: So we would be talking about a net cost, Doug, if that is what you are looking for then.

Douglas Barthold: Yeah.

Ben Rome: So if wanted -- if you wanted rebate information from me and separately, Doug, you'd have to ask the plans that information if they are not already

reporting it to your state in some way. Some states have reporting more requirements, but that is generally aggregated and rolled up, but it is not at the clean level, right?

Douglas Barthold; Right.

Ben Rome: So if your analyst is doing work to sort of look at APCD, they didn't provide them information that's going to be pre-rebate, pre-coupons, manufacturer's assistance program [cross-talk], etc.

Douglas Barthold: Yeah. I did know if it was possible to sort of -- figure out how much rebate -- to disaggregate the rebate into [cross-talk] --

Ben Rome: [Cross-talk] So there are -- right -- so there are data sets that give an estimated rebate for a [cross-talk]. Drugs like [indistinct] our health, and so it means that -- anyway, there are datasets that provide those sorts of estimates, so the way Colorado dealt with this is they just had this as part of their data that they reviewed as well. And again, it wasn't like they didn't sort of combine those two data points together, they kept them separate for the [cross-talk] selection.

Douglas Barthold: So that's a really good point. Maybe another one of the additional criteria that we consider is rebates. Actually, I think it was on the list. Wasn't it, Kelly?

Kelly Wu: Yeah, but we don't have access to that data at this point because the bill says that they have to cooperate with us to provide data, but at the affordability review stage. I mean, we could ask, but they by law don't have to cooperate if they don't want to.

Douglas Barthold: What about SSR Health?

Ben Rome: Yeah, so those are not actual rebates. Those are just estimated rebates by a third party, so they get you in the right ballpark, generally, of whether is sort of a highly rebated or a non-highly rebated drug. If you want specifically how much on a particular drug in the state -- in your state by a particular plan, you would need to ask the plan or the manufacturer, you know [cross-talk] --

Douglas Barthold: [Cross-talk] Yeah. It mentions [cross-talk] --

Hung Truong: [Cross-talk] Can we make a level, Doug? That is extremely difficult on a drug level to get. A lot of time they collate with others in the same specific category or within the manufacturing. You know, it's all combined, even as a plan sponsor myself, I'm trying to get a drug-level rebate amount, and I'm not able to. That's how difficult it is.

Douglas Barthold: Yeah. Um, I in the -- and so I guess like I think that is sort of motivates Colorado's approach that Ben just told us about, where you don't actually -- you don't use the rebate information to calculate in that cost. You just -- you have -- you know, you use that as additional criteria in that you are evaluating when you are deciding to do an affordability review or to -- actually, what's today's -- do they incorporate it now in deciding to do the affordability review? Or do they decide to do it the next level when deciding on the upper payment limits? Ben, do you know in Colorado which [cross-talk]?

Ben Rome: [Cross-talk] Sorry, can you repeat your question one more time?

Douglas Barthold: So you said they had the rebate information from SSR Health, and they incorporated those in the additional criterion.

Ben Rome: Right. So they couldn't share that information publicly, so if you look at the public dashboard that's [cross-talk] --

Douglas Barthold: [Cross-talk] Okay.

Ben Rome: Right because they have a data use agreement [cross-talk] --

Douglas Barthold: But then what? So what stage of their [cross-talk] --

Ben Rome: It was part of the dashboard that the Board Members could review when determining drugs, but it was not one of the key factors that they decided on when sort of, like, moving right to the -- when deciding whether to select drugs, right? They focused on that information more in the affordability review [cross-talk] --

Douglas Barthold: [Cross-talk] Well, like in drugs for the affordability review, or for UPLs?

Ben Rome: The data was there. It was presented to the Board Members.

Douglas Barthold: Okay. [Cross-talk] --

Ben Rome: [Cross-talk] I can't -- I don't remember off the top of my head from Maryland, but we can look into that information. Again, I would just note that, like, SSR Health is imperfect in these sort of estimates, and so I would not -- you want to be -- and it's not going to be available for all drugs, right? Yeah. So, I think that's why, like, you want to make sure that whatever data points you are sort of heavily relying on in terms of when whittling down your list of drugs to ones that you ultimately want to select, you want to make sure that they are stable estimates that can be calculated for all of the drugs, and rebate estimates are not going to be in that category. So just putting it out. So there might be a factor. I believe that Colorado flagged it as a contextual factor that the Board Members could consider when making those decisions.

Douglas Barthold: Yeah. I mean, I like that approach. I don't know if it's -- if Mike can tell us if it is feasible for us acquire new datasets like SSR Health.

Mike Neuenschwander: Yeah, we could look into that. I mean, right now, as Kelly was saying, we don't have access to it, so it's something we could try and look into so we can rate estimates based on that, but I would kind of -- right now, the data that we have and what we can run with, I think that the total cost would just be like the patient and plan paid amounts, and that's kind of where we can run right [cross-talk] now.

Douglas Barthold: [Cross-talk] Yeah, I definitely agree with that as the calculation to use for total cost. Me, I mean, I think that -- having rebates as a separate -- the existence of rebates as a separate measure separately measured when it's observable if contextual factor would certainly be helpful for as making the decisions out at the next stage.

Hung Truong: I think it's -- they're less hesitant to provide it if nothing is extremely specific. So we may, I think, perhaps try asking for PMPM of the specific drug line because then the total cost but it's, like, how many lives are on it are using it, right? So PMPM of the specific drug in a plan, they might be able to have that. Or I don't know if they are willing to share it. They have it. I don't know if they're willing to share it.

Mike Neuenschwander: Yeah. And as we're doing specific drug reviews on a much smaller group of drugs, that's where we could go out and ask for manufacturer information

more easily because it's a lot easier to ask for a handful versus 400, right? And so that's where we could probably dig in more is on the specific drug review, and that would help, obviously, influence, like, oh, is this a portable? Is it not? You know, there are other factors on the [cross-talk] --

Douglas Barthold: [Cross-talk] That's a good point, yeah.

Mike Neuenschwander: So, yeah. We don't have to kick everything in this one around to get, we're just trying to with what we have, how do we whittle this down to a smaller more manageable list to choose from? Yeah. We can look into the other data, and we can definitely on the review itself [indistinct] [cross-talk] --

Ben Rome: And Doug, to your point, like, I think there are two questions. One is what data points you want, and then, two, is how you're going to think about those data points in the form of selection. And so -- and again, for when you have -- the more data points you have, the more conflicting directions you'll have between different drugs. So I think helping sort of to prioritize among a small number of data points just to sort of get you into the universe of drugs that you're going to dive deep on does not mean that you're going to review those drugs and deem them unaffordable. It doesn't mean you're going to move forward and an upper payment limit on those drugs, right? You're just trying to get a small universe of drugs to do a deep dive, so your staff has the resources to provide a much deeper level of conversation. And so I'm just recon -- [indistinct] you know, what Mike just said that, like, at the point of the dashboard there are going to be imperfections in the data that you are going to have to recognize and sort of yet move forward to make decisions based on what you have and -- what's readily available for all of the drugs and what you think is at least getting in the ballpark of drugs that when you ultimately review that you may be worried about affordability challenge -- or affordability for consumers.

MaryAnne Lindeblad: Kelly, anything else that you need from this slide, or comments, or should we move on to discussion points and really talk about specialty? We can really talk about -- yeah -- specialty versus non-specialty.

Kelly Wu: Yeah. So I'm wondering how the Board wants to classify specialty versus non-specialty drugs.

Hung Truong: I think it's -- a lot of time it's defined by the payers. You know, there are cases where the PCSK-9s when they first came out, all the headache medication,

the injections started out as specialty, and then it, basically, became non-specialty. Um, I mean, there's a specific -- I have a definition for it, but it's a lot of times like the 80/20. We know that 80% of it, and then there's 20 of them are like the specialty light, or it's -- it can be one or the other depending on the payer.

Douglas Barthold: Can I ask? I'm curious. Whoever, like, decided -- wanted to include that as criteria, what's, like, what's the motivation for -- why does specialty matter when we're considering affordability?

MaryAnne Lindeblad: Any thoughts on that one? Does it matter?

Douglas Barthold: My only -- my thought for why it would matter is basically a specialty drug would be less likely to have a therapeutic equivalent or alternative, but that's already captured in our other criteria that we have to consider -- the ones we must consider. So this one, it just seems -- unless there's another element of specialty that I'm missing, it seems redundant with the equivalent and alternative availability.

Hung Truong: I don't know. Perhaps the tiering the formulary or [cross-talk] --

Douglas Barthold: [Cross-talk] Right. See, I guess specialty is more likely to be in the more expensive tier [cross-talk] but then that would get captured in the out-of-pocket costs. Yeah.

MaryAnne Lindeblad: Speaking of, what will you pick up by defining that that you don't already have?

Douglas Barthold: Yeah, I don't know. That's my question, too.

Mike Neuenschwander: Yeah. And if there's no, you know, nothing that anyone's passionate about -- you know, I want this for this reason, or if it's we are looking at it and other things, you know, we can't look at every single thing, so it's good.

Hung Truong: I think maybe it's just the need to have, like, a better definition or something or information, but we can use a generic description.

Kelly Wu: Okay. Well, that slows -- that flows nicely into the next slide that I have about discussion points. So for some of the categories, like drug costs, there are a lot of very similar measures. So, for example, on this slide there are a bunch

of similar measures like, um, out of -- like, I feel like I don't know if the Board wants to just choose a few measures or they want to, like I mentioned, just look at all the measures that they are available. Um, and then on the same note, we can also talk about methodology. Like, do you want to rank and weigh the data measures, and use some sort of formulas to choose the drugs for review, or some sort of hybrid measure, where you agree on a few that are important to you, but then you also want to look at other data measure, I guess, on your own. Or yeah. Um, I guess this is going to be the hardest part, like, choosing how you want to use the data available. So, yeah, PORTAL, feel free to chime in here with more information on what other states have done.

Douglas Barthold: Yeah, I think Ben had to run, unfortunately.

Mike Neuenschwander: We still have Matt here, I believe.

Douglas Barthold: Oh, okay. Great.

Matt Martin: Yeah, I'm happy to sort of chime in in terms of what other states have done. So Colorado's approach, in general, they went through a sort of weighting exercise, where each Board member prioritized there the sort of set list of criteria -- selection criteria that they had to review under statute, prioritize that, and then went through a process to weight those elements based on the prioritization of each individual Board member to try to get to a prioritized list of drugs. So that was sort of one approach, and then they used that dashboard. The Maryland Board did more of a -- they had like an in -- more of an internal process, and Board members were able to nominate drugs or put drugs forth for discussion based on the criteria that they were presented with and then would have votes on adding or removing drugs from the selected list over the course of their meeting. So more of a sort of guided weighting exercise versus more of a deliberation discussion-based approach. There is opportunity to sort of be in the middle of those two approaches. Those are no by no means the only two, but that's just sort of the path that others have gone down thus far.

Douglas Barthold: I really like the Colorado approach of the Board members sort of ranking and weighting the measures they care about.

Matt Martin: And there may be an opportunity to go through that sort of weighting exercise to narrow the list down from like 500 down to 100, and then from there you can be sort of more deliberative and get more detail on the specific

subset of drugs. I believe that is what Colorado did as well is they presented some data points for all of the 500 -- 400+ drugs qualified under their statute, and then before they made the final selection decisions asked their staff to provide additional details on a smaller cohort of drugs before they then selected the final five that they did for this round.

Hung Truong: Yeah, I think we've already been talking about this [laugh] these discussion points for the past half an hour.

Douglas Barthold: But yeah, I mean, I do think that, like, in order to formalize a ranking of all of the drugs, you know? It sounded to me like I was more in favor of out-of-pocket costs, and then others maybe were more in favor of total cost. And so it's okay, we can disagree on that. I think that's -- but, like, formally attaching a weight to the different measures will allow us to then get a list of drugs ranked by how much we want to do a review. And so is there -- I mean, is there an option for us to -- Kelly, do you think that you'd be able to conduct some type of ranked choice voting with weights among us to figure out what those weights are for each of the different criteria?

Kelly Wu: I think there's sort of like two questions here. So first is do you want -- to use all the measures, and then the second would be the ranking and weighting of the data measures you want to use.

Douglas Barthold: I agree. So do you want -- I mean, do we have a proposed full list of measures, and then we can add and strike as we -- ?

Mike Neuenschwander: [Cross-talk] Kelly, you kind of had some lists previously. Do we want to go through those? Because I know we've talked about total cost. I know we've talked about out-of-pocket costs. Uh, and do we want to pick the top four or five to try and -- because we don't want to be pulling data on 20 different things, right? Then it starts to get impossible to manage and sort.

Douglas Barthold: Yeah.

Kelly Wu: [Cross-talk] Yeah. And I also want to mention that these measures were collected from the Board members, and all of them seem to be the most important to them, so it might not be as easy as we imagined to strike off and continue [cross-talk] --

Douglas Barthold: [Cross-talk] Okay. Maybe it's -- maybe then each Board member gets 25% of the ranking power, and then I'll just [indistinct] where my measures are worth 25%, Hung's are worth 25%, etc. But I did have one idea for getting rid of some measures that maybe we can talk about. I just think about cost and utilization. You know, we have, like, out-of-pocket costs. Let's just say we are looking at mean out-of-pocket costs per user. I think that's important. But then because we also care about how many people use it, how many people are paying that mean out-of-pocket cost, we would want to see -- if we multiply mean out-of-pocket costs by the number of users, we would have the total out-of-pocket costs for all users in the state, which I think would be a nice way of incorporating sort of the prevalence or how common the use of that drug is, and that way I don't think we would need any other of the utilization measures. Correct me if I'm -- if anyone else has other instincts on that. But to me, it's just if we can -- if we're capturing the total out-of-pocket costs among all users and then also per user, and then that gives us a nice picture of the total burden to the state as well as the burden to individual users.

Eileen Cody: Well, let me just -- I'll lay something out, and tell me if it is trying to follow this. I'm not doing that well. If let's say, oh God, hemophilia, where there is not as -- it's very expensive drugs but not as many people. So where -- I don't -- and I mean, I'm not sure how expensive it is these days. But anyhow, would that fit the utilization? Like utilization by disease state, if they all have to use the drugs, but it's a small population, would that make the cut? I guess that's what I'm trying to figure out by the way -- how the way [cross-talk] you phrased it.

Douglas Barthold: So yeah, that would -- if it's a very expensive drug for a small population, the out-of-pocket costs -- the mean out-of-pocket costs per user would be high. And so, if that -- if we decided that was a measure we care about, then yes, it would make the cut. Um, and so I think -- like the, I guess, like what Matt was talking about in Colorado, where they put weights on it where they ranked the measures they care about and put weights on them, that would allow us to say, like, okay, that's a measure we really care about because we would capture something like hemophilia, where it's expensive for a small number of people. And then, alternatively, like, let's say that there's a drug that's like moderately expensive, but it's used by, like, a million people [cross-talk] --

Eileen Cody: [Cross-talk] Right.

Douglas Barthold: Then that would be captured by this other measure, which would be like the total out-of-pocket costs in the state.

Hung Truong: Yeah. And for those, like, hemophilia, I mean it's probably going to be an orphan or rare disease cases, which would not be included, likely, right?

Douglas Barthold: Yeah, it wouldn't have made the original cut if it's not an eligible drug because it's orphan, right? Is that what [cross-talk] you are saying? [Cross-talk] --

Hung Truong: [Cross-talk] picked the wrong disease.

Multiple Speakers: [Laughter].

Douglas Barthold: [Laugh] No, but your point totally -- your point makes total sense. Yeah.

Mike Neuenschwander: Okay. So we got total cost. We got out-of-pocket cost. Then we have the out-of-pocket cost times usage as our third thing that we're thinking about looking at?

Hung Truong: Yeah. I want number of people using that drug or a percent, which is related to population -- percentage of population, I think, because we want to affect the masses. Please.

Mike Neuenschwander: Okay. So number of people using the drug. Do we want, like, the therapeutic equivalent availability?

Douglas Barthold: Yes.

Mike Neuenschwander: Okay.

Douglas Barthold: So how do we define that? Does that just if there's another -- so if it's an equivalent, that means there's -- a generic or a biosimilar, right?

Eileen Cody: Right. And that's biotherapeutics [cross-talk] --

MaryAnne Lindeblad: So yeah.

Douglas Barthold: And then an alternative would be if there are options within the same class? Is that right? But not the same ingredient?

Mike Neuenschwander: Yeah. I think the alternative would just be anything else that could be used to treat that condition.

Douglas Barthold: Kelly, do you -- is that feasible for you to sort of operationalize in the data?

Kelly Wu: So for alternative, my understanding is that it can also include drugs in a different class because sometimes like a drug of a different indication could also treat that. I don't know if Ryan or Donna is on, and they can comment on that. So that's why it's not as straightforward to pull as just pulling other drugs in the same class.

Ryan Pistoresi: Right. Yeah. And that's something that we've been exploring. I know that PORTAL since a methodology proposal of looking at therapeutic guidelines, and so that may be another option to look at. You know, we don't necessarily have that in readily available electronic format, and we would need to do searching to find what are appropriate guidelines, but that could be one way of doing that therapeutic alternative selection.

Mike Neuenschwander: But for the purposes of this exercise of trying to just whittle down the list, might it be easier to just stick with the equivalent for now to saying, okay, there are other options that we know about that we can easily compare. And then if we want to, for example, like a drug review where we got to do more manual stuff or more data digging, we could look at the alternatives for specific drug review, right? But for this just trying to get this list down, would the equivalent be an easier, better thing to stay with?

MaryAnne Lindeblad: I mean, I think it's important that we think about this first cut [cross-talk] --

Mike Neuenschwander: [Cross-talk] Yeah, yeah.

MaryAnne Lindeblad: -- and we can get more sophisticated once we get that first list of, I don't know, 50, 100, whatever it is [cross-talk] -- but it seems like that's where our focus needs to be.

Matt Martin: Yeah. And I will say that other states the therapeutic alternative process that happened during the review itself because there is a bit of clinical decision-making that goes on in terms of what you include, whether it's first-line, second-line, etc., and because there may be variation within indications,

whereas, for the therapeutic equivalents, are there generics or biosimilars as a more of a binary that could be pulled for a larger set of drugs upfront.

Douglas Barthold: I agree. That sounds reasonable. And then on the equivalent, what seems to be generic availability and therapeutic equivalent availability? Therapeutic equivalent would just include biosimilars as well as generic equivalents? Is that right?

Matt Martin: Generally, yes. I think the therapeutic equivalent term is sort of the terminology that is used like in the Orange Book, which is where it lists all of the drugs and their equivalents.

Eileen Cody: [Indistinct].

MaryAnne Lindeblad: Yeah.

Matt Martin: Yeah.

Douglas Barthold: Okay. So it seems like we could remove generic availability from this list because it's already included in the therapeutic equivalent availability?

Hung Truong: Well, are we saying -- so equivalent would be like a substitute available, whereas an alternative availability is a provider will have to write the prescription. Right? It's a drug that -- it may not be the same active ingredient, but it does, um, it [cross-talk] --

Douglas Barthold: [Cross-talk] Yeah. I agree on the alternative. And I think what Mike had suggested was that we ignore alternative availability for now just because that's quite complicated for the [cross-talk] filter at this stage.

Mike Neuenschwander: Yeah, but the generic and the therapeutic equivalent, I think we can kind of combine that as a one [cross-talk] --

Douglas Barthold: [Cross-talk] Yes. That's what I suggested. Yeah.

Mike Neuenschwander: Yeah.

Eileen Cody: Yeah.

Kelly Wu: Yeah, I don't think the generics are considered therapeutic equivalents based on our definition because they're using the Orange Book. And then also, we are re-classifying biosimilars as therapeutic equivalents based on the bill but, other than that, it's completely based on the Orange Book.

Douglas Barthold: So Orange Book has a separate distinction for generic availability? Is it like therapeutic equivalent availability does not include generics in the Orange Book?

Kelly Wu: I think therapeutic equivalent is different from generic. Can a [cross-talk] pharmacist chime in?

Eileen Cody: [Cross-talk] different interp -- definition. I know when we pass the bills that generic is classified as one thing, and therapeutic equivalent we had to be very careful how we phrased all of that, so [cross-talk] --

Douglas Barthold: [Cross-talk] Right. Well, I guess we got to learn what these words mean before we make a decision on it. Oh, do you know, your pharmacist friend here?

Mike Neuenschwander: Ryan, do you have a thought?

Ryan Pistoresi: Yeah, I was thinking about it. I'm trying to figure out is therapeutic equivalent all types of ratings in the Orange and Purple Books, whereas generic availability is AB rated -- I mean, is that kind of how it may have been intended, or is it -- yeah, so I need to think about it a bit longer to think about what is the difference between the equivalent and the generic. Um, I'm thinking there might be some aspect of interchangeability and the different ratings within the Orange and Purple Book, but I don't know right now.

MaryAnne Lindeblad: But I mean, even with that, it's adding one more component with the generic availability, so it seems to me that it's probably not a huge issue to include both.

Eileen Cody: Yeah, I would agree.

Douglas Barthold: I agree.

Mike Neuenschwander: Okay. [Cross-talk] so we can make sure what we're doing -- I guess the point is that the equivalents are both in there.

Eileen Cody: Yeah.

Mike Neuenschwander: Okay. So we've got total pocket -- or total cost, out-of-pocket costs, number of people using the drug therapeutic and generic, therapeutic equivalent and generic availability. And then we were talking about the out-of-pocket [cross-talk] time usage. So that's five. Anything else?

Eileen Cody: Well, I think we still want to know if it's multiple thresholds.

Mike Neuenschwander: Okay. [Cross-talk] by that.

Eileen Cody: Like if there's more that it meets, that it's how much it costs, 50% increase, you know, but they already did that. I mean, basically [cross-talk] --

Douglas Barthold: [Cross-talk] Yeah.

MaryAnne Lindeblad: Ah, on the first -- that [cross-talk] --

Eileen Cody: [Cross-talk] First cut, yeah.

MaryAnne Lindeblad: [Cross-talk] That first 400 [cross-talk] --

Eileen Cody: [Cross-talk] Yeah.

MaryAnne Lindeblad: Starting with that first 400, yeah.

Mike Neuenschwander: Instead of qualify under multiple [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] Yeah.

Eileen Cody: [Cross-talk] Right.

Mike Neuenschwander: [Cross-talk] [Indistinct] Yep.

MaryAnne Lindeblad: Right, [indistinct]. Yeah.

Mike Neuenschwander: Anything else on those lists that Kelly had?

Eileen Cody: So you're going to get back to us on the question about how -- and how other -- I guess how other states are doing it with like the nitroglycerin, when there was, what, five or six all on the multiple lists, but it's just different strengths of the same thing? So is that one drug review, or is that six drug reviews? That's one of the questions I have.

Douglas Barthold: I had a question.

Ryan Pistoresi: [Indistinct] we will probably review one drug rather than six drug reviews, I think, in terms of some of these aspects that would be the same. In terms of looking at utilization and costs, we could probably pool that together and show you here the differences between the NDCs but have that kind of be together as one drug review.

Eileen Cody: I would hope it would only be one drug review. I just want to make sure when we are, you know --

Matt Martin: I will say, in terms of Colorado and Maryland, their general approaches have been, I think, that if one NDC, like, qualified, or if the Board selected one NDC, then all of the NDCs -- all other NDCs would get rolled up into that affordability review. Now that, obviously, depends on sort of statute and rule that may differ between your Board and theirs, but the data was displayed to them or given to their Board disaggregated, which there are both pros and cons to that, and that if the utilization and some of these measures are more evenly distributed across different NDCs, NDCs may show up lower down the list in terms of ranking, but if you aggregated them all together at once, that drug may move higher up the list. But their rule was established that regardless of if they picked the NDC, then all of the other NDCs that correspond to that, the active ingredient, would fall into their review.

Douglas Barthold: So to me, I mean, I think it comes down to I think we have to define this level, right? And the way that we defined level when we made the eligibility list was at the NDC level. We can change that for the review level. We can have a different level for review. But what I want to know is, do we know what our level is for the UPL because I feel like we should be doing at the same level for the affordability review. Does that makes sense? And does anyone know what the level is for UPL?

Eileen Cody: Can you ask that again? I guess I didn't follow you.

Douglas Barthold: So since, ultimately, the upper payment limit will be -- the policy leverage that we have, what level does the UPL apply at? Does the UPL apply to an NDC? Like, if we use the nitroglycerin example, does it apply to one of those NDCs, or does it apply to all six? And so that, I mean, I don't know. Matt, do you know what Colorado did?

Matt Martin: I think there, since they've just now sort of got to the UPL phase in rulemaking, I'm not quite sure sort of where they've landed on that question. But I think, generally, that the thinking is that the bucket of NDCs that were in the review, they may at least consider during the UPL process, but I don't think they've been specific yet on sort of at the granular level where that UPL would apply.

Douglas Barthold: Does anyone know if our law specifies anything about this, or if we -- or do we have flexibility? I don't know.

Eileen Cody: That's one that the AG's office needs to look at that question, I think. We might be able to clarify in WAC. I don't know whether -- and I don't know what the -- remember what the statute on that.

Mike Neuenschwander: [Indistinct] Yeah, I think we need to have a little bit further discussion with the AG on that one.

Eileen Cody: Yeah.

Douglas Barthold: Okay. So that sounds like a -- I agree this is critical -- and will be super important for how we do this. Selecting drugs for the affordability review means that we have to have -- like they have to be put into the buckets that they would be in in their review. And so I think for that we need to know what the level is -- would be for the UPL.

Mike Neuenschwander: Okay.

MaryAnne Lindeblad: Okay, any further discussion?

Douglas Barthold: Well, just to ask, are we -- so Mike just made a list of the measures we care about. Is that going to be, like, sent out to us to give weights and things?

Mike Neuenschwander: So, yeah. We can send out the list right now. So what I got, total cost, the out-of-pocket cost, out-of-pocket cost times usage calculation, number of

people using the drug therapeutic equivalence of generics, and did it meet the multiple thresholds? So these are different things. So then, yeah, I think we need to send that out to take a look at. We can have our data team starting to figure out how to pull that. Now -- and, yeah, it comes to the point of waiting here, so -- and, Kelly, did we have anything else further in this presentation here that you needed to get through here before I went into [indistinct] stuff? [Laughter]

Kelly Wu: Um, no. I just wanted to remind everyone that we -- the Board would have to consider like when they want to incorporate the Advisory Group and put into process because that's a required thing from the bill.

Douglas Barthold: Yeah, I don't know why we wouldn't do that at every stage. Is there any -- I mean, I guess it would slow us down a little bit, but -- because you were presenting options of like doing it, you know, now, later, or both, with those basically the options, right?

Mike Neuenschwander: So in terms of the Advisory Group, right, so right now we're selecting the metrics that the Board wants, correct, to take a look at this. The Advisory Group has not been appointed yet, so they're not even here to select these metrics. So if we waited for them to do this, that's more time. Whereas I think maybe something that would be a good way to do, so the Board selects the metrics. We can weight it. We can create the dashboard, and then from there, we can share that dashboard with the Advisory Group here in the fall. They can then look through all of this data, and look through the drug list, and discuss what they think is important. Are their specific drugs on an advocacy standpoint X, Y, Z that they want to look at? And then so from there, while the Board is looking at the dashboard, the Advisory Group can also look at the dashboard, come through to try and use those recommendations to create the shortlist, and then the Board can [audio cuts out].

MaryAnne Lindeblad: I mean that makes sense, and I think that's really the purpose of the Advisory Board, not to get in the very front end but once we have that front end done.

Mike Neuenschwander: Yeah. I see them more as advising with their different perspectives on the data that we're putting together, but I don't know that they necessarily need to be building this data.

MaryAnne Lindeblad: You could have a lot of [cross-talk] --

Mike Neuenschwander: [Cross-talk] for use, right?

MaryAnne Lindeblad: And probably take a very long time [cross-talk] to accomplish what we're trying [cross-talk] --

Mike Neuenschwander: [Cross-talk] Too many cooks [cross-talk] in the [cross-talk] kitchen at [cross-talk] that point.

Eileen Cody: There would not have been a separate Advisory Board that does the same thing at the Board. That's not [cross-talk] --

Mike Neuenschwander: [Cross-talk] Yeah. Yeah, that's not the purpose of the [cross-talk]. Does that kind of make sense? And any comments, questions? Kelly, does that answer what you need to know?

Kelly Wu: Yeah, sounds good.

Eileen Cody: She didn't sound convinced. [laugh]

Mike Neuenschwander: Okay, any other burning questions you need answered, Kelly?

Kelly Wu: Nope.

Mike Neuenschwander: Okay. And then -- so that takes us to the end of your presentation, right? Kelly?

Kelly Wu: Oh, yeah. I think we just skip the next step slide because I think we kind of covered it during the discussion.

Mike Neuenschwander: Okay.

Eileen Cody: So like [indistinct].

Mike Neuenschwander: So then I guess the next part then is, Kelly, we -- you can use these data measures to create a dashboard. And then in terms of waiting, what do you need to sort out or prioritize this?

Kelly Wu: Well, I think the Board would need to come back to us with their rankings.

Mike Neuenschwander: So like, which -- what they think is the most important out of these?

Kelly Wu: Yeah. So I guess everybody would theoretically rank the measures in order, and then we would have to somehow reconcile the rankings.

Douglas Barthold: I have a suggestion. If we rank -- ranking -- a flaw in ranking is that let's say there are six measures. Let's say that I say that I only actually care at all about five of them. I don't want that sixth one given any weight at all. So rather than -- just if I ranked them one to six, it implicitly assumes that I still care about the sixth one, right? But if we give them, like, a weight, and so let's say there is the six options, and I decide I want to give 80% weight to the first one, 5% to the second one, and then -- actually, 15% of the second one, 5% to the third one, and then zero to the other three, that way it gives the Board Members the opportunity to omit the measures that they don't care about.

Mike Neuenschwander: So if each Board Member gets 25 points, they assign those 25 points to the six measures. We add those up, and then we will get our 100% from that.

Douglas Barthold: Love that.

Hung Truong: Yeah.

MaryAnne Lindeblad: And [cross-talk] ranking [indistinct]. That makes sense.

Mike Neuenschwander: Okay. Cool. So we can send these out and then ask for the division of your 25 points, and then we can add that up and then use that to help create the dashboard.

MaryAnne Lindeblad: That'll work, I think.

Mike Neuenschwander: I love solving problems. Great.

Multiple Speakers: [Laughter]

MaryAnne Lindeblad: Yeah.

Eileen Cody: Sounds [indistinct] too easy.

MaryAnne Lindeblad: Yeah. It's all right.

Mike Neuenschwander: Okay. Um, so any other questions or comments on -- it sounds like we've got our data we want to look at. We know where we are going to pull it from. We've got our ranking that we can send out here after this meeting. Anything else on this for the Board Members?

Douglas Barthold: Just a quick question on the -- you know, I think there are some details on some of those measures that I'm sure Kelly will make the decisions on, but I'm just curious if we will be able to see, you know, that whatever the out-of-pocket cost, it is like, among users it is the average cost per month of a claim or of all of their claims. Like, again, I trust her to make the decision on that, I just want to make sure that we can see those details somewhere.

Mike Neuenschwander: Yeah. And then think as we are writing this up because this again could be another policy in terms of how our selection methodology, right? We can write up where we are getting the data from, how we are calculating that. So, yeah, we can share that with the Board at the next meetings.

Douglas Barthold: Sounds good.

Mike Neuenschwander: Okay?

MaryAnne Lindeblad: All right, are we ready for the next agenda item?

Eileen Cody: Meeting.

MaryAnne Lindeblad: Meeting times.

Mike Neuenschwander: I think so.

MaryAnne Lindeblad: All right. We'll turn it over to Simon [indistinct].

Simon Borumand: This is pretty quick, and it kind of falls in a category like the annual report where you have to book out the room very far in advance, and so we're just setting the meeting times. We're thinking of sticking with the same schedule where we meet approximately every 3rd Wednesday on the odd months. So that would be January 15th, March 19th, May 21st, July 16th, September 17th, and November 19th.

Douglas Barthold: It's the third, it's third Wednesday of the odd months?

Mike Neuenschwander: Yeah.

MaryAnne Lindeblad: Get into habit.

Mike Neuenschwander: What I can do is send this out in e-mail to the Board Members, and I just check it against your calendars.

MaryAnne Lindeblad: That'd be great.

Mike Neuenschwander: And I think it was this year the schedules were tough. So we, obviously, had Doug online for most of it, but if there's a way to make it work where people would prefer to be in person, or if everybody wants to be online, we can work that out over e-mail, too.

MaryAnne Lindeblad: It's nice to see faces.

Mike Neuenschwander: Yeah.

Douglas Barthold: I mean as long as it is Wednesdays, I am going to be remote because it's, like, my busiest day, and it's like all of this afternoon stuff. I don't mind being remote, but if we want -- because I feel like we chose Wednesday because it worked better for everybody else, and so I'm fine with that.

MaryAnne Lindeblad: It could be a Tuesday or Thursday if we wanted to change it.

Eileen Cody: Thursdays are bad for me because [cross-talk] --

MaryAnne Lindeblad: Thursdays are usually bad for me, too, but [cross-talk] Tuesdays are good days.

Eileen Cody: Okay. Just to upset you, Simon. [Laughter]

MaryAnne Lindeblad: [Cross-talk] Simon, I mean, if you want to look at Tuesdays as a possibility, but I do understand the room issue and -- yeah.

Simon Borumand: We're pretty flexible. I can also reflect with our team [cross-talk] --

Eileen Cody: We just have to get ahead of everybody else.

Simon Borumand: Yeah, exactly.

Eileen Cody: I know that was a [cross-talk] --

Mike Neuenschwander: Yep, sounds good. I'll shoot an email out with these and then figure out the right date.

Simon Borumand: Okay.

Mike Neuenschwander: Great. Any other questions, comments on that? Doug?

Douglas Barthold: Not on the timing, just another question unrelated, so we can -- I can wait.

Mike Neuenschwander: I think that's kind of it [cross-talk] --

Eileen Cody: [Cross-talk] Go ahead.

Mike Neuenschwander: -- as far as the meetings.

Douglas Barthold: Um, yeah. I just wanted to ask about the UPL coverage guide spreadsheet. I think -- Simon, did you make this?

Simon Borumand: Uh, yes, based on advice from the AG.

Douglas Barthold: Um, yeah, it's great. I love it. I just don't -- can you explain to me -- there is like the three tabs. We've got [indistinct] review, OIC [indistinct] breakdown, and then UMP Cover [indistinct] breakdown. So the OIC is the Office of the Insurance Commissioner, and there's the UMP, that's the Uniform Medical Plan. So the UMP plans are not under the OIC? Is that right?

Ryan Pistoresi: Those are regulated through Health Care Authority. We do follow some of the OIC regulations, so things like the appeal rights and the patient Bill of Rights. But, otherwise, the jurisdiction for UMP is under the umbrella of Health Care Authority.

Douglas Barthold: Okay. And then is that -- so the UMP tab is empty. Is that just a work in progress?

Mike Neuenschwander: That gets updated when there are PDFs online, and so I just shared those separately instead of copying all the information [cross-talk] --

Douglas Barthold: Oh, I got it. Okay. And I did see this. Okay. Makes more sense now.

Eileen Cody: But the UMP is covered under the most -- almost all of the same things. Like the UPL, the UMP is covered under it.

Douglas Barthold: Yeah. And that's what the spreadsheet says. That makes sense. I was just confused about why sort of just the breakdown of the different tabs and what went where, but now I get it.

Mike Neuenschwander: Other questions?

Douglas Barthold: Not from me.

MaryAnne Lindeblad: Do we have anyone signed up for public comment?

Mike Neuenschwander: Yes. We got one e-mail in advance from Dharia McGrew asking to speak, and then I'll look to see if there's any participant hands up as well.

MaryAnne Lindeblad: Okay, thanks. Okay.

Mike Neuenschwander: We've got also one other hand up, Brian Warren. And then anyone in the room want to speak? No? I don't know if Dharia McGrew since he had signed up in advance, if you want to go first, I'll allow to talk.

Dharia McGrew: Thank you. Confirming you can hear me.

Mike Neuenschwander: Yep, go ahead.

Dharia McGrew: Awesome. Thanks so much. Dharia McGrew, Director of State Policy on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA). Thank you very much for the thoughtful and nuanced discussion today. It's really heartening to hear all the Board Members and staff engaged so deeply in this. We appreciate the Board going back to revisit how you are defining a drug. It's really important that it be consistent across your analysis and not. defined differently for different drugs, and it is important to get the data right at this early stage as we're seeing this rollout in other states. I want to highlight beyond the legal discussion today a couple of reasons why that seven-year on the market metric is really important. The current proposal runs the risk of lumping together entirely different drugs that happen to have a common ingredient. There are many combined therapies on the market

these days that offer big advances in treatment that could be treated as if they're the exact same drug when they're not. Also, at the time that the underlying statute was passed by the Legislature, there was discussion about risks of unintended consequences of a UPL. We have very -- we have significant concerns that it could limit access to the newest and best drugs when they come on the market. So not considering drugs until they have been on the market for at least seven years was intended to mitigate potential harms of a UPL. And I caution the Board against policy that whittles away or goes against the intent as it pertains to new and innovative drugs on the market. We have filed several letters, appreciate the Board's consideration. We continue to highlight just a couple of other concerns submitted in those letters. One is intentional overcalculation by choosing high dose x high duration. I know the Board has described the policy rationale there in the policy, but what you're saying is that you're intentionally choosing outliers and not an average patient. So it is, of course, hard to boil down people to averages, but we do have concerns with the intentional inclusion of outliers. And additionally, finally here in Washington and in other states, manufacturers continue to ask for some kind of confidential mechanism where they can submit additional information as needed. There was a lot of discussion today about potentially in the future requesting fata from manufacturers, and there may be cases in which a manufacturer would like to submit competitive or proprietary information for the Board to consider when it isn't publicly available, and they'd like to have a kind of portal where they can submit or ask questions or submit proprietary information should that be necessary in the future. And again, I refer you to our letters over the past couple of months for additional detail on any of these. Thank you so much.

MaryAnne Lindeblad: Thank you.

Mike Neuenschwander: Thank you. Next on the list is Brian Warren.

Brian Warren: Hi, good morning. Can you hear me?

MaryAnne Lindeblad: Yep.

Eileen Cody: Yep.

Brian Warren: Thank you. Brian Warren with the Biotechnology Innovation Organization or BIO. We represent Biotech and Life Sciences companies in Washington as

well as the rest of the country. My comments are specific to the drug eligibility list methodology policy, and it's something that I know that you guys discussed today and are going to be making or potentially making some changes based on Board member feedback today. There was one other thing that we wanted to bring to your attention as a potentially unintended consequence of the way the policy was written that authorizing statute RCW re-exempts drugs from affordability review if they are approved only to treat rare diseases. And the way that the policy is written, it specifically essentially defines those drugs as treating rare diseases if they're approved under the FDA's Orphan Drug approval pathway. However, not every drug that is treating a rare disease was approved under the Orphan Drug Act approval pathway, so it's not a large number of products. However, this is something that, again, during the authorizing statutes consideration by the Legislature, the rare disease drug exemption was intended to avoid access problems for a population of patients that oftentimes don't have a lot of other options. They have serious medical needs, -- which is why this was created. So you may want to consider a pathway or option for the Board to pull something off of the list of eligible products, even though it was not approved by through the Orphan Drug Act. As long as it is approved only for treating a rare disease, which is something that is defined in federal and could be defined also in this rule. Usually as the standard is a disease affecting fewer than 200,000 patients in the country. That is all that I have and thank you for your attention.

MaryAnne Lindeblad: Thank you.

Mike Neuenschwander: Thank you and next is [cross-talk] --

Eileen Cody: Seth Greiner.

Mike Neuenschwander: Seth Greiner.

Seth Greiner: Good morning. Thank you for the discussion and presentation regarding the current eligibility list and ongoing review criteria. My name is Seth Greiner, and I'm an Advocacy Manager for the National Multiple Sclerosis Society. The MS Society supports affordability Boards nationwide, and we will be submitting continued written comments concerning patient costs, assistance, data utilization, and stakeholder engagement. We again thank the Board for their time and continued support for Washington consumers.

Mike Neuenschwander: Any other speakers? There was a Q&A box, and two people asked if the recording will be available after the meeting. It will be. It will be posted on the PDAB website. If there's no other [indistinct] and other comments, we'll close the public comment period.

MaryAnne Lindeblad: All right. It looks like we have accomplished what we hoped to today. I appreciate everyone's engagement, and the meeting can be adjourned.

Eileen Cody: All right. Thank you. [Indistinct]

[end of audio]